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Report to the Congress; by Elmer B. Staats, Comptroller General.

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Authority: Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301). Fair Packaging and Labeling Act (15 U.S.C. 1451). Color Additive Amendments (P.L. 86-618). Federal Insecticide, Fungicide, and Rodenticide Act of 1947 (7 U.S.C. 135). 16 C.F.R. 1500. 16 C.F.R. 1700. 21 C.F.R. 310. 21 C.F.R. 700. Almay v. Califano, 569 F.2d 674 (D.C. Cir. 1977). Toilet Goods Association v. Finch, 419 F.2d 21 (1969). S. 2365 (95th Cong.).

Cosmetics are regulated under the Federal Food, Drug, and Cosmetic Act which requires that a cosmetic be free of injurious substances and be produced under sanitary conditions. Many ingredients available for cosmetic use are suspected of causing cancer or birth defects or of having adverse effects on the nervous system. Findings/Conclusions: In spite of the significant risk of injury to consumers, the Food and Drug Administration (FDA) does not have an effective program for regulating cosmetics. The act does not authorize FDA to require manufacturers to register their plants or products, file data on ingredients, file reports of cosmetic-related injuries, or test their products for safety. Also, exemptions in the act do not permit effective regulation of coal tar hair dyes. FDA has not effectively used its existing authority. For example: it has not inspected most manufacturers' plants or sampled products for compliance with the act; it has established regulations governing the use of only 11 ingredients used in cosmetics; the safety of about 25 color additives has not been established; and it has had difficulty developing appropriate tests to be used by manufacturers in evaluating safety. Recommendations: FDA should: require the listing of known allergens, help to develop product standards, define "adequate substantiation of safety," insure childproof packaging of toxic cosmetics, evaluate data from literature on cosmetic product safety, evaluate restrictions of other countries, establish an information system on cosmetic-related injuries and complaints, establish

regulations related to cosmetics containing drugs, hasten the review of color additive safety, evaluate safety data on coal tar hair dye ingredients, and establish a more effective market surveillance program. The Congress should amend the act to: give FDA adequate authority for regulating cosmetic products, authorize FDA to require cosmetic manufacturers to submit data to FDA supporting the effectiveness of preservatives used, and repeal exemptions concerning coal tar hair dyes. It should also authorize FDA to obtain access to cosmetic manufacturers' production and control records and to assess civil penalties for violations of the act. (HTW)

7260

BY THE COMPTROLLER GENERAL

Report To The Congress

OF THE UNITED STATES

Lack Of Authority Hampers Attempts To Increase Cosmetic Safety

The Congress should authorize the Food and Drug Administration to require cosmetic manufacturers to prove the safety of their products. Because the agency does not have enough authority to effectively regulate cosmetics, products are being marketed which may pose a hazard to consumers. About 125 ingredients available for use in cosmetics are suspected of causing cancer, and about 25 are suspected of causing birth defects. Although many of the reported adverse effects have not been verified, 30 of the ingredients are known to cause cancer in humans or animals or contain impurities known to cause cancer. The ability of these ingredients to cause toxic effects through cosmetic use has not been determined.

Manufacturers do not have to determine the safety of their products before selling them or tell the Food and Drug Administration what products they are selling and what ingredients are used in them. Many manufacturers have not voluntarily given such information to the agency. As a result, a hazardous cosmetic can be marketed until the Food and Drug Administration obtains information to prove that the product may be injurious to users.

HRD-78-139
AUGUST 8, 1978

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-164031(2)

To the President of the Senate and the
Speaker of the House of Representatives

This report shows the need for additional legislative authority to enable the Food and Drug Administration to better ensure the safety of cosmetic products in interstate commerce. The Food and Drug Administration, Department of Health, Education, and Welfare, is responsible for administering the activities discussed in this report.

We made our review pursuant to the Budget and Accounting Act, 1921 (31 U.S.C. 53), and the Accounting and Auditing Act of 1950 (31 U.S.C. 67).

We are sending copies of this report to the Director, Office of Management and Budget, and to the Secretary of Health, Education, and Welfare.

Comptroller General
of the United States

COMPTROLLER GENERAL'S REPORT TO THE CONGRESS

LACK OF AUTHORITY HAMPERS ATTEMPTS TO INCREASE COSMETIC SAFETY

D I G E S T

In 1975 Americans spent as much on cosmetics as they did on prescription drugs. In 1977 cosmetic sales were about $9 billion.

Cosmetics, such as makeup, perfumes, baby lotions and powders, bubble baths, hair dyes, and toothpastes, may pose significant hazards to consumers. Toxic effects from cosmetic exposure can occur through

--oral ingestion (i.e., toothpastes, mouthwashes),

--inhalation (i.e., hairsprays, deodorant sprays), or

--absorption through the skin or scalp (i.e., hair dyes, makeup, body lotions and powders).

About 125 ingredients available for use in cosmetics are suspected of causing cancer, according to studies. In addition, about 25 are suspected of causing birth defects and 20 may cause adverse effects on the nervous system, including headaches, drowsiness, and convulsions. (See p. 9.)

Many different routes of exposure and species of animals were used in the studies of the ingredients. Because the appropriateness and reliability of the tests have not been determined, no conclusion can be reached concerning the ability of most of the ingredients to cause the reported effects.

Although many of the reported adverse effects have not been verified, 12 of the ingredients are known to cause cancer in humans or contain impurities known

to cause cancer in humans. Another 18 ingredients have been found to cause cancer in animals by the Food and Drug Administration, the National Cancer Institute, or an agency of the World Health Organization.

Before the ability of the ingredients to cause toxic effects through cosmetic use can be determined, such factors as the amount of the ingredient used; the route, frequency, and length of administration; and the amount of absorption through the skin must be evaluated. Additional injuries associated with cosmetic use are discussed in chapter 2.

Although there is increasing evidence that some cosmetic products and ingredients may carry a significant risk of injury to consumers, the Food and Drug Administration does not have an effective program for regulating cosmetics.

Cosmetics are regulated under the Federal Food, Drug, and Cosmetic Act. The act requires that a cosmetic be free of substances that may make it injurious and be produced under sanitary conditions. It does NOT authorize the Food and Drug Administration to require manufacturers to

--register their plants or products,

--file data on the ingredients in their products,

--file reports of cosmetic-related injuries, or

--test their products for safety.

In addition, exemptions in the act do not permit the Food and Drug Administration to effectively regulate coal tar hair dyes, the dyes most widely used.

While attempts by the Food and Drug Administration to regulate cosmetics are hampered by a lack of adequate legislative authority, the agency could make improvements under its present authority to regulate cosmetics.

NEED FOR ADDITIONAL LEGISLATIVE AUTHORITY

Before 1972 the Food and Drug Administration did not have a formal program to regulate cosmetics. It took regulatory action on a case-by-case basis. Since then it has established several regulations to improve its control over cosmetics. However, the effectiveness of many of these regulatory efforts has been limited because it lacks adequate legislative authority.

For example, in 1972 and 1973 the agency asked cosmetic manufacturers, packers, and distributors to register their plants and file information on the ingredients used in their products and the injuries reported from their use.

As of December 1977, about 40 percent of the manufacturers and packers had registered their plants; less than 20 percent of the manufacturers, packers, and distributors had filed ingredient listings; and less than 4 percent had filed injury reports.

A Food and Drug Administration regulation requires that labeling of cosmetics that have not been adequately tested for safety include a warning to that effect.

This regulation cannot be effectively enforced because the agency is not authorized to require manufacturers to test their products for safety or to make their test results available to the agency.

In addition, many manufacturers have refused Food and Drug Administration inspectors access to manufacturing records, such as

qualitative and quantitative formulas, sales or shipping records, and consumer complaint files. The agency lacks authority to require that such records be made available. (See p. 100.)

The Congress should amend the act to provide the Food and Drug Administration additional authority to regulate cosmetics. (See pp. 48, 71, and 105.)

BETTER USE OF EXISTING AUTHORITY

The Food and Drug Administration is authorized to

--inspect cosmetic plants and collect and test cosmetic samples,

--establish manufacturing standards,

--take regulatory action against violative manufacturers,

--restrict the use of hazardous cosmetic ingredients and require precautionary labeling on cosmetic products,

--require manufacturers to prove the safety of color additives used in cosmetics, and

--establish by regulation the appropriateness of the tests used in its market surveillance program for evaluating the safety of cosmetics.

However, the agency has not effectively used this authority.

Limited market surveillance and enforcement

The Food and Drug Administration has not inspected most manufacturers' plants or sampled most of their products for compliance with the Federal Food, Drug, and

and Cosmetic Act. Only about half the cosmetic establishments were inspected between fiscal years 1969 and 1975. Since 1975 the agency identified about 1,000 additional manufacturers, which it had never inspected because they had been unknown to the agency. (See pp. 92 and 93.)

The Food and Drug Administration also has not established criteria to determine whether adequate methods, facilities, and controls are used in all phases of manufacturing and distribution of cosmetics.

According to an agency official, about 75 percent of a sample of over 300 firms inspected since 1976 had deficiencies in their manufacturing practices. (See pp. 93 to 95.)

Between 1974 and 1976 Food and Drug Administration inspectors and laboratories identified over 400 violations of the cosmetic provisions of the act which they believed warranted some form of regulatory action. Yet only 141 regulatory actions were taken; 54 involved 1 violative product. No prosecutions were started. (See pp. 95 to 100.)

Product and ingredient restrictions

Establishing regulations to prohibit or limit the use of an individual ingredient or requiring the use of a specific warning on the label is an effective way to increase consumer safety with regard to a specific product or class of products. However, as of January 1, 1978, the Food and Drug Administration had established regulations governing the use of only 11 ingredients used in cosmetics and had required precautionary labeling only on feminine deodorant

sprays, aerosols containing chlorofluorocarbon propellants, and aerosol cosmetics in self-pressurized containers.

Although the Consumer Product Safety Commission has established regulations requiring that specific warnings be placed on labels of products containing certain toxic ingredients, restrictions have not been established by the Food and Drug Administration for use of these ingredients in cosmetics. (See p. 34.)

Drug ingredients are subject to cosmetic rather than drug regulation as long as the product is not "intended" or "understood" to have a drug effect. Because the intended effect of a product is not always clearly stated on the label, there is often no clear distinction between drug and cosmetic products. GAO identified about 90 drug ingredients available for use in cosmetics.

The Food and Drug Administration has not, in some cases, required the same warnings on labels of cosmetic products containing drug ingredients that are required on drug products containing the ingredients. (See pp. 59 to 64.)

Color additive safety

The 1960 Color Additives Amendments to the Federal Food, Drug, and Cosmetic Act require the Food and Drug Administration to establish regulations listing color additives that are safe for use in cosmetics. Although color additives are sometimes used at concentrations exceeding 50 percent, the safety of about 25 color additives available for use in cosmetics has not been established. (See pp. 65 and 66.)

Definition of product safety

Although the Food and Drug Administration cannot require cosmetic manufacturers

to test the safety of their products, it can establish regulations identifying appropriate tests which should be used by manufacturers in evaluating safety. The agency said that development of appropriate tests is both difficult and resource demanding.

Coal tar hair dyes

Some coal tar hair dyes may pose a significant risk of cancer to consumers because they contain colors known to cause or suspected of causing cancer in humans or animals.

However, exemptions granted to coal tar hair dyes under the Federal Food, Drug, and Cosmetic Act prevent the Food and Drug Administration from regulating hair dyes effectively.

The exemptions bar the agency from banning or restricting the use of coal tar hair dyes containing cancer-causing colors, if their labels warn of possible skin irritation or blindness. The Congress should repeal these exemptions. (See pp. 90 and 91.)

Although coal tar hair dyes are subject to Food and Drug Administration labeling requirements, the agency has not used this authority to require a cancer warning on labels of coal tar hair dyes containing known human or animal carcinogens. The agency has proposed to require such a warning on labels of coal tar hair dyes containing two ingredients found to cause cancer. (See ch. 6.)

GAO is making recommendations to the Secretary of Health, Education, and Welfare (HEW) to enable the Food and Drug Administration to improve its regulation of cosmetics. (See pp. 44, 56, 69, 90, and 104.)

HEW agreed in principle with many of GAO's recommendations, but said that it did not

necessarily agree that they could be implemented under the present statute. HEW does not believe that an extensive expenditure of resources toward the regulation of cosmetics is a wise investment because of the Food and Drug Administration's limited statutory authority to regulate cosmetics. (See pp. 44, 57, 69, 91, and 104.)

Contents

ABBREVIATIONS

CIR	Cosmetic Ingredient Review
CPSC	Consumer Product Safety Commission
CTFA	Cosmetic, Toiletry and Fragrance Association
EDF	Environmental Defense Fund
EEC	European Economic Community
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FPLA	Fair Packaging and Labeling Act
FTC	Federal Trade Commission
GAO	General Accounting Office
GMP	good manufacturing practice
HEW	Department of Health, Education, and Welfare
IARC	International Agency for Research on Cancer
NCI	National Cancer Institute
NDELA	N-nitrosodiethanolamine
NEISS	National Electronic Injury Surveillance System
NIOSH	National Institute for Occupational Safety and Health
OTC	over the counter
PPPA	Poison Prevention Packaging Act

CHAPTER 1

INTRODUCTION

In 1975 Americans spent as much on cosmetics as they did on prescription drugs. Cosmetic sales have doubled in the past 10 years and are expected to increase at a rate estimated as high as 15 percent annually. Total sales of cosmetics were estimated to be $9 billion in 1977.

WHAT DOES THE TERM "COSMETIC" MEAN?

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended (21 U.S.C. 301 et seq.), defines a "cosmetic" as an article (except soap) intended to be rubbed, poured, sprinkled, sprayed on, introduced into, or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance.

Although the term "cosmetics" has frequently been interpreted as referring to products such as makeup, nail polishes, and perfumes used primarily by women, the term actually applies broadly to products used by men, women, and children. For example, the baby powder, bubble bath, and toothpaste used by children are cosmetics. Similarly, products used by men, such as deodorants, shaving cream, hair tonics and sprays, hair dyes, toothpastes, colognes, suntan lotions, and mouthwashes, are cosmetics.

According to the Food and Drug Administration (FDA) there are at least 25,000 different cosmetic formulations marketed under 50,000 or more brand names. FDA estimates that about 4,000 cosmetic and another 4,000 fragrance ingredients are used in cosmetics.

WHO REGULATES COSMETICS?

Authority to regulate cosmetics in interstate commerce is derived from the FD&C Act and the Fair Packaging and Labeling Act (FPLA) (15 U.S.C. 1451 et seq.). FDA, Department of Health, Education, and Welfare (HEW), administers the two acts as they pertain to cosmetics. Within FDA, the principal organization identifiable with regulation of cosmetics is the Division of Cosmetics Technology, Bureau of Foods.

The FD&C Act requires that a cosmetic be

--free of substances that may make it injurious to users under normal use;

--packaged in a safe and nondeceptive container;

--produced under sanitary conditions; and

--labeled with information about the product's manufacturer, packer, or distributor and the quantity of its contents.

FPLA authorizes FDA to require that a cosmetic sold for home use list the ingredients on the label.

Since July 12, 1960, the Color Additive Amendments to the FD&C Act (Public Law 86-618) have required the establishment of regulations listing color additives that are safe for use in food, drugs, or cosmetics. Under these amendments a color additive must be approved for safety by FDA before its use in cosmetics is permitted. FDA is not authorized to require premarket approval of other cosmetic ingredients.

HOW DOES FDA ENFORCE THE FD&C ACT?

The act prohibits the sale in interstate commerce of cosmetics that are adulterated or misbranded. The establishment inspection is FDA's basic tool to determine if goods are in compliance with the law and to obtain evidence to support legal action when violations are found. In addition, FDA inspectors collect cosmetic samples during inspections and from the channels of trade; these are submitted to FDA laboratories for selective testing and label review to determine whether they comply with specific requirements of the FD&C Act, FPLA, and applicable regulations.

When FDA discovers an adulteration or a misbranding violation during inspection or sample analysis, it can, through the Department of Justice:

--Prosecute an individual who violates the act.

--Enjoin a producer or an individual from violating laws and regulations.

--Seize any cosmetic that is adulterated or misbranded when introduced into, or while in, interstate commerce.

Although the FD&C Act does not authorize FDA to require a recall, FDA may request producers to voluntarily recall cosmetics that are alleged to violate the act.

A citation, or notice of hearing, is required by the act when criminal proceedings are contemplated. It gives the manufacturer an opportunity, through a hearing, to explain any extenuating circumstances which would eliminate the need for prosecution.

FDA is not required to issue a citation or prosecute a violator if a violation is minor and if the public interest would be served by a written notice or warning.

In addition to issuing citations and information letters, FDA issues regulatory letters in the case of violations which do not create a danger to health. According to the FDA Director, Division of Regulatory Guidance, failure by a manufacturer to take corrective action after receiving a regulatory letter would probably result in a seizure or injunction, but not in a prosecution.

The FD&C Act provides for criminal penalties of up to 3 years in prison and/or a $10,000 fine for violation of the adulteration or misbranding provisions. The act does not authorize civil penalties for violations of its cosmetic provisions.

Cosmetics introduced into commerce in violation of FPLA are deemed to be misbranded under the FD&C Act and are subject to seizure or injunction under the FD&C Act. However, violations of FPLA are not punishable by criminal penalties under the FD&C Act.

HOW DOES FDA REGULATE COSMETICS?

Before May 1972 FDA did not have a formal program to regulate cosmetics but took regulatory action on a case-by-case basis. According to an article by the editor of the Drug and Cosmetic Industry magazine, the cosmetic industry is the least regulated of all the consumer-goods-manufacturing industries. Because of increasing concern among consumers about the safety of cosmetics, and efforts in the Congress to enact a comprehensive new cosmetics law, the Cosmetic, Toiletry, and Fragrance Association (CTFA), an industry trade association, proposed the establishment of three voluntary programs for controlling cosmetics. Between May 1972 and October 1973, FDA implemented the three programs, which provide for:

--Voluntary registration of cosmetic manufacturers.

--Voluntary filing of cosmetic product ingredient and raw material composition statements.

--Voluntary filing of cosmetic product experiences (injury reports).

In addition, FDA has issued regulations requiring ingredient labeling of cosmetic products subject to FPLA and precautionary labeling of certain products. Also the use of several ingredients in cosmetics has been restricted.

In fiscal year 1977, funding for FDA's regulatory program for cosmetics was $2.8 million; about 1 percent of FDA's overall budget of $250 million. As of July 1, 1977, the Division of Cosmetics Technology had only 15 professional employees to regulate the $9 billion cosmetics industry.

CHAPTER 2

COSMETICS POSE HAZARDS TO CONSUMERS

In February 1974 hearings before the Subcommittee on Health, Senate Committee on Labor and Public Welfare, the FDA Commissioner said that:

> "One thing to keep in mind when discussing cosmetic safety is that cosmetics, unlike food or drugs, are not essential to health and well-being, regardless of their esthetic or camouflage value. * * *
>
> "In the case of drugs, a benefit-risk judgment can apply in which the expected benefits may justify the assumption of substantial risk. But since there are few, if any, cosmetics or cosmetic ingredients which we could not do without, were we forced to, we should be much less tolerant of any potential for injury from these products."

Although there is increasing evidence that some cosmetics and their ingredients pose a hazard to consumers, FDA does not have an effective program to identify and remove them from the market. Cosmetics are being marketed in the United States which contain:

- --Ingredients which may cause cancer, birth defects, central nervous system disorders, and other chronic toxic effects. (See p. 8.)
- --Ingredients which may cause skin or eye irritations, genitourinary infections, allergic reactions, and other acute toxic effects. (See p. 10.)
- --Drugs which may affect normal body functions. (See p. 59.)
- --Bacteria which may cause serious eye injury. (See p. 17.)
- --Ingredients which are banned or restricted for use in cosmetics in other countries. (See p. 50.)
- --Flammable ingredients. (See p. 19.)

--Ingredients which could deplete the Earth's protective ozone layer. (See p. 19.)

Also some cosmetics have been found to contain N-nitrosodiethanolamine (NDELA), a known animal carcinogen, as a contaminant. (See p. 20.) In addition, available data indicate that the colors used in some coal tar hair dyes, essentially exempt from cosmetic regulation, may cause cancer and/or mutations. (See ch. 6.)

TOXICITY

In this report the term "toxicity" refers to the short-term or long-term capacity of a cosmetic to produce personal injury or illness to man or experimental animals. The term may be used to refer to the toxicity of an individual ingredient or to a formulated product.

Acute versus chronic effects

Toxic effects may occur after one use of a cosmetic or after repeated use.

In this report effects which appear soon after use are referred to as acute toxic effects because of the short time before onset of the injury. The injury may be either temporary, such as a skin rash, or permanent, such as loss of sight.

Injuries or illnesses whose symptoms appear months, and possibly years, after use of a cosmetic are referred to in this report as chronic toxic effects. Such effects include cancer, birth defects, central nervous system disorders, and lead poisoning. The injuries or illnesses usually result from repeated use over a long time.

Mode of use

Toxicity may result from either oral ingestion, absorption through the skin, or inhalation of toxic ingredients. Lipsticks and all oral hygiene products, such as toothpastes, mouthwashes, and breath fresheners, may be ingested during normal usage. Cosmetics may also be accidentally ingested.

Most cosmetics are applied to the skin or hair. After application, however, ingredients may be absorbed into the bloodstream through the skin.

A 1970 study 1/ on the skin absorption of organic chemicals included nine chemicals listed in the 1977 edition of the CTFA Cosmetic Ingredient Dictionary 2/ for use as cosmetic ingredients. Total absorption of those nine ingredients over a 5-day period after application of the compound to the forearm ranged from 1 to 43 percent of the applied dose, as shown below.

Compound	Total absorption (as a percent of applied dose)
Benzoic acid	43
p-Aminobenzoic acid (PABA)	28
Salicylic acid	23
Diethyltoluamide	17
Nicotinamide	11
Urea	6
Phenol	4
Hexachlorophene	3
Thiourea	1

Other studies have demonstrated the absorption of coal tar hair dyes through the scalp. Inclusion of surfactants (wetting agents; detergents; and emulsifiers, such as triethanolamine), in cosmetics may increase the absorption of other ingredients in the formulation through the skin.

1/R. Feldmann and H. Maibach, "Absorption of Some Organic Compounds Through the Skin in Man," Journal of Investigative Dermatology, vol. 54, 1970, p. 399.

2/This dictionary was prepared by CTFA on the basis of data supplied by the cosmetic industry on the ingredients being used or promoted for use in cosmetics. It contains about 2,600 ingredients, and was designed, in cooperation with FDA, to provide uniform nomenclature for ingredients available for use by the cosmetic industry. As noted in the dictionary, "Inclusion of an ingredient in the Dictionary does not imply that it is or should be used by the cosmetic industry; absence of an ingredient in the Dictionary does not mean that it is not or should not be used."

Also cosmetic ingredients and aerosol propellants may be inhaled. According to a study by Dupont Laboratories, concentrations of the Freon aerosol propellant as high as 460 parts per million were found in a ventilated room following use of an aerosol hairspray or deodorant. In determining the extent of consumer exposure to aerosol particles, factors other than the initial concentration of the aerosol must be considered, including the extent to which aerosol particles remain suspended in the air after use of an aerosol product and the size of the particles and disposition after they are inhaled. Some particles may remain suspended for several hours.

Inhalation of talc-containing products, such as baby, body, and foot powders, may result in the lodging of talc particles in lung tissue.

Toxic ingredients used in cosmetics

To obtain data on the general toxicity of cosmetic ingredients, we compared a list of about 2,750 cosmetic ingredients 1/ with the list of toxic substances in the 1976 Registry of Toxic Effects of Chemical Substances prepared by HEW's National Institute for Occupational Safety and Health (NIOSH). NIOSH defines a "toxic substance" to be one that demonstrates the potential to

--induce malignant tumors (cancer) or benign tumors in man or animals (suspect carcinogens);

--induce a permanent transmissible change in the characteristics of an offspring from those of its human or experimental animal parents (mutagens);

--cause birth defects in humans or experimental animals (teratogens);

1/Includes about 2,600 ingredients listed in the second edition of the CTFA dictionary and about 150 ingredients reported to FDA as being used in cosmetic products under the voluntary program for filing of cosmetic ingredient statements but not included in the dictionary. FDA estimates that there may be as many as 4,000 cosmetic and another 4,000 fragrance ingredients used in cosmetic products.

--produce death in animals exposed via the respiratory tract, skin, eye, mouth, or other routes;

--diminish mental alertness, reduce motivation, or alter behavior of humans (nervous system effects); or

-- adversely affect the health of an individual by producing reversible or irreversible bodily injury or by endangering life or causing death from exposure via the respiratory tract, skin, eye, mouth, or any other route.

Although we relied primarily on the NIOSH registry in identifying reported toxic effects of ingredients, additional data on carcinogenic effects were obtained from reports by the National Cancer Institute (NCI), FDA, the World Health Organization, and the Environmental Protection Agency (EPA).

We identified reported toxic effects of about 600 of the approximately 2,750 ingredients reviewed. Although we did not identify any reported toxic effects for the remaining ingredients, exclusion of an ingredient from the registry does not necessarily imply that the ingredient is nontoxic because (1) many ingredients have not been adequately tested for their toxic effects, (2) cosmetic ingredients included in the dictionary which are trade name products representing compounded or formulated proprietary mixtures are excluded from the registry, and (3) the lack of consistent nomenclature for cosmetic ingredients made it difficult to trace individual ingredients to the registry.

Most of the ingredients whose reported toxic effects we identified are listed in the registry because of lethal responses of test animals to single or short-term exposure. However, many were shown to have other toxic effects. Of the approximately 600 ingredients

--125 are known to cause or suspected of causing cancer (12 are human carcinogens or contain contaminants known to cause cancer in humans),

--26 are suspected of causing birth defects,

--20 may cause nervous system disorders,

--17 may cause irritation,

--6 may cause eye damage, and

--3 may cause mutations.

Other ingredients may damage the skin, the digestive system, the blood, or the respiratory system or affect blood pressure, mental activity, or the metabolic and excretory function of the liver and kidneys.

Appendix I lists the cosmetic ingredients reported to cause these effects.

Many different routes of administration and species of animals were used in the studies showing the adverse effects. The applicability of the test methods and results to cosmetic exposure has not been evaluated. (See p. 40 for a discussion of an industry-sponsored program to evaluate the safety of cosmetic ingredients.)

Allergens, irritants, and photosensitizers

Most cosmetic injuries suffered by consumers are attributed to contact dermatitis (i.e., a redness and an inflammation of the skin caused by exposure to chemicals). Two main types of chemicals may cause contact dermatitis: irritants and allergens. If light is needed to induce a reaction, the chemical is classified as either a phototoxin or photosensitizer. In addition, many cosmetics irritate eyes or mucous membranes, if they come in contact with the eyes or lips, or may cause hair or fingernail breakage.

Irritants are substances which cause inflammation or more severe reactions of normal skin. Cosmetics commonly associated with primary irritation reactions include hair straighteners, deodorants, depilatories, bleaches, and permanent wave preparations. Among the substances in these cosmetics causing such irritations are the ammonium, calcium, and potassium salts of thioglycolic acid; ammonia; alkali hydroxides; and peroxides.

Unless adequate directions are given for use of cosmetics containing irritants, consumer injury may occur. Of course, failure to follow directions may also result in injury.

Eye irritants are substances which cause inflammation, swelling, or other injury to the eyes. Among the most common eye irritants are soap and several shampoo ingredients. These ingredients may cause eye irritation when the shampoo accidentally gets in the user's eye; in some cases irritation occurs even when the shampoo is promptly rinsed out of the eye. (See p. 13.)

Allergens are substances which produce an exaggerated or a pathological reaction (such as sneezing, itching, swelling, or skin rashes) in some individuals.

The National Institute of Allergy and Infectious Diseases estimates that 31 million people in the United States may have some form of allergy. Although any cosmetic ingredient can cause an allergic reaction in some users, certain ingredients, particularly perfume ingredients, preservatives, and some coal tar hair dyes, are more likely to cause allergic reactions. An individual may exhibit an allergic reaction to a cosmetic the first time the product is used or may suddenly exhibit an allergic reaction to the product after years of use without adverse effects. The presence of an allergen at essentially any concentration may trigger an allergic reaction in a sensitive individual.

Photosensitizers are substances which cause an abnormal reaction to sunlight characterized by redness; itching; burning; and, in severe cases, blistering of the skin at and beyond the site of application. These reactions are most commonly associated with sunscreening and antimicrobial agents.

Toxicity of cosmetics

Although many potentially toxic ingredients are used in cosmetics, their ability to cause toxic effects when used in cosmetics depends on such factors as (1) the amount of the ingredient used, (2) the route and frequency of administration, (3) the amount of absorption through the skin, (4) the presence of other ingredients which may heighten or lessen the toxic effects, and (5) the length of exposure. Many cosmetics, including some bubble baths, hairsprays, shampoos, and feminine deodorant sprays, may be hazardous.

Bubble baths have gained wide popularity since their development in the 1940s; their sales totaled almost $32 million in 1972. Adverse reactions were noted by physicians as early as 1955. Reported injuries have included rashes, skin irritations, and genital/urinary tract disorders. The severity of the rashes and skin irritations ranges from minor skin redness, itching, and discomfort to the Stevens-Johnson syndrome (an illness characterized by rashes, fever, joint pain, eye disorder, and prostration). In June 1975 FDA's Office of Planning and Evaluation prepared an analysis of bubble bath product complaints received by FDA between 1967 and 1974.

According to the report on the analysis, of the 165 adverse reactions to bubble baths reported to FDA by consumers during the 8-year period, 107 (65 percent) were severe enough that the consumers contacted physicians. The nature of the complaints is summarized in the following table.

Nature of injury	Number of complaints	Complaints confirmed by physician as product related (note a)
Rash/skin irritation	69	26
Urinary tract/bladder/ kidney disorder	48	20
Genital disorder	26	14
Eye irritation/injury	2	-
Respiratory disorder	13	1
Stomach disorder	7	1
Total	165	62

a/These figures are based on the 107 cases attended by physicians. Physicians did not report whether the injuries were product related in 40 cases. In only five cases did the physicians state the injuries were not product related.

According to an FDA Consumer Safety Officer, there are strong indications that FDA is receiving notification of only a fraction of the actual injuries being caused by bubble baths. About 59 percent of the adverse reactions reported involve one major manufacturer's products.

FDA officials believe that the detergent ingredients used in the bubble baths remove the protective coatings from the body and allow infections and/or inflammations to occur. The Office of Planning and Evaluation report notes that although the manufacturer has reformulated the product at least twice to reduce or replace the detergent ingredients, the actions have "seemingly failed to eliminate consumers' complaints."

Although FDA has not compiled statistics on bubble bath complaints received since 1974, the Deputy Director of the Division of Cosmetics Technology said they are still being received.

Feminine deodorant sprays were first introduced in the United States in 1966. In 1972 sales totaled about $40 million. Between 1969 and 1972 FDA received 174 adverse reaction complaints involving these sprays. According to FDA, the 174 complaints may represent only a small percentage of the actual number of injuries. Data from the Consumer Product Safety Commission's (CPSC's) National Electronic Injury Surveillance System (NEISS) indicates that about 1,300 persons were treated in hospital emergency rooms alone during 1976 due to adverse reactions to genital area products, including feminine deodorant sprays. The reactions reported to FDA included itching; burning; rashes; infections; and, in a few cases, inflammation of the lower urinary tract.

FDA has been unable to identify the specific ingredient or ingredients which cause the adverse reactions. In an attempt to reduce the incidence of adverse reactions, FDA, in March 1975, issued a regulation requiring that warning labels be placed on feminine deodorant sprays. The regulation became fully effective in September 1977.

Because of the controversy concerning adverse reactions to feminine deodorant sprays, FDA's ban on the use of hexachlorophene in them and questions concerning their usefulness, sales of these sprays have decreased since 1972.

Shampoos may cause varying degrees of eye injury if they accidentally enter the eye, especially in the undiluted state. Painful, transitory, and sometimes incapacitating lesions requiring medical treatment may occur. If the lesions become infected or if the chemical burn caused by the shampoo penetrates the Bowman's membrane (a thin membrane covering the front of the cornea), scar tissue may form, resulting in a clouding of the cornea thus interfering with vision. Loss of the eye could occur if this type of damage occurred in the presence of certain pathogenic organisms which may be present in eye makeup or other cosmetics coming in contact with the eye.

Two 1969 FDA studies demonstrated the ability of marketed shampoo to cause eye damage in rabbits.

In the first study, 11 shampoos for which consumer complaints were filed were tested for eye irritancy. 1/ Ten of the 11 shampoos were found to be eye irritants; 5 were irritants even if the shampoo was washed out of the eye within 30 seconds after application.

In the second study, 11 of the 13 shampoos tested for anesthetic effects were found to produce loss of feeling or sensation lasting from less than 1 hour to over 7 hours. By producing anesthesia the shampoos could make the user unaware of injury to the eye, including injury resulting from the irritant effects of the shampoo. The Division of Cosmetics Technology, FDA, estimated that at least 90 percent of the marketed shampoos would produce anesthetic effects. (See p. 32 for a discussion of FDA efforts to regulate shampoos.)

Although many of the shampoos included in FDA's 1969 studies are currently being marketed, we could not readily determine whether they have been reformulated since 1969 to eliminate their irritant or anesthetic effects.

However, an FDA summary of adverse reaction complaints involving shampoos received between January 1970 and November 1973 shows that 27 of the 117 complaints involved eye injuries, including irritations, chemical burns, corneal abrasions, and epithelial damage. Although FDA has not compiled statistics on eye injuries caused by shampoos since 1973, a Division of Cosmetics Technology summary of cosmetic-related injuries reported to FDA between December 1, 1973, and December 31, 1977, included 46 complaints of eye irritations associated with use of shampoo.

Aerosol hairsprays have been shown to cause a lung disease known as pulmonary thesaurosis. Among the symptoms are nodules on the lungs, shortness of breath, and a mild cough. Since publication of the first report on pulmonary thesaurosis in 1958, at least two other reports have been published. According to these reports, the symptoms often disappeared when use of hairspray was discontinued.

1/A shampoo was considered to be an irritant if it produced ulceration of the cornea, opacity of the cornea (other than a slight dulling of normal luster), inflammation of the iris, or obvious swelling with partial eversion of lids or diffuse crimson red in the conjunctivae.

In the March 3, 1975, Federal Register (40 FR 8912-8929), FDA analyzed available data on the hazards of aerosol products and concluded that there were not sufficient scientific data demonstrating a degree of health hazard to justify a total ban on all aerosol products. With regard to hairsprays, FDA cited the conclusion of the authors of a 1972 article 1/ that the diagnosis of thesaurosis in hairspray users has not been confirmed through experimental animal studies and human observation.

Subsequently, in August 1975 NIOSH issued a report on a "Morbidity Survey of Respiratory Symptoms and Functions Among Utah Beauticians." In the survey, a probability sample of 262 student cosmetologists and 213 graduate cosmetologists were medically tested and compared with a nonoccupationally exposed control group of 569 people matched by age, smoking history, and region. The survey report concluded that female cosmetologists

> "* * * are at increased risk of developing chronic respiratory disease and atypical sputum cytology which may progress toward more severe changes suggestive of lung malignancy. The thesaurosis-sarcoidosis syndrome was demonstrated in 22.5% of the graduate cosmetologists whereas students and controls were not significantly different from each other (12% and 14% respectively)."

Cosmetologists were shown to use significantly more hairsprays, beauty aerosols, and household aerosols than the control group. An increased prevalence of chronic respiratory disease was noted in small salons where adequate ventilation was often lacking.

Toxicity from accidental ingestion

During 1974 over 10,600 possible poisonings from cosmetics were reported to poison control centers, of which almost 9,300 involved children under 5 years of age.

1/J. M. Gowdy and M. J. Wagstaff, "Pulmonary Infiltration Due to Aerosol Thesaurosis," Archives of Environmental Health, vol. 25, August 1972, pp. 101-108.

Three deaths were reported. According to the former Director of FDA's Division of Poison Control, most of the possible poisonings resulted from accidental ingestion of the products. As shown by the following table, the majority of the possible poisonings involving children under 5 were from accidental ingestion of perfumes, colognes, toilet waters, fingernail preparations, and cosmetic lotions and creams.

Type of cosmetic	Possible poisonings reported	Poisoning symptoms present	Hospitalizations reported
Lotions and creams	1,844	98	19
Fingernail preparations	1,632	106	22
Hair preparations, except shampoo	679	57	6
Shampoo	667	37	7
Perfume, cologne, and toilet water	3,385	187	40
Personal deodorants	317	29	3
Miscellaneous	767	43	7
Total	9,291	557	104

While most cosmetics are virtually nontoxic or only slightly toxic, some are moderately to highly toxic upon oral ingestion. According to the draft poison control guidelines prepared by HEW's National Clearinghouse for Poison Control Centers, the cosmetics having the greatest acute toxicity are permanent wave neutralizing solutions containing sodium or potassium bromates. The clearinghouse notes that:

> "One to two teaspoonsful of this [permanent wave] can produce serious poisoning in children."
>
> * * * * *
>
> "Ingestion may produce vomiting, diarrhea, abdominal pain, methemoglobinemia [a condition resulting from the presence of an abnormal hemoglobin compound in the blood which interferes with the absorption of oxygen by the tissue], hemolysis [breakdown of the red blood cells], cyanosis [a bluish discoloration of the skin and mucous membranes due to reduced hemoglobin in the blood]. Restlessness followed by central nervous depression with apathy, lethargy, hypotension, tachycardia [excessively rapid heart action], coma, convulsions. Oliguria

[reduced output of urine], anuria [no urine output], azotemia [an increase of nitrogenous compounds in the blood resulting from kidney disease] with death from renal failure."

Among other cosmetics which the clearinghouse considers slightly or moderately toxic are colognes, perfumes, toilet waters, permanent wave lotions containing sodium perborate, hair bleaches, dandruff shampoo, hair tonics, hair dyes, mouthwash concentrates, depilatories, skin fresheners, and preshave lotions. In addition, the clearinghouse reports that accidental breathing of dusting and talcum powders may cause acute bronchitis (inflammation of bronchial tubes) and bronchiolitis (inflammation of small bronchi in the lungs), cardiopulmonary failure, and death in young children. The poison control guidelines note that several deaths have been reported involving massive talcum powder aspiration but that most cases of accidental breathing of such powders can now be successfully treated.

The need for childproof packaging of cosmetics to prevent accidental ingestion is discussed on pages 38 to 40.

MICROBIAL CONTAMINATION

FDA has received several reports of substantial vision loss resulting from the use of microbially contaminated cosmetics. Pseudomonas aeruginosa, a pathogenic bacterium that may be found in cosmetics, poses a serious threat to vision if it comes in contact with a scratched or an abraded eye.

Although the healthy eye is relatively resistant to microbial infection, the cornea or outer eye could easily become infected if accidentally injured by a makeup applicator brush or contact lens. Total corneal destruction and irreversible vision loss may occur within 24 to 96 hours after Pseudomonas becomes established in the injured eye.

Microbial contamination may be present in shampoos, lotions, creams, and eye makeup when they are sold or they may become contaminated during use. In a 1969 FDA survey 1/ of hand and body lotions and creams, about 20 percent of the products sampled contained microbial contamination. Over 11 percent contained gram negative organisms, including Pseudomonas and coliforms, which FDA believes may pose a moderate to serious health hazard.

1/A. P. Dunnigan and J. R. Evans, "Report of a Special Survey: Microbiological Contamination of Topical Drugs and Cosmetics," TGA Cosmetic Journal, Winter 1970, pp. 39-41.

The greatest hazard, however, appears to come from contamination of eye makeup during use. Microorganisms are always present on the human body and can be transferred to eye makeup by an applicator brush or the hands or through saliva. Unless the makeup contains an effective preservative system, the microorganisms may become established in the makeup and multiply rapidly.

Results of an FDA-sponsored study by researchers at the Medical College of Georgia and Emory and Georgia State Universities between 1971 and 1976 1/ demonstrated that:

--About 10 percent of eye cosmetics were contaminated when sold.

--Fungi were isolated from about 10 percent of all used eye cosmetics tested.

--Bacteria were isolated from about 50 percent of all used eye cosmetics tested.

--Some popular brands of mascara have been marketed without preservative systems.

--About half the eye cosmetics yielding bacteria during in-use studies had a persistent, reproducing microbial population over a 30-day storage period.

--Most preservative systems used in mascaras were broken down during use of the product and support bacterial growth.

1/L. A. Wilson and D. G. Ahearn, unpublished progress reports under FDA contracts 71-74 and 223-2016, 1971-1976.

L. A. Wilson, J. W. Kuehne, S. W. Hall, and D. G. Ahearn, "Microbial Contamination in Ocular Cosmetics," American Journal of Ophthalmology, vol. 71, no. 6, June 1971, pp. 1298-1302.

D. G. Ahearn, L. A. Wilson, A. J. Julian, D. J. Reinhardt, and G. Ajello, "Microbial Growth in Eye Cosmetics: Contamination During Use," Developments in Industrial Microbiology, vol. 15, 1974, pp. 211-216.

L. A. Wilson, A. J. Julian, and D. G. Ahearn, "The Survival and Growth of Microorganisms in Mascara During Use," American Journal of Ophthalmology, vol. 79, no. 4, April 1975, pp. 596-601.

--Over half the cosmetics used for demonstrations at cosmetic display counters were contaminated; some contained pathogens.

The need for product class standards for eye area cosmetics is discussed on pages 36 and 37.

FLAMMABILITY

Serious burns have been reported from use of flammable cosmetics. Among those most likely to ignite at the time of application are perfumes and colognes which usually contain a high concentration of alcohol and nail polish removers which contain flammable ingredients, such as acetone and ethyl acetate. Some hairsprays and nail polishes have proven flammable after application. Some of the injuries reported to FDA since 1970 are indicated below.

Second and third degree burns on the head	Victim used hairspray before going out to dinner. After returning home, victim struck a match and her hair ignited.
Thermal burns on the neck	Victim sprayed herself with cologne, then lit a match 12 to 14 inches from her throat. The cologne ignited, burning her throat.
Thermal burns on the head	Victim's hair ignited 6 to 8 hours after hairspray was applied.
Thermal burns under the arm	Victim used an aerosol underarm deodorant, then reached over a stove. The deodorant ignited.
Death caused by burns on upper part of body	Victim used a hairspray and then attempted to light a cigarette. Her hair and clothes immediately ignited.

EFFECTS OF CHLOROFLUOROCARBONS ON THE OZONE LAYER

In June 1974 two University of California scientists reported their theory that once released into the atmosphere, chlorofluorocarbons, the most widely used aerosol propellants

in the United States, could deplete the Earth's protective ozone layer. Ozone, a gas formed by the action of sunlight on oxygen, shields the planet from harmful solar radiation. Depletion of the ozone layer may lead to increased incidence of skin cancer, destruction of certain forms of plant life, and changes in the Earth's climatic conditions.

A September 1976 report by a panel of the National Academy of Sciences confirmed the potential hazards first identified by the California scientists. According to the Academy's report, continued release of chlorofluorocarbons at 1973 levels could result in an ultimate reduction in ozone of about 7 percent. Cancer specialists estimate that with each 1-percent decrease in the ozone layer, a 2-percent increase in the incidence of skin cancer would occur.

In 1976 Americans were using over 3 billion aerosol cans annually, about half of which used chlorofluorocarbons as the propellant. Cosmetic usage accounted for about 90 percent of the chlorofluorocarbons used in aerosols. It has been estimated that sales of aerosol products have declined by about 40 percent during the past 3 years. Many consumers have switched from aerosol to roll-on or stick deodorants and to pump-top hairsprays. In addition, manufacturers are switching from chlorofluorocarbons to hydrocarbons or other propellants.

FDA published in the Federal Register of November 26, 1976, a notice of its intent to phase out nonessential use of chlorofluorocarbons in FDA-regulated products. After analyzing the comments received on the notice, FDA, on May 13, 1977, published a proposed rule in the Federal Register (42 F.R. 24536) prohibiting the use of chlorofluorocarbons in most FDA-regulated products manufactured or packaged on or after December 15, 1978 (or finisned products initially introduced into interstate commerce on or after April 15, 1979). A final rule was published in the Federal Register on March 17, 1978 (43 F.R. 11301), with the same effective dates as the May 1977 proposal.

NITROSAMINES

Research sponsored by the National Science Foundation has identified the presence of a nitrosamine, N-nitrosodiethanolamine, in many cosmetics. NDELA has been found to cause cancer when fed to rats.

The researchers at a March 1977 meeting of the American Chemical Society reported that NDELA was found

in 25 of 27 cosmetics tested at concentrations ranging from a trace (less than 10 parts per billion) to 48,000 parts per billion. The products tested included makeup, hand and body lotions, and shampoos.

According to the researchers: 1/

> "It is not possible at the present time to assess properly the potential hazard to man from NDElA since the carcinogenicity of NDElA has been studied only via ingestion and not via absorption through the skin. However, since triethanolamine is a wetting agent and is used industrially to increase the penetration of organic liquids into wood, it does not seem unreasonable to assume that a significant amount of NDElA applied to the skin may be absorbed. NDElA is a known liver carcinogen in rats and belongs to a group of compounds which have been demonstrated to be carcinogenic to all species which have been tested."

FDA considers the presence of NDELA in cosmetics to be a potentially serious problem. To evaluate the extent of the human health hazard, FDA plans to:

--Perform studies on the absorption of NDELA through human skin.

--Develop metnods for identification and determination of amount of NDELA in cosmetics.

FDA has purchased the equipment needed to detect NDELA in cosmetics and has begun to analyze products for NDELA.

ESTIMATES OF COSMETIC-RELATED INJURIES

Adequate estimates of cosmetic-related injuries are not available. While the product or ingredient causing acute toxic effects, such as allergic reactions, accidental poisonings, and eye irritations, can often be identified, the cause of chronic toxic effects, such as cancer or birth defects,

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1/T.Y. Fan, U. Goff, L. Song, D. H. Fine, G. P. Arsenault, and K. Biemann, "N-Nitrosodiethanolamine in Cosmetics, Lotions, and Shampoos," Food and Cosmetics Toxicology, vol. 15, October 1977, pp. 423-430.

cannot be readily identified because of the time between use of the toxic substance and onset of the toxic effects. Thus estimates of cosmetic-related injuries generally account for only acute toxic effects.

None of the three studies we reviewed attempted to assess the extent of chronic injuries from cosmetic exposure. In addition, each study was inadequate for estimating the extent of acute injuries. The three studies are discussed below.

National Commission on Product Safety estimate

In its June 1970 report to the President on public exposure to unreasonable risk of injury from consumer products, the Commission reported that cosmetics injure about 60,000 persons annually, so seriously as to restrict activity for 1 day or require medical attention. The injuries reported included skin eruptions, loss of hair, severe allergic reactions, burns, itching, and lacerations. The Commission also reported that beauty aids alone rank second among products reported in its survey of product liability insurance claims.

According to a former Special Assistant to the President for Consumer Affairs, the Commission's estimate was based largely on data on accidental cosmetic ingestions. She noted that the most frequent problems with cosmetics are skin reactions, which go unrecorded because they do not require hospital treatment.

NEISS estimate

CPSC's NEISS program estimates that about 21,000 cosmetic-related injuries were treated in hospital emergency rooms in the 48 contiguous States during calendar year 1977. However, the estimate does not include injuries treated by the medical community outside emergency rooms or injuries not requiring medical treatment.

FDA survey

In an attempt to gather more reliable data on cosmetic-related injuries, FDA sponsored a 3-month survey of about 35,500 persons' use of cosmetics. Participants in the survey, published in June 1975, kept a diary of cosmetic usage and reported any adverse reaction they perceived. These reports were reviewed by a team of physicians to determine, in their professional judgment, if the injuries may have been cosmetic related.

During the survey period, about 1 of every 60 participants suffered an injury confirmed by a physician as probably or definitely cosmetic related; about 1 of every 450 participants suffered a severe or moderate injury. Because the survey was based on injuries perceived by consumers as being cosmetic related, injuries which consumers could not readily associate with use of a cosmetic product are not included in the estimates. The injury data and criteria used in assessing the severity of the injuries are summarized below.

Number and severity of cosmetic-related injuries

Severity	Number of survey participants	Number of confirmed injuries (note a)	Ratio of injuries/ participants
Severe (note b)	35,490	13	1:2,730
Moderate (note c)	35,490	63	1: 563
Mild (note d)	35,490	505	1: 70
Undetermined	35,490	8	1:4,436
Total	35,490	589	1: 60

a/Number of injuries confirmed by physicians as probably or definitely cosmetic related.

b/Severe injuries were described as those whose symptoms (1) might have been of systemic nature and were painful to the patient, (2) would cause a loss of time from normal activities, (3) were of such a degree of severity that, in the opinion of the survey's consulting physician, the subject would have been well advised to see a physician, and (4) persisted for a prolonged period.

c/Moderate injuries were described as those whose symptoms (1) would be considered rather annoying to the patient, (2) could have caused loss of time from normal activities, (3) might have led the patient to see a physician, and (4) persisted for a prolonged period.

d/Mild injuries were described as those whose symptoms (1) were of minor irritant type, (2) could cause no loss of time from normal activities, (3) would not require medication or physician evaluation, and (4) were of a fleeting nature.

Although the survey results cannot be projected to the total U.S. population because participants were not selected using a probability sample, the sociodemographic characteristics of the participants are highly representative of the total U.S. population.

CONCLUSIONS

Cosmetics are being marketed in the United States which may pose a serious hazard to the public. Some contain toxic ingredients which may (1) cause cancer, birth defects, or other chronic toxic effects, (2) contain contaminants known to cause cancer in animals, or (3) deplete the Earth's protective ozone layer. Because exposure to these ingredients can occur through skin absorption and inhalation as well as oral ingestion, it is important that the hazards posed by them be carefully assessed.

Available estimates of cosmetic-related injuries do not accurately reflect the extent to which consumers are exposed to toxic cosmetic products and ingredients. Because symptoms of chronic toxic effects may not occur until months or years after exposure, injury estimates generally account for only acute toxic effects. Estimates of acute cosmetic-related injuries are probably understated in that they include only injuries resulting from accidental ingestion, injuries treated in hospital emergency rooms, or injuries perceived by consumers.

The following chapters discuss other hazards posed by cosmetics and the effectiveness of Federal efforts to insure cosmetic safety.

CHAPTER 3

NEED TO STRENGTHEN COSMETICS REGULATION

Before May 1972 FDA did not have a formal program to regulate cosmetics but took regulatory action on a case-by-case basis. Since then FDA has established several regulations designed to improve its control over cosmetic safety. Because FDA lacks adequate legislative authority for regulating cosmetics, compliance with many provisions of the regulations is voluntary, thus minimizing FDA's effectiveness.

Under existing legislative authority, however, FDA could:

--Require that labels of cosmetics containing fragrance or flavoring ingredients frequently associated with allergic reactions specifically list those ingredients.

--Provide guidance to manufacturers as to what constitutes adequate substantiation of safety.

--Establish product and ingredient standards identifying when a product or an ingredient can safely be used.

--Require childproof packaging on highly toxic cosmetics.

However, because FDA cannot require manufacturers to provide FDA access to data on the safety of their products, FDA must develop data to demonstrate that (1) a product contains a harmful substance and (2) the substance renders the product dangerous to consumers under customary conditions of use before it can issue a regulation to control use of the substance in cosmetics. By providing FDA additional authority to regulate cosmetics, the Congress could place the burden of proof for safety where it belongs--on manufacturers.

FDA'S PROGRAM

Since May 1972 FDA has established regulations which provide for:

--Voluntary registration of cosmetic manufacturers.

--Voluntary filing of product ingredient and raw material composition statements.

--Voluntary filing of cosmetic product experiences.

--Ingredient labeling of some cosmetics subject to the Fair Packaging and Labeling Act.

--Restricting the use of certain cosmetic ingredients.

--Precautionary labeling of certain cosmetics.

Although FDA also established a regulation defining the term "hypoallergenic" and describing the type of substantiation needed to support the claim that a cosmetic is hypoallergenic, the regulation was revoked effective March 14, 1978, pursuant to a court order.

Voluntary registration and submission of data

FDA is not authorized to require registration of cosmetic manufacturers or filing of data on cosmetic ingredients and adverse reactions (product experience reports). Therefore, FDA relies on manufacturers to voluntarily register and to submit this data. Agency officials consider the data requested under the voluntary programs essential to identify and remove from the market adulterated or misbranded cosmetics.

In the fall of 1971 the Cosmetic, Toiletry and Fragrance Association petitioned FDA to begin a voluntary regulatory program for cosmetics. The first phase--voluntary registration of manufacturers---was implemented in May 1972. In September 1972 the program was expanded to include the filing of product ingredient and raw material composition statements; in October 1973 it was further expanded to include filing product experience reports.

Although the voluntary program was first proposed by and developed in coordination with CTFA, manufacturers' participation has been limited. As of December 31, 1977,

--896 (about 40 percent) of the approximately 2,200 manufacturers identified by FDA had registered;

--768 of the estimated 4,000 to 5,000 manufacturers, packers, and distributors had filed ingredient statements; and

--130 of the 4,000 to 5,000 manufacturers, packers, and distributors had filed product experience reports.

The percentage of cosmetic products for which ingredient statements have been filed could not be determined because the total number being marketed is unknown. CTFA estimates

that FDA has formulation data on about 80 percent of the products. FDA believes, however, that the percentage is much lower, possibly as low as 40 to 50 percent.

In addition, FDA does not know how many of the products for which it has ingredient data are still being marketed. For example, one hair dye manufacturer reported formulation data on 26 products to FDA in April 1973, but did not notify FDA when production of the products was stopped in December 1973. Thus FDA was unaware until December 1977 that the products were no longer being produced.

Ingredient labeling

On October 17, 1973, FDA published in the Federal Register regulations requiring that cosmetic product labels subject to FPLA

--list product ingredients in descending order of predominance,

--indicate the presence of flavoring or fragrance ingredients,

--identify the presence of trade secret ingredients through use of the term "and other ingredients," and

--list active drug ingredients first if the cosmetic is also a drug.

All cosmetics sold to consumers for home use are subject to these regulations. However, cosmetics sold to beauty salons for application in the salon are exempt, as are free samples.

Implementation of the regulations, however, was delayed until April 1977 because of industry objections. Manufacturers claimed that ingredient labeling could prove cumbersome and could release trade secrets. The issue was not resolved until the U.S. Court of Appeals in Washington, D.C., ruled in April 1977 that FDA could legally enforce the regulations. All cosmetics subject to FPLA labeled after April 1977 must comply.

Hypoallergenic cosmetics

On June 6, 1975, FDA published in the Federal Register regulations defining the term "hypoallergenic" and describing the type of substantiation a manufacturer must submit to FDA to support the claim. Under the regulation the term

"hypoallergenic" can be used on a cosmetic label only if it has been shown by scientific studies that the frequency of adverse reactions in humans is significantly less than the frequency of such reactions from each "reference" product. The "reference" product must consist of one or more similar products on the market which represent at least 10 percent of the industry's combined volume in that cosmetic category.

However, implementation of the hypoallergenic cosmetics regulations was also delayed by a court challenge. A district court decided in favor of FDA, and the regulations became effective September 3, 1976. 1/

However, in December 1977 the U.S. Court of Appeals ruled in the case of Almay v. Califano, 569 F. 2d 674 (D.C. Cir. 1977), that FDA's action in establishing a definition of "hypoallergenic" was arbitrary and capricious and directed the district court to declare the regulation invalid. As a result, effective March 14, 1978, FDA repealed its rule requiring manufacturers to substantiate hypoallergenic label claims.

Ingredient restrictions

Before 1972 FDA had issued specific regulations governing the use of only two noncoloring ingredients in cosmetics. Since then regulations governing nine other ingredients have been issued. The regulations are summarized on the following page.

1/Manufacturers of hypoallergenic cosmetics in commercial distribution as of June 6, 1975, were given until June 6, 1977, to substantiate the hypoallergenic claim.

Date of regulation	Ingredient	Purpose of regulation
7/16/58	Egg	Standard for egg content in "egg shampoo."
2/14/68	Bithionol	Banned as a cosmetic ingredient effective 3/16/68.
9/27/72	Hexachlorophene	Banned as a cosmetic ingredient effective 9/27/72, except as a preservative at a level of less than 0.1 percent if no other preservative is effective.
1/5/73	Mercury	Banned as a cosmetic ingredient effective 1/5/73, except as a preservative for eye area cosmetics at a level of less than 65 parts per million where no safe and effective substitute is available.
8/26/74	Vinyl chloride	Banned as an ingredient in cosmetic aerosols effective 9/25/74.
10/30/75	Tribromsalan Dibromsalan Metabromsalan TCSA (note a)	Banned as a cosmetic ingredient after 12/1/75.
6/29/76	Chloroform	Banned as a cosmetic ingredient effective 7/29/76.
8/16/77	Zirconium	Banned for use in aerosol cosmetics effective 9/15/77.

a/3,3',4,5'-tetrachlorosalicylanilide.

Warning statements

In March 1975 FDA established a regulation requiring that the label of a cosmetic product bear a warning statement whenever necessary or appropriate to prevent a health hazard. Since then FDA has established regulations requiring specific warnings to be placed on the labels of certain products. FDA regulations now require that warnings appear on the labels of feminine deodorant sprays, aerosols containing chlorofluorocarbon propellants, and cosmetics in self-pressurized containers. FDA has also proposed that warnings be placed on the labels of bubble baths but as of April 1978 had not issued a final regulation.

In addition, labeling of cosmetic products for which safety has not been adequately substantiated for either the finished product or any ingredient in it must bear the statement: "Warning--The safety of this product has not been determined."

LABELS SHOULD IDENTIFY CERTAIN FRAGRANCE AND FLAVORING INGREDIENTS

One of the claimed benefits of ingredient labeling is that it enables persons with known allergies to specific ingredients to avoid purchase of cosmetic products containing them. However, FDA regulations require that the presence of fragrances or flavorings in a cosmetic be declared on the labeling, but do not require the identification of individual fragrance or flavoring ingredients because of the large number of such ingredients that may be present in any one product.

Many fragrance and flavoring ingredients, such as oil of cinnamon, oil of jasmine, and Peruvian balsam, are among the cosmetic ingredients most likely to cause allergic reactions. In June 1975 testimony before the Subcommittee on Health, Senate Committee on Labor and Public Welfare, three members of the American Academy of Dermatology said that they believe that perfume allergy represents a significant proportion of adverse reactions.

Hypoallergenic cosmetics are intended to exclude ingredients to which a significant number of persons are known to be allergic. The list of ingredients excluded from one hypoallergenic cosmetic manufacturer's products included 43 ingredients which, according to a February 1978 FDA printout of data reported to the agency by manufacturers under the voluntary program, were being used in other manufacturers' products. Of the 43 ingredients, 12 were reported by the manufacturers to be fragrances or flavorings.

According to FDA, some of the ingredients included in the hypoallergenic cosmetic manufacturer's list are commonly known to be allergens but many others have been implicated only in occasional reports of sensitization. FDA said that some ingredients on the list may be irritating to sensitive skin but that it seriously doubts that they cause a sufficient number of sensitization reactions to be considered "allergens." FDA also pointed out that only limited data is supplied to FDA on fragrance ingredients used in cosmetics.

Because individual fragrance and flavoring ingredients need not be listed on labels, consumers with known allergies to them cannot identify products containing them.

NEED TO DEFINE ADEQUATE SUBSTANTIATION OF SAFETY

Although FDA has established a regulation requiring that labeling of products that have not been adequately tested for safety bear a warning to that effect, the agency has not specifically defined what constitutes "adequate substantiation of safety" for a cosmetic product or an ingredient. According to the Bureau of Foods' Director, Division of Cosmetics Technology, the safety of a cosmetic

> "* * * can be considered to be adequately substantiated if the manufacturer, packer, or distributor has accumulated all the appropriate toxicological and other test data available to him at the present state of science and technology, and which provide him with the assurance that the cosmetic is not injurious to users under the conditions of prescribed or customary use." 1/

Under the above definition, however, each manufacturer must determine what tests, if any, are needed to support the safety of a product or an ingredient. According to FDA's March 1975 Compliance Program Guidance Manual, FDA inspections of manufacturers indicated that more than 67 percent did not conduct pharmacological or chemical studies on new or reformulated products to determine their safety before they were distributed.

1/H. J. Eiermann, "Safe and Truly Labeled Cosmetics," Drug and Cosmetic Industry, vol. 115, November 1974, p. 39.

Even when tests are performed, they are not always appropriate to establish the safety of the cosmetic. For example, when a major bubble bath manufacturer reformulated its product in April 1973 in an attempt to reduce the frequency of injury complaints, it completed a "guinea pig immersion test" and a human use test to support the safety of the new formulation.

However, an FDA official stated that on the basis of a cursory evaluation of the tests, he had concluded that they were not indicative of actual use conditions and could not be extrapolated to a large use population. FDA maintained that the guinea pig immersion test had not included a non-irritating reference product and that the human use study had not had enough participants to be of statistical significance.

Although FDA determined that the tests by the manufacturer were not appropriate to support the safety of its product, FDA has not issued regulations establishing testing protocols and criteria for substantiating the safety of bubble baths. Nor has FDA required manufacturers to place the statement "Warning--the safety of this product has not been determined" on bubble bath labels. FDA, however, proposed in the Federal Register of January 28, 1977 (42 F.R. 5368-5370), that the following statement appear on labels of bubble baths:

> "Caution--Use only as directed. Excessive use or prolonged exposure may cause irritation to skin and urinary tract. Discontinue use if rash, redness or itching occur. Consult your physician if irritation persists. Keep out of reach of children."

Furthermore, unless FDA establishes by regulation that a specific test is appropriate for evaluating the safety of a cosmetic, it may have difficulty in using the test for enforcement purposes. For example, FDA attempted to prosecute a shampoo manufacturer for marketing an adulterated product, but could not show that the test used by the agency to evaluate the safety of the shampoo was appropriate.

After a young girl suffered an eye injury from a shampoo concentrate that accidentally squirted in her eye, FDA performed eye irritancy tests on the product using the "Draize rabbit eye test" developed by an agency employee.

FDA found that the shampoo was an eye irritant under the Draize rabbit eye test and attempted to prosecute the

manufacturer for marketing an adulterated product. However, in January 1974 the court 1/ ruled in favor of the manufacturer in part because FDA had failed to show that (1) the results of tests on rabbit eyes can be extrapolated to humans and (2) that the shampoo was any more hazardous than any other shampoo on the market. 2/

In a February 6, 1974, memorandum analyzing the reasons why FDA lost the case, FDA's then Chief Counsel said that:

> "In the future, we must ascertain that the product in question is potentially more dangerous than other competing products against which we are taking no action, and that there is some rational basis for concluding that the potential injury involved is limited to this type of product and is not appplicable to other cosmetics unless we also take concurrent action against those other products. We must, in short, have a clear and consistent policy which singles out truly dangerous products and distinguishes them from other products against which no action is warranted.
>
> "* * * In the future, we must clearly have sound evidence, and a consistent medical and scientific rationale, for charging potential injury to health. (It would be far preferable, of course, to specify by regulation standards that will classify a product as unacceptable, but this approach is not an absolute necessity.)"

1/ United States of America v. An article consisting of approx. 95 cases of 12 bottles each, more or less, labeled in part: (bottle) "Beacon Castile Shampoo with Lanolin, 16 Fl. oz. (1 pt.) Distributed by Topco Associates, Inc., Skokie, Ill." No. 71-53 (N.D. Ohio).

2/ The court also ruled that FDA had failed to show that (1) the full concentrate of shampoo might get into the user's eye under the usual or customary conditions of use and (2) that the user would not ordinarily flush or wash out the eye. In the injury resulting from use of the shampoo, the shampoo squirted into the user's eye when she dropped the bottle. The user did not wash out the eye. Data on the injury were not introduced as evidence in the court case, however, because FDA lost some of the documentation.

The Director of FDA's Division of Cosmetics Technology told us that FDA might have won the case if the agency had established regulations governing the use of eye irritants in cosmetics. As of April 1978, however, FDA had not formally adopted the Draize rabbit eye test or any other eye irritancy test as the appropriate test to be used in testing shampoos or other cosmetic products.

The Consumer Product Safety Commission has issued a regulation establishing a modified Draize rabbit eye test as the appropriate eye irritancy test for determining the safety of products regulated under the Federal Hazardous Substances Act (15 U.S.C. 1261). The agency regularly uses the test in its enforcement program.

Although FDA cannot require that cosmetic manufacturers test their products for safety, by establishing a specific definition of adequate substantiation, including protocols for conducting tests and criteria for evaluating the results, FDA could provide guidance to manufacturers in determining what tests to perform. FDA could also establish a comprehensive market surveillance and enforcement program in which samples of products are tested using the protocols.

Knowledge that FDA may test their products and take enforcement action against products not meeting safety criteria should provide an incentive to manufacturers to perform safety tests before marketing cosmetics. However, FDA told us that it needs authority to require the submission of test results before it can effectively enforce any safety substantiation requirements.

NEED TO ESTABLISH INGREDIENT AND PRODUCT CLASS STANDARDS

According to the Deputy Director of FDA's Division of Cosmetics Technology, FDA has found:

> "As a general rule * * * the most effective means to increase consumer safety with regard to a specific category of products is to promulgate an appropriate regulation. The regulation may prohibit or limit the use of an individual ingredient or require the use of a specific warning statement on the label. For example, the frequency of complaints of eye irritation associated with the consumer use of shampoos may warrant a regulation calling for a reduction in the concentration

of certain ingredients in these products as well as label warning statements." 1/

However, except for the regulations discussed on pages 28 and 29, FDA has not set safety standards for cosmetic ingredients or products.

As discussed in chapter 2, about 22 percent of the ingredients listed in the 1977 edition of the CTFA Cosmetic Ingredient Dictionary as available for use in cosmetics are considered toxic substances by the National Institute for Occupational Safety and Health because of their acute toxicity or because they may cause toxic effects, such as cancer, birth defects, or central nervous system disorders. Finished cosmetic products may be hazardous if they contain unsafe levels of toxic ingredients or if the label does not contain adequate directions for use and precautionary statements. In addition, combinations of toxic substances, each at a level below which it could be considered "toxic," may be toxic.

Ingredient and product class standards might be established to:

--Limit the concentration of an ingredient that can be used in cosmetics.

--Restrict the use of an ingredient to certain types of products, such as those used externally.

--Provide for special labeling requirements, including directions for use and precautionary labeling.

By analyzing cosmetic samples for compliance with such standards, FDA could better insure the safety of cosmetics.

The following examples illustrate the need for ingredient and product class standards.

Example 1

CPSC has established regulations requiring that specific warnings be placed on the labels of products containing certain toxic ingredients. FDA's August 1977 printout of data submitted to the agency by cosmetic manufacturers under the voluntary program showed the use of six of the ingredients

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1/J. A. Wenninger, "Cosmetic Legislation: Technical Consideration," Journal of the American Medical Women's Association, vol. 29, no. 7, July 1974, p. 320.

in cosmetics at concentrations exceeding the level requiring special labeling in other products. The CPSC regulations, however, do not apply to cosmetic products, and FDA has not established regulations requiring precautionary labeling on cosmetics containing the ingredients.

The following table shows the required warnings for the six ingredients when used in products subject to CPSC regulation and their use in cosmetics.

Comparison of Warnings Required on Labels of Products Regulated by CPSC and on Cosmetic Products by FDA

	Household products		Cosmetic products		
Ingredient	Concentration requiring warning	Required label warnings	Cosmetic uses (note a)	Maximum concentration reported by manufacturer (note a)	Required warnings
Ammonia	5%	"Poison"	Hair bleaches	5% to 10%	None
Ammonium hydroxide	5%	"Poison"	Permanent waves	10% to 25%	None
Mineral spirits	10%	"Danger" "Harmful or fatal if swallowed." "If swallowed do not induce vomiting. Call physician immediately."	Eyeliner, mascara	Over 50%	None
Toluene	10%	"Danger" "Harmful or fatal if swallowed." "If swallowed do not induce vomiting. Call physician immediately." "Vapor Harmful."	Nail polish and enamel, other manicuring preparations	Over 50%	None
Xylene	10%	"Danger" "Harmful or fatal if swallowed." "If swallowed do not induce vomiting. Call physician immediately." "Vapor Harmful."	Manicuring preparations	10% to 25%	None
Turpentine	10%	"Danger" "Harmful or fatal if swallowed."		Over 50%	None

a/Reported to FDA by cosmetic manufacturers under the voluntary program for filing of cosmetic product ingredient statements as of August 1977.

Example 2

Results of studies at Emory University have shown the presence of potentially harmful bacteria in about 50 percent of the used eye makeup tested. (See p. 18.) One researcher has recommended to FDA on several occasions that expiration dates be required on the labels of eye cosmetics because the preservative systems used to prevent the growth of bacteria in the products break down during use.

According to the Director of FDA's Division of Cosmetics Technology, cosmetics which become contaminated during use and injure consumers are adulterated and violate the Federal Food, Drug, and Cosmetic Act. Despite the findings of the university studies and the researcher's recommendations, FDA has not established a product class standard for eye cosmetics. Such a standard might:

--Establish safe levels, if any, of bacterial contamination.

--Establish protocols for testing the effectiveness of the preservative system.

--Require inclusion of statements on the labels of eye cosmetics to warn users (1) about the potential for bacterial contamination and (2) to discontinue use if the eye becomes irritated.

--Require inclusion of expiration dates on product labels.

Example 3

A December 1974 Bureau of Foods safety evaluation of a mouthwash concentrate revealed that the product contained formaldehyde, a powerful germicide that may injure oral tissues. The Bureau of Foods reviewer concluded that:

> "Reputable scientific opinion that continued use of formaldehyde in mouthwash formulations at any dilution cannot be recommended may have no legal status in connection with this mouthwash concentrate which contains formaldehyde. We would concur in the opinion that formaldehyde use be discouraged in a mouthwash which might be ingested."

Because FDA has not issued an ingredient standard limiting the use of formaldehyde to externally applied cosmetics, it can still be used in cosmetics which may be ingested. According to FDA's February 1978 printout of data reported to FDA under the voluntary program for filing of cosmetic product ingredient statements, manufacturers reported the use of formaldehyde in three mouthwashes. Because of limited participation in the voluntary program, the actual number of mouthwashes containing formaldehyde could not be determined.

Example 4

In following up on an injury complaint, the Bureau of Foods' Division of Cosmetics Technology obtained the opinion of an official from the Bureau's Division of Toxicology concerning the safety of the use of mineral oil in a hairspray at a concentration of 16.7 percent. It was the opinion of the Division of Toxicology official that mineral oil should not be used in a hairspray even though available data did not show that mineral oil in a hairspray is a hazard. He said that he had recently informed the Bureau's Division of Regulatory Guidance that regulatory action against a hairspray containing 30 percent mineral oil could not be supported because there were insufficient data to show it was a hazard.

However, regulations (16 C.F.R. 1500.14(b)(3)(ii)) established by CPSC under the Federal Hazardous Substances Act require that labels of products (excluding cosmetics) containing 10 percent or more by weight of mineral oil bear the warnings "Danger," "Harmful or fatal if swallowed," and "If swallowed, do not induce vomiting. Call physician immediately." The regulation states that mineral oil "may be aspirated into the lungs, with resulting chemical pneumonitis, pneumonia, and pulmonary edema."

By establishing a similar ingredient standard for cosmetics, FDA could require that appropriate warnings be included on the labels of hairsprays or other cosmetics containing more than 10 percent mineral oil and take regulatory action against manufacturers not complying with the standard.

NEED FOR CHILDPROOF PACKAGING

The Poison Prevention Packaging Act (PPPA) of 1970 (15 U.S.C. 1471 et seq.) authorizes CPSC to require special packaging on household substances, including cosmetics, when necessary to protect children from serious personal injury or illness resulting from handling, using, or ingesting them.

FDA is responsible under the FD&C Act for insuring that cosmetics are marketed in compliance with regulations issued by CPSC under PPPA. Section 601(f) of the FD&C Act states that a cosmetic shall be deemed misbranded if its packaging or labeling violates a regulation issued under PPPA.

Neither CPSC nor FDA, however, has taken effective action to insure that cosmetics are marketed in compliance with CPSC packaging requirements or assessed the need for additional packaging requirements for toxic cosmetics not presently covered by regulations.

CPSC has established regulations describing when special packaging is required for certain kinds of products, such as aspirin and furniture polishes, and for products containing certain ingredients, such as ethylene glycol. Seven of the regulations apply to ingredients listed in the 1977 edition of the CTFA Cosmetic Ingredient Dictionary as available for use in cosmetics. FDA's August 1977 printout of data submitted to the agency under the voluntary program showed that at least three of the ingredients--turpentine, potassium hydroxide, and sodium hydroxide--had been reported by manufacturers to be used in some cosmetic products at concentrations requiring special packaging.

Although CPSC regulations (16 C.F.R. 1700.14(b)) require that manufacturers of substances requiring special packaging submit to CPSC a sample of each type of special packaging used, the Director of CPSC's Division of Poison Prevention Packaging told us that he was unaware of any submissions of special packaging by the cosmetics industry. He said that CPSC has not taken any actions concerning childproof packaging for cosmetics.

Nor has FDA taken any actions concerning childproof packaging for cosmetics. For example, CPSC regulations require that household products, including cosmetics, containing more than 2 percent free or chemically unneutralized sodium or potassium hydroxide be marketed in CPSC-approved childproof packaging. FDA analyzed 22 hair straighteners for alkali content between June 1970 and October 1975 and found that 19 contained more than 2 percent sodium or potassium hydroxide and thus were subject to the CPSC packaging regulations. Although none of the 19 products were marketed in CPSC-approved childproof packaging and thus were misbranded under the FD&C Act, the Deputy Director of FDA's Division of Cosmetics Technology said he was not aware of any regulatory action against the manufacturers of the products.

Nor has FDA requested that CPSC establish additional special packaging requirements for other toxic cosmetic ingredients. Some toxic ingredients are used in cosmetics at concentrations high enough to cause serious poisoning from ingestion. For example, sodium and potassium bromates are used in permanent wave solutions in concentrations ranging from 10 to 25 percent. Serious poisoning has been reported in young children (1-1/2 to 3 years old) following ingestion of 1.5 to 3 grams (about 1 to 2 teaspoonsful) of a 2-percent solution of potassium or sodium bromate.

Similarly toluene and xylene are used in manicuring preparations at concentrations of 10 percent to over 50 percent. Ingestion of these substances, when present in a product at concentrations exceeding 10 percent, may be harmful or fatal. During 1973, 1,670 accidental ingestions involving manicuring preparations were reported to poison control centers. Over 90 percent of the ingestions involved children under 5 years of age, 30 of whom required hospitalization.

The Director of CPSC's Division of Poison Prevention Packaging told us that FDA has never made any recommendations to CPSC concerning special packaging for cosmetics containing sodium or potassium bromate, toluene, xylene, or any other toxic ingredient.

COSMETIC INGREDIENT REVIEW

In September 1976 CTFA established the Cosmetic Ingredient Review (CIR), a panel of scientists to review the safety of all cosmetic ingredients presently used in commercially distributed cosmetic products. Priority lists of ingredients to be reviewed are developed on the basis of such factors as (1) the frequency of use of the ingredient in cosmetics, (2) the availability of chemical specifications or descriptions, (3) any known questions about the ingredient's safety, and (4) the availability of sufficient data for the panel to make an informed scientific judgment on safety. Public comment is invited during preparation of the priority lists.

After an ingredient is selected for review, a literature search is performed in which a bibliography of the U.S. and foreign toxicological or other scientific literature, together with a description of each literature reference and a summary of the information found, is prepared. Interested parties are given 90 days to submit additional data, information, and views relevant to the safety of the ingredient.

The panel then reviews the available data to determine whether the ingredient is safe or unsafe or whether additional data are needed before a decision can be made with regard to safety. The preliminary findings of the panel are made available for public comment. The panel, after reviewing the comments received, makes a final determination with respect to the ingredient's safety and publishes the results in a final report.

In October 1977 the panel established its first priority list of 189 ingredients for review, but as of April 1978 had not completed its review of any of the ingredients.

In an April 1977 article 1/ evaluating different approaches to cosmetic safety substantiation, a Georgetown University Law Center professor and one of his third-year students evaluated the CIR program. According to the authors:

--No standards are set for determining the final priority list of ingredients to be reviewed.

--Consumer and FDA input into selection of ingredients to be reviewed would be more effective at the initial stage of priority planning.

--Manufacturers are not required to notify the CIR program of possible safety problems with cosmetic ingredients, thus the program may be unaware of the need to review certain products.

--Composition of the steering committee, 2/ which appoints members of the expert panel, does not furnish an impartial method of selecting panel members.

--Effectiveness of nonvoting liaison members of the expert panel representing consumers and FDA is highly questionable because they are excluded from closed meetings of the panel, where confidential data on a product are submitted by a manufacturer or discussed by the panel. (Since publication of the article, CIR procedures no longer exclude liaison members from closed meetings. However, the FDA representative, who serves as a contact person rather than as a liaison member, does not attend closed meetings.)

1/J. A. Page and K. A. Blackburn, "Behind the Looking Glass: Administrative, Legislative, and Private Approaches to Cosmetic Safety Substantiation," UCLA Law Review, vol. 24, April 1977, pp. 795-837.

2/Composed of the CTFA President, a dermatologist representing the American Academy of Dermatology, a toxicologist representing the Society of Toxicology, the Chairman of the CTFA Scientific Advisory Committee, and the CTFA Vice President for Science.

--The standard used to measure safety is deficient from a consumer's viewpoint in that the CIR program defines a cosmetic ingredient as safe when there is "no evidence in the available information that demonstrates or suggests reasonable grounds to suspect a hazard * * *." (The definition also states that "A lack of information about an ingredient shall not be sufficient to justify a determination of safety.")

The authors conclude that:

"The regulatory impact of the CIR program will be and should be minimal. While the CTFA's program could be used to generate safety substantiation data through the pooling of scientific resources, CIR cannot become a substitute for badly-needed FDA intervention in the area of cosmetic safety. An evaluation of the CIR plan must include recognition of the lack of success thus far enjoyed by other voluntary programs sponsored by the industry. Skepticism about CIR is fortified by industry's lack of cooperation with the FDA's OTC Drug Review of ingredients found in both nonprescription drugs and cosmetics."

According to FDA, the CIR program will neither "alter the need for new statutory authority" nor affect "FDA's ability to detect safety problems and to monitor industry substantiation of data."

Although many large cosmetic manufacturers are members of CTFA, fewer than 225 of the 2,200 known cosmetic manufacturers are members. The extent to which nonmembers will participate in and adhere to the decisions made in the CIR program is questionable. Nor will CTFA members be bound by the monographs developed under the CIR program.

PENDING LEGISLATION

Legislation was introduced in the 95th Congress to amend the FD&C Act to strengthen FDA's program for assuring the safety of cosmetics. The bill, Senate bill 2365, would give FDA a clear mandate for controlling cosmetics, making mandatory the provisions of FDA's current voluntary programs. Senate bill 2365 would:

--Require registration of cosmetic manufacturers.

--Require them to submit formulas for cosmetic products to FDA.

--Require them to periodically forward consumer complaints about adverse reactions to cosmetics to FDA.

--Give FDA specific authority to prohibit use of certain ingredients in cosmetics, require additional labeling, limit the amounts of certain ingredients that may be used in cosmetics, or ban a cosmetic if necessary to protect the public health.

--Require manufacturers to submit safety test data to FDA upon request.

--Authorize FDA to require specific testing when necessary to assure safe cosmetics.

--Require registration of new cosmetics unlike types previously marketed.

--Provide clear authority for FDA to require ingredient, cautionary, and information labeling of cosmetics under the FD&C Act.

--Provide a procedure for informal notice-and-comment rulemaking subject to direct review in a U.S. court of appeals.

CONCLUSIONS

Because FDA lacks adequate legislative authority, the success of its regulatory program depends largely on the cooperation of the cosmetics industry. However, many manufacturers have not participated in FDA's voluntary programs for registration of manufacturers and filing of product ingredient and experience reports. FDA is also hindered by the failure of many manufacturers to adequately substantiate the safety of their products and FDA's lack of authority to require manufacturers to provide FDA access to their safety data.

Although FDA has made a significant effort to improve its control over cosmetics since 1972, it could take additional steps under existing authority. FDA could (1) require that certain fragrances and flavorings be listed on product labels, (2) establish testing criteria to guide industry in substantiating the safety of its products, (3) establish ingredient and product class standards, and (4) insure that toxic cosmetics are packaged in childproof packages.

However, efforts to establish ingredient and product class standards and testing criteria would be hindered by FDA's lack of access to manufacturers' test data and complaint files. By providing FDA additional legislative authority, the Congress could place the burden of proof for cosmetic safety where it rightfully belongs, on the manufacturers.

RECOMMENDATIONS TO THE SECRETARY, HEW

We recommend that the Secretary direct the FDA Commissioner to strengthen FDA's program for insuring the safety of cosmetic products. Specifically, FDA should:

--Require the listing of fragrances and flavorings on cosmetic labels when they are known allergens.

--Hasten the development of ingredient and product class standards.

--Establish a specific definition of "adequate substantiation of safety," including specific testing criteria.

--Take steps, in coordination with CPSC, to insure that toxic cosmetics are packaged in childproof containers.

AGENCY COMMENTS AND OUR EVALUATION

HEW commented (see app. VI) that although it agrees in principle with many of our recommendations, it does not necessarily agree that they can be implemented under the present statute.

HEW pointed out that the FDA Commissioner had stated in testimony before the Subcommittee on Oversight and Investigations, House Interstate and Foreign Commerce Committee, that

> "As the law stands, cosmetics are the only products for which the legal burden rests on the Food and Drug Administration (FDA) to prove a hazard to the public, rather than on the industry to demonstrate that their product has been tested in accordance with currently accepted methodology and that it is safe."

HEW said that it does not believe that, under the current statutory authority, an extensive expenditure of resources toward regulation of cosmetics is a wise investment. The Commissioner also testified that

"* * * if you have important public health responsibilities in three different areas, and if each of them lays compelling claims to statutory authority, and in the other two it is at least better, then a wise man is going to allocate [resources] more heavily to where he is going to get a return."

HEW comments on specific recommendations and our evaluation of them are presented in the appropriate chapters of the report.

Listing of fragrance and flavoring ingredients on labels

HEW said that there is a lack of adequate scientific information to classify a fragrance or flavor ingredient as a known allergen. HEW explained that any ingredient can give rise to allergic contact dermatitis in some susceptible individuals. According to HEW, the question that remains to be answered is the frequency of such reactions which would permit an unambiguous classification of the ingredient as a known allergen. The matter, HEW said, is further complicated by the fact that the rate of allergic responses is related to the exposure concentration and that some allergens can be safely used in some products and not others.

According to HEW, if a substance produces allergic reactions to a significant extent, FDA may take regulatory action to restrict its use as a cosmetic ingredient, as it has done in the case of bithionol and halogenated salicylanilides. (See p. 29.) Moreover, HEW said that the listing of all ingredients in a fragrance or flavor would in many instances require declaration of over 100 chemical names on a product label and may raise trade secret issues.

Although it may not now be possible to classify all fragrance and flavoring ingredients as either allergens or nonallergens, we believe there are adequate data to classify certain ingredients as allergens.

For example, a project manager in the Division of Cosmetics Technology's Registration and Product Experience Branch told us that some ingredients, "such as formaldehyde or orris root are commonly known to be allergens." Also FDA officials told us that oil of cinnamon, oil of jasmine, and Peruvian balsam are among the cosmetic ingredients most likely to cause allergic reactions.

There are also several published lists of common cosmetic allergens. For example, the Ar-Ex Products Company prepared a list of "Common Cosmetic Irritants and Allergens." The list identifies the substance, the types of cosmetics it is used in, and the symptoms observed in persons allergic to it. Similar, but less extensive, lists were published by the American Medical Association's Committee on Cutaneous Health and Cosmetics and by Almay, Incorporated.

We believe that requiring identification of the limited number of fragrance and flavoring ingredients that are known allergens on product labels would enable consumers sensitive to those ingredients to avoid products containing them without requiring the listing of all fragrance and flavoring ingredients.

Development of ingredient and product class standards

HEW said that before FDA could issue regulations establishing standards, it must show that a cosmetic violating the standards may be injurious under the conditions of use or otherwise in conflict with the existing law. HEW said that FDA is not authorized to require industry to submit the data necessary for developing ingredient and product class standards and does not now have resources available to collect the data in-house.

Although FDA's ability to establish product and ingredient standards is hindered by the lack of adequate statutory authority, we believe establishing such standards is fundamental to developing a more effective cosmetics program. Once established, product and ingredient standards should enable FDA to more effectively use available resources to better ensure cosmetic safety. Therefore, the initial commitment of resources to establish such standards would appear to be cost effective, especially where substantial data are already available. For example, available data indicate that mineral oil and formaldehyde should not be used in hairsprays and mouthwashes, respectively. (See pp. 37 and 38.)

Definition of adequate substantiation of safety

According to HEW, FDA has already clarified the meaning of "adequate substantiation of safety" in relation to cosmetics by publishing in the Federal Register of March 3, 1975 (40 F.R. 8916), a notice:

"* * * that the safety of a product can be adequately substantiated through (a) reliance on already available toxicological test data on individual ingredients and on product formulations that are similar in composition to particular cosmetics, and (b) performance of any additional toxicological and other tests that are appropriate in the light of such existing data and information. Although satisfactory toxicological data may exist for each ingredient of a cosmetic, it will still be necessary to conduct some toxicological testing with the complete formulation to assure adequately the safety of the finished cosmetic."

HEW also said that FDA is not authorized to (1) require that cosmetic manufacturers substantiate the safety of their products, (2) establish specific testing criteria, or (3) require the submission of data to support development of such criteria at this time.

Although the notice tells manufacturers how they can substantiate the safety of their products (i.e., through new or existing toxicological test data), it does not offer them guidance in determining what tests, if any, should be performed. For example, the manufacturer of a cosmetic likely to come in contact with the eyes, such as shampoo, determines (1) whether eye irritancy tests are needed to substantiate the safety of its product and (2) the appropriateness of the tests. By establishing specific testing criteria for cosmetics, FDA could provide guidance to the cosmetics industry in determining (1) what tests to perform and (2) what tests are considered appropriate by FDA.

Although FDA cannot require manufacturers to test their products according to the criteria, the criteria would serve as the basis for FDA's enforcement testing of cosmetics. As a result, manufacturers might test their products for compliance with the criteria before they were marketed.

Moreover, testing criteria would seem especially important in view of the position taken by FDA's Chief Counsel in February 1974 that before FDA can charge that a cosmetic may cause injury, FDA must have sound evidence and a consistent medical and scientific rationale for the charge. He stated that it would be preferable for FDA to establish standards by regulation that would classify a product unacceptable. (See p. 33.)

Childproof containers

HEW agreed that requiring childproof packaging would be worthwhile for those cosmetics revealed to be the cause of poison ingestions leading to injury. HEW said that at present FDA is not aware of any hazard associated with cosmetic products that warrants such packaging but that FDA will continue to evaluate data from CPSC's National Electronic Injury Surveillance System and take appropriate action as the need arises.

As our report points out, some cosmetics contain toxic ingredients, such as sodium and potassium bromates, toluene, and xylene, which have caused serious poisoning in young children who accidentaly ingested them. (See pp. 39 and 40.) On the basis of such information, FDA should consider the need for childproof packaging of cosmetics containing these ingredients. Also, in its continuing evaluation of the need for childproof packaging, FDA should consider data from poison control centers, as well as the NEISS program, since reports to poison control centers involve primarily accidental ingestions by children under 5 years old.

RECOMMENDATIONS TO THE CONGRESS

We recommend that the Congress amend the FD&C Act to give FDA adequate authority for regulating cosmetic products. Specifically, we recommend that the Congress authorize FDA to require:

--Registration of all cosmetic manufacturers.

--Registration of cosmetic products and filing of ingredient statements.

--Manufacturers to submit to FDA data to support the safety of their products and the ingredients in them.

--Premarket approval by FDA of certain classes of cosmetics or ingredients when the agency deems such approval necessary to protect the public health.

--Manufacturers to submit to FDA consumer complaints about adverse reactions to cosmetics.

--Manufacturers to perform specific testing FDA deems necessary to support the safety of a cosmetic or an ingredient.

CHAPTER 4

NEED TO MORE EFFECTIVELY OBTAIN AND USE DATA ON COSMETIC SAFETY

Because FDA lacks authority to require cosmetic manufacturers to submit data concerning the safety of their products and the ingredients in them, the agency must systematically obtain information concerning cosmetic safety from other sources.

FDA, however, has only limited data on the safety of cosmetic ingredients and has not actively sought to obtain and use additional data. Specifically, FDA has not:

--Obtained safety studies available from published literature.

--Analyzed restrictions on use of cosmetic ingredients in other countries.

--Established an effective adverse-reaction-reporting system to obtain and analyze data on cosmetic-related injuries.

Even when data questioning the safety of a product causing an adverse reaction have been obtained, FDA has not always taken effective action to remove the product from the market.

LIMITED SAFETY DATA

To effectively evaluate the safety of a cosmetic, FDA must have adequate data on the toxicity of the ingredients in it. In April 1975 we reviewed the Bureau of Foods' toxicology files for safety data on 148 randomly selected cosmetic ingredients 1/ and found they did not contain safety data on 106 ingredients.

Although FDA cannot require manufacturers to submit data supporting the safety of their products or the ingredients

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1/Although the ingredients were randomly selected from the 1973 CTFA Cosmetic Ingredient Dictionary before issuance of the 1977 edition, they are also listed in the later edition.

in them, it could obtain data on the toxicity of many ingredients from published literature. As noted on page 9, the NIOSH registry and other published sources contain information on the reported toxic effects of about 600 cosmetic ingredients. The registry contains specific literature references for each ingredient listed. Of the 106 ingredients for which no safety data were available in FDA files, 28 are listed in the NIOSH registry, along with literature citations.

In addition, several available computer data bases can provide additional references on the toxicity of cosmetic ingredients. For example, we obtained several printouts of literature citations on the toxicity of formaldehyde and mercury.

According to officials in the Bureau of Foods' Division of Toxicology, the safety data in their files is generally limited to data accumulated in response to specific inquiries.

INGREDIENTS BANNED IN OTHER COUNTRIES USED IN U.S. COSMETICS

Many European countries have established "negative" lists of ingredients that cosmetics may not include or lists of restrictions on use of certain ingredients. A number of these ingredients are available for use without restriction in cosmetics sold in the United States. FDA, however, has not requested data on the basis for the actions taken in other countries.

Restrictions in the European Economic Community

The European Economic Community (EEC), 1/ an association of countries for economic cooperation, proposed that its member countries adopt a directive on cosmetics to reduce the multiplicity of national laws existing in member countries. The proposed directive lists (1) ingredients which may not be used in cosmetics and (2) ingredients which may be used in cosmetics subject to restrictions as to types of products, maximum concentration, and special labeling requirements. The directive did not indicate why the

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1/The nine full members are: the United Kingdom, France, West Germany, Italy, Belgium, Denmark, Ireland, the Netherlands, and Luxembourg.

ingredients were to be banned or restricted. The lists have been approved by several countries.

According to an August 1977 printout of data submitted to FDA under the voluntary program for filing of cosmetic product ingredient statements, manufacturers had reported the use of eight ingredients which would be banned for use in cosmetics by the proposed EEC directive. 1/ Use of the eight ingredients was reported by manufacturers at concentrations ranging from 1 to 50 percent. Four other ingredients--2-naphthol, 2,5-dinitrophenol, stramonium, and vitamin D--which would be banned by the directive were listed in the 1977 CTFA dictionary as available for use in cosmetics in the United States. No manufacturers had reported the use of the four ingredients to FDA.

FDA has not established restrictions or special labeling requirements for any of the 12 ingredients which would be banned by the directive, or requested data from EEC on the reason for banning use of the ingredients.

Another 19 ingredients to be subject to restrictions under the proposed directive are listed in the 1977 edition of the CTFA dictionary as available for use in cosmetics or were reported by manufacturers as being used. Although the directive would establish maximum allowable concentrations for each of the 19 ingredients, FDA has not established similar restrictions for 16 of the 19 ingredients.

Appendix IV compares the restrictions which would be placed on the use of toxic ingredients in cosmetics by the proposed EEC directive and the restrictions on those ingredients in the United States.

FDA's August 1977 printout of data submitted to FDA by manufacturers under the voluntary program indicates that some of the ingredients are used in cosmetics in the United States at concentrations in excess of the maximum concentrations established by the proposed directive. For example, the directive would limit the use of lead acetate, a coloring agent used to gradually cover gray hair, to concentrations of up to 1.75 percent. Use of lead acetate was reported to FDA to be between 10 and 25 percent in one hair dye.

1/The eight ingredients are antimony potassium tartrate, barium sulfide, brucine, cantharides (Spanish Fly), iodine, phenol, tricresyl phosphate, and tetrachloroethylene.

Other restrictions

Individual countries have banned or restricted use of certain additional ingredients in cosmetics which can be used without restriction in the United States. For example:

--France requires that hair dressings containing thioglycolic acid be sold only by a qualified pharmacist. Thioglycolic acid is used without restriction in home permanents in the United States.

--Holland banned the use of p-phenylenediamine and quaternary ammonium compounds in cosmetics and restricts the amount of thioglycolic acid that can be used in home permanents. P-phenylenediamine is widely used in permanent coal tar hair dyes in the United States. Also at least 49 quaternary ammonium compounds are listed in the 1977 CTFA dictionary as available for use in cosmetics in the United States. Such use has not been restricted by FDA.

--Switzerland has banned the use of certain substances, including mercury, lead, and p-phenylenediamine, in cosmetics. Use of all three is permitted in the United States.

We could not readily identify the basis for the restrictions placed by other countries.

NEED TO ESTABLISH AN ADVERSE-REACTION-REPORTING SYSTEM

FDA does not receive reports of most adverse reactions to cosmetics and does not adequately follow up on those it does receive. Systematic reporting of adverse reactions could alert FDA to severe reactions and identify reaction trends that may be associated with certain cosmetics. Because cosmetics are not subject to premarket clearance, adverse reaction reports may offer the first indication that a cosmetic product or ingredient is hazardous.

Limited reporting

FDA obtains data on cosmetic-related injuries from two major sources, the public and manufacturers. However, neither group reports more than a small fraction of injuries to FDA.

Although CPSC's NEISS program for reporting product-related injuries treated in hospital emergency rooms estimated that nearly 22,000 cosmetic-related injuries were treated in emergency rooms during calendar year 1977, FDA received reports from the public on only about 430 cosmetic-related injuries. Most reports came from consumers, either directly or through referral from the Federal Trade Commission, CPSC, or the President's Office of Consumer Affairs. In a sample of about 100 consumer complaints reported to FDA since late 1969, 55 percent of the consumers indicated that they had sought medical treatment. However, few reports of cosmetic-related injuries were sent to FDA by the medical community.

Although the voluntary program for filing product experience reports by cosmetic manufacturers was established by FDA in October 1973, only about 3 percent of the manufacturers were participating as of December 31, 1977.

Other sources of injury data

FDA needs a system to obtain data on cosmetic-related injuries from other sources, such as the medical community, insurance companies, and lawyers who have filed claims on behalf of injured consumers. Such sources could be especially important because they would normally become involved in only the more serious or disabling injuries. According to FDA, some information from the medical community is available to FDA under contract arrangements. FDA currently has several dermatologists and an ophthalmologist under contract.

The medical community, including skin specialists and eye doctors, could offer valuable assistance to FDA by reporting unusual or serious injuries which the consumer might not associate with cosmetic usage. This is true especially with respect to chronic injuries where it is difficult to identify the cause of the injury.

Insurance companies should be encouraged to provide data to FDA on cosmetic-related injury claims, which, according to the National Commission on Product Safety's 1970 report, ranked second among products reported in the Commission's survey of product liability claims. In helping FDA identify and remove hazardous cosmetics from the market, the insurance companies would also be reducing the number of insurance claims resulting from use of such products.

Although FDA receives many letters of inquiry from lawyers suing cosmetic manufacturers because of alleged

cosmetic-related injuries suffered by their clients, FDA does not attempt to obtain data on the nature of the injuries or the outcome of the lawsuits. Because of the documentation necessary in preparing for such lawsuits and the serious nature of the alleged injuries, such data could be useful in evaluating the hazards of the products.

Inadequate followup

To determine the adequacy of FDA's followup on consumer complaints, we selected a random sample of about 100 complaints received by FDA since 1970. While the complainant was generally interviewed by FDA and a sample was sometimes collected for chemical analysis, there was little additional followup. FDA did not always

--contact the manufacturer to determine whether similar injuries had been reported and whether adequate data existed to support the cosmetic's safety,

--contact the complainant's physician to verify that the injury was cosmetic related,

--refer complaints involving cosmetics that are also subject to drug regulations to the Bureau of Drugs for followup, or

--utilize data to remove hazardous cosmetics from the market.

The following examples illustrate the lack of adequate followup.

Example 1

A trial attorney with no history of mental disorder claimed that an aerosol antiperspirant caused a marked depressive effect on her 1 to 3 hours after use. She stated that on some days she found herself thinking about suicide.

FDA performed a chemical analysis of the product and interviewed the complainant. The Division of Cosmetics Technology's Medical Director concluded that:

> "Because of the unusual nature of this complaint I am inclined to consider it legitimate. Analysis might be helpful, but if such an effect is real, it is probably due to the propellant."

Because the product is an antiperspirant, it is subject to both the cosmetic and drug provisions of the FD&C Act. However, the Division did not seek access to the manufacturer's records or refer the complaint to the Bureau of Drugs for further followup.

Example 2

Our random sample of about 100 complaints included complaints from 3 individuals of excessive loss of hair following the use of the same brand of shampoo. FDA had received 35 complaints of hair loss following use of the product.

The Division of Cosmetics Technology interviewed some of the complainants and performed a chemical analysis of the product, but made no attempt to contact the manufacturer to discuss the complaints or review its complaint and/or safety files. The Division concluded that no additional followup was needed, but that it would be on the lookout for other complaints about the shampoo.

Example 3

The Division of Cosmetics Technology's complaint files contain numerous complaints involving lead-based hair dyes, including a 1971 complaint in which lead was discovered in the blood of the complainant during a routine physical examination. Another complainant claimed that the hair dye had caused a low blood count. A third claimed that use of a lead acetate hair dye had contributed to the death of her husband. FDA did not contact the complainants' physicians in these cases.

Available evidence indicates that lead may be absorbed through the skin. Adequate studies have not been performed, however, to determine the rate of absorption and possible buildup of lead in the body.

Example 4

In reviewing a consumer complaint involving an aerosol cosmetic finish (a type of facial makeup), the Division of Cosmetics Technology's Assistant Director for Medical Review noted that:

> "There is a serious question of the safety of these preparations. We believe their marketing should be discontinued until such time as all doubts are removed by appropriate testing."

To support his conclusion, he cited the following.

--The product cannot be used without directing the spray into the eyes, nose, and mouth.

--In spite of closing the eyes, some of the product might be propelled into the eyes, where it would be expected to cause irritation.

--Inhalation of Freon, the propellant in the product, may cause cardiac irregularity and sudden death.

--Ingestion of one of the ingredients could increase myocardial irritability and increase the likelihood of cardiac arrhythmia from any toxic agent.

--Certain ingredients are toxic to the liver.

FDA files we reviewed, however, contained no indication that the concerns of the Assistant Director had been expressed to the manufacturer or that any action had been taken to remove the product from the market.

CONCLUSIONS

FDA has not systematically obtained information concerning the safety of cosmetic products. Its regulation of cosmetics could be improved if the agency (1) obtained and evaluated data on the safety of cosmetics and ingredients from published literature, (2) evaluated the basis for restrictions on the use of toxic ingredients in cosmetics in other countries, and (3) established an effective adverse-reaction-reporting system.

RECOMMENDATIONS TO THE SECRETARY, HEW

We recommend that the Secretary direct the FDA Commissioner to:

--Obtain and evaluate data from published literature on the safety of cosmetic products and ingredients.

--Obtain and evaluate the basis for restrictions on the use of certain ingredients in cosmetics in other countries and, where appropriate, adopt similar restrictions on their use in cosmetics used in the United States.

--Establish a system to (1) develop additional sources of information on cosmetic-related injuries and (2) ensure effective followup on consumer complaints.

AGENCY COMMENTS AND OUR EVALUATION

HEW concurred with our recommendations and explained how FDA was complying with them.

Evaluate published literature

HEW said FDA scientists continuously review new scientific information both from published literature and other sources. But officials in the the Bureau of Foods' Division of Toxicology advised us that the safety data in their files are generally limited to data accumulated in response to specific inquiries. Furthermore, we identified published studies for 28 ingredients for which no safety data were available in FDA files. Therefore, we believe FDA should expand its review of scientific literature.

Evaluate ingredient restrictions in other countries

HEW said that (1) it would be appropriate to evaluate the basis for the restrictions on the use of ingredients by other countries when the conditions of use of such ingredients in cosmetics marketed in the United States warrant such action and (2) FDA is already familiar with the restrictions imposed by many countries and continues to review the basis for new restrictions as the need arises. HEW said that because under current statutes use of cosmetic ingredients in the United States can be prohibited or restricted only if proven to be harmful to users under conditions of use, FDA cannot take action on the basis of foreign restrictions alone.

Although HEW said that FDA is familiar with the restrictions on the use of cosmetic ingredients in many countries, FDA could not give us data on the basis for the restrictions discussed on pages 50 to 52. FDA should obtain such data to enable it to determine the need for establishing similar restrictions.

Adverse-reaction-reporting system

HEW said that monitoring adverse reactions to cosmetic products is an important activity that has resulted in the removal of unsafe cosmetics from the market. According to

HEW, FDA is using and has used a substantial portion of its cosmetics resources for this type of activity, including (1) a program for evaluating adverse reactions reported directly to FDA, (2) monitoring reactions at selected hospital emergency rooms under the NEISS program, (3) evaluating voluntarily submitted product experience reports from the cosmetics industry, (4) conducting a comprehensive consumer survey, and (5) contracting with dermatolgists to evaluate and report adverse reactions from patients. Further improvement in this area, HEW said, would require a change in the statute enabling FDA to require mandatory reporting by industry.

We agree that FDA needs additional legislative authority to enable it to require manufacturers to report adverse reactions. However, a more effective system could and should be established under existing authority by using other sources of adverse reaction reports, such as the medical community, insurance companies, and lawyers.

HEW also said that effective followup on consumer adverse reaction complaints is conducted when facts available to FDA indicate a possibility that a significant health hazard is involved and that such followup could lead to FDA action to improve the safety of a specific product or cosmetics in general. FDA's ability to follow up in every instance is limited, according to HEW, by the lack of resources, cooperation of the complainant or the physician, lack of reliable information to relate the product to the alleged injury, and lack of authority to review complaint files of cosmetic firms and the safety data used to substantiate the safety of the product. HEW said that when consumer or physician information indicates serious injury, complaints are currently investigated to the fullest extent possible.

However, our review indicated that FDA did not always adequately attempt to follow up on reports of serious cosmetic-related injuries. For example, FDA often failed to contact the complainant's physician or the manufacturer to obtain further information about the alleged injury and any similar injuries reported to the manufacturer. Because the success of FDA's followup depends on the cooperation of physicians and manufacturers, FDA should make a greater effort to contact them.

CHAPTER 5

INADEQUATE REGULATION OF DRUG INGREDIENTS, COLOR ADDITIVES, AND PRESERVATIVES IN COSMETICS

The use of drug ingredients, color additives, and preservatives in cosmetics is not being effectively regulated.

--About 90 drugs available for use in cosmetics are not subject to the restrictions on drugs.

--About 25 color additives have been provisionally approved for use in cosmetics since 1960 although their safety has not been determined.

--Preservatives are used to prevent the growth of bacteria and other microorganisms in cosmetics, although their safety and effectiveness has not been determined.

NEED FOR STRICTER REGULATION OF DRUG INGREDIENTS

Drug ingredients are subject to cosmetic rather than drug regulation as long as the product is not "intended" or understood to have a drug effect. FDA, however, lacks adequate legislative authority to insure the safety of drug ingredients used in cosmetics. Furthermore, because the intended effect of a product is not always clearly stated on the product's label, there is often no clear distinction between drug and cosmetic products.

Although FDA has adequate authority under the cosmetic provisions of the FD&C Act to require inclusion of warning labels on cosmetic products containing drug ingredients, consistent with label warnings required on drug products, it has not always required such warnings.

Drug or cosmetic?

Under the FD&C Act (21 U.S.C. 321 (g)(1)), the term "drug" means:

--Articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary.

--Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.

--Articles (other than food) intended to affect the structure or any function of the body.

--Articles intended for use as a component of any of the above articles.

Although articles recognized in the Pharmacopeia or National Formulary are defined as drugs, products containing them are classified and regulated as drugs only if they meet one of the other criteria listed above.

Before 1976 FDA judged the intended effect of a product primarily on the basis of labeling claims. For example, if a product was marketed as an antiperspirant deodorant, FDA considered it an OTC (over-the-counter) drug because its label indicated that it was intended to affect a normal body function, i.e., perspiration. However, if the product was marketed as a deodorant claiming only to mask or cover up odor, FDA considered it a cosmetic even if it contained the same drug ingredient and would have the same effect on body function as the antiperspirant.

The following table lists examples of drug claims and similar or related cosmetic claims.

Drug claim	Cosmetic claim
Antiperspirant deodorant	Deodorant
Removes wrinkles	Softens wrinkles
Prevents sunburn	Promotes tanning
Prevents splitting nails	Hardens nails
Antiseptic mouthwash	Prevents bad breath

According to an article by an FDA attorney in the March 1977 issue of the Food Drug Cosmetic Law Journal, 1/ FDA reevaluated the distinction between drugs and cosmetics in 1976 and determined that a product whose labeling contains only cosmetic claims, but which contains a drug intended or understood to have a drug effect, can be classified as a drug product. FDA ruled that a product labeled solely

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1/M. Gilnooley, "Update," Food Drug Cosmetic Law Journal, vol. 22, March 1977, pp. 121-128.

as a suntan lotion (a cosmetic claim) is a drug if it contains an effective sunscreen because it is intended and understood that sunscreens prevent sunburn. According to the article, drug/cosmetic determinations may be made on a case-by-case basis because each determination is based on the attributes of the particular product and the intention in marketing it.

FDA could clarify the distinction between drug and cosmetic products by issuing regulations identifying drug ingredients which are "intended or understood" to have a drug effect when used in certain types of products. For example, rather than declaring suntan products containing sunscreens drugs on a case-by-case basis, FDA could issue a regulation stating that all suntan products containing effective sunscreens are drugs. Similarly FDA could declare products containing effective antiperspirants drugs regardless of labeling claims made for them.

Drug ingredients available for use in cosmetics

When an intended drug effect is not identified, the product is subject to cosmetic rather than drug regulation, even though the product contains a drug.

About 90 drugs listed in the Pharmacopeia or National Formulary were either (1) listed in the 1977 CTFA Cosmetic Ingredient Dictionary as available for use in cosmetics or (2) listed in the August 1977 FDA printout of data reported by manufacturers under the voluntary program for filing of product ingredient statements as being used in cosmetics. Among the drugs listed are ingredients which induce vomiting, relieve pain, fight infections, remove pigmentation from the skin, or corrode or destroy living tissue. Appendix II lists the drug ingredients available for use in cosmetics and their intended drug functions.

Although some of the ingredients are used in externally applied drugs and thus might produce the same drug effects when used in cosmetics, especially if used at similar concentrations, other drug ingredients, such as ipecac, are administered only orally. The ability of ingredients such as ipecac to cause drug effects when used in externally applied cosmetics depends on factors such as the amount of the ingredient in the product and the extent to which it is absorbed through the skin. There is no need to regulate a cosmetic product as a drug if the drug ingredient is not absorbed and has no drug effect. However, FDA lacks legislative

authority to require cosmetic manufacturers to prove that the drug ingredients used in their cosmetics do not cause drug effects on users.

Drug versus cosmetic regulation

The FD&C Act provides for far stricter regulation of drug products than for cosmetic products. The act requires a drug manufacturer to:

--Register its manufacturing establishments and products with FDA.

--File new drug applications with FDA and obtain FDA's approval of them before introducing new drugs into interstate commerce. Such applications must prove the drugs' safety and effectiveness.

--Report adverse reaction information to FDA on drugs for which it holds new drug applications.

--Conduct clinical tests to demonstrate the safety of the drugs before they are marketed.

By contrast, the act does not require that cosmetic manufacturers register either themselves or their products, obtain FDA approval to market new cosmetics or cosmetics containing new ingredients, test their products or product ingredients for safety and effectiveness, or report adverse reaction information to FDA.

When a drug is used in a drug product, the manufacturer has the burden of proof of the product's safety. When a drug is used in a cosmetic product, FDA has the burden to prove the product is not safe.

Regulation of drug ingredients in cosmetics in other countries

Some countries have stricter regulations governing use of drug ingredients in cosmetics. For example:

--Norway's drug regulations contain lists of substances which are meant for medical purposes and may be used in cosmetics in free sale only with the permission of the Government. For example, the active drugs used in deodorants, antiperspirants, dandruff shampoos, and medicated skin creams cannot be used in cosmetics without permission.

--Austria is authorized to enforce restrictions on use of drugs in cosmetics, including restrictions on the maximum concentration of drugs allowed in the products and the purity of the drugs. The Government can authorize the use of active drug ingredients in cosmetics under certain conditions.

--Swiss law has established an extensive list of active drug ingredients that may be used in cosmetics. Maximum permitted concentrations are established for the drugs in three different groups of cosmetic products: (1) products likely to come in contact with mucous membranes, such as toothpastes and mouth washes, (2) products for external application which will remain on the skin, such as face creams and hair lotions, and (3) products for external application which will normally be washed or rinsed off directly after application, such as shampoos. Swiss law also sets out in detail the specific advertising claims permitted in connection with the sale of cosmetic products without any risk of their being considered drugs.

Warning labels not required

FDA requires inclusion of adequate warnings on the labels of OTC drug products. While the actual wording is left to the manufacturer, FDA has established suggested warnings for labels of OTC drug products containing certain drugs.

Although many of the drugs are also used in cosmetics through the same routes of administration, FDA has not required similar warnings for cosmetic labels. In some cases the cosmetic use of the drug directly conflicts with the OTC drug label warning. For example, the label of OTC drug products containing boric acid must warn against its use as a dusting powder, but FDA's August 1977 printout of data submitted to the agency by manufacturers shows that the reported cosmetic uses of boric acid include its use in dusting powders.

The following table identifies some of the warnings suggested for OTC drug labels and the cosmetic uses of those drug ingredients identified in FDA's August 1977 printout that require no warnings.

Selected Drug Ingredients Requiring Special Labeling When Used in OTC Drugs but Not Requiring Special Labeling When Used in Cosmetics

Drug ingredient/product requiring special labeling	Recommended warning	Cosmetic uses
Boric acid **powder, crystals,** or granules used in externally applied OTC drugs	"Warning - Do not use as a dusting power, especially on infants, or take internally. Use only as a solution. Do not apply to badly broken or raw skin or to large areas of the body."	External application through a variety of products, including fragrance dusting powders, face powder, and foot powder. Use in foot powders at concentration of up to 25 percent. May be taken internally through use in oral hygiene products.
Methyl salicylate in externally applied OTC drugs	"Warning - Do not use otherwise than as directed. Keep out of the reach of children to avoid accidental poisoning." If the preparation is a counter-irritant or rubefacient the statement: "Caution- Discontinue use if excessive irritation of the skin develops. Avoid getting into the eyes or on mucous membrances."	Direct application to mucous membranes through use in mouthwashes, breath fresheners, and douches. Also used in a variety of skin care preparations.
Sulfur in externally applied OTC drugs	"Caution - If undue skin irritation develops or increases, discontinue use and consult physician."	External application through use in skin and hair care preparations.
Zinc stearate when used in OTC drugs as a dusting powder	"Warning - Keep out of reach of infants and children; avoid inhaling."	Wide variety of uses, including baby, face, and dusting powders.
Sodium perborate in OTC mouthwash and gargle and toothpaste	"Caution - Dicontinue use if irritation or inflammation develops, or increases. Avoid swallowing."	Used in mouthwashes and breath fresheners.
Resorcinol (other than the monoacetate) used in OTC hair preparations	"Caution - Excessive use of this preparation may temporarily discolor blond, white, or red hair."	Hair dyes and face, body, and hand lotions.
Creosote in externally applied OTC drugs	"Caution - do not apply to large areas of the body."	Shampoos.

REGULATION OF COLOR ADDITIVES

Color additives are used in cosmetics at concentrations sometimes exceeding 50 percent.

Although the 1960 Color Additives Amendments to the FD&C Act require FDA to establish regulations listing color additives that are safe for use in food, drugs, and cosmetics, the safety of many color additives used in cosmetics has not been established. In some cases FDA permitted continued use of color additives in cosmetics for over 15 years without submission of data to support their safety.

FDA regulations specify that any interested person may submit a petition to FDA proposing that a color additive be listed for use in a food, drug, or cosmetic. Under the 1960 amendments, color additives which were commercially established before July 12, 1960, were provisionally listed in the FDA regulations to make possible their use on an interim basis for "a reasonable period" pending completion of the scientific investigations needed for determining their safety.

As of April 1978, 42 color additives had been permanently listed for use in cosmetics. The provisional listing of 26 other additives available for use in cosmetics has been extended while manufacturers perform additional studies to support their safety. The provisional listing of most of the colors has been extended to January 31, 1981, thus providing the manufacturers over 20 years to establish the safety of the colors. Appendix V lists the color additives permanently or provisionally listed by FDA for use in cosmetics.

Some additives used in cosmetics were provisionally listed for over 15 years before petitions were filed seeking permanent listing of the colors. In one case, gold, a petition was never submitted and FDA finally terminated the provisional listing in September 1976. However, FDA permitted the use of gold in cosmetics for 16 years without submission of safety data.

In another case, caramel, a color additive petition was not filed until February 1976. 1/ FDA will permit the

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1/A single color additive petition for caramel and six other colors was submitted in December 1975, but was rejected by FDA in January 1976 because separate petitions were required for each color.

continued use of caramel as a color additive until January 1981, although the February 1976 petition did not contain the studies required to support its safety. The petition lacked data on eye area studies, short-term subchronic studies, and skin-painting studies.

According to an FDA official, FDA initially told manufacturers of certain color additives that they did not have to file petitions because FDA had adequate data to determine the safety of the colors, but subsequently required that petitions be submitted when new criteria and methods for determining the safety of additives were developed.

NEED FOR CLEAR AUTHORITY TO REGULATE PRESERVATIVES

Many cosmetic products, including eye makeup, shampoos, and hand and body creams and lotions, provide a good medium for the growth of microorganisms. Preservatives such as mercury and hexachlorophene can be used in some cosmetic products to prevent growth of microorganisms. Because microorganisms can pose a serious threat to vision in a scratched or an abraded eye (see p. 17), it is important that a safe and an effective preservative be used in cosmetics where microorganisms are likely to flourish.

FDA, however, lacks clear authority under the FD&C Act to require that manufacturers prove the safety and effectiveness of preservatives in their products, or even to require that manufacturers add preservatives to their products. Although the Environmental Protection Agency could regulate cosmetic preservatives as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of 1947, as amended (7 U.S.C. 135 et seq.), EPA has not attempted to do so.

Safety and effectiveness of preservatives

Although they are used in small amounts, some preservatives, such as hexachlorophene and mercury, are absorbed through the skin and have been shown to cause toxic effects in animals or humans. Several preservatives, including boric acid, dehydroacetic acid, captan, and formaldehyde, are suspected of causing cancer in animals. Others, including captan, hexachlorophene, EDTA (ethylenediaminetetraacetic acid), and phenyl mercuric acetate, have been found to cause birth defects in animals. Hexachlorophene and boric acid also affect the central nervous system.

In addition, some preservatives such as formaldehyde, propylparaben, and methylparaben, may be skin sensitizers.

As stated on page 17, studies at Emory University showed that preservatives used in mascaras often broke down during use of the product and became ineffective. Other mascaras were marketed without preservatives.

FDA authority to regulate preservatives

FDA has the same authority to regulate cosmetic preservatives that it has to regulate other cosmetic ingredients; i.e., FDA can ban use of a preservative it proves is hazardous under conditions of use. FDA, however, cannot require a manufacturer to prove the safety of the preservatives it uses.

Nor can FDA require a manufacturer to prove that its preservatives effectively prevent growth of microorganisms in its products and that the preservatives are not broken down by (1) other ingredients in the products or (2) microorganisms introduced into the products during use.

In the Federal Register of October 11, 1977 (42 F.R. 54837-54838), FDA announced its intention to propose a regulation regarding preservation of cosmetics coming in contact with the eye. FDA said that the proposal will include not only a requirement for preservation sufficient to protect a cosmetic against likely contamination during manufacture, processing, packing, or holding, but also the requirement that a cosmetic be adequately preserved to withstand contamination under intended or customary conditions of use.

The Federal Register notice also states that FDA considers inadequately preserved cosmetics to be in violation of the FD&C Act and that the agency will take whatever action is necessary to remove from the market any cosmetic that poses an unreasonable risk of injury because of inadequate preservation to withstand contamination under customary conditions of use.

EPA authority to regulate preservatives

FIFRA defines the term "pesticide" to include substances intended for preventing, destroying, repelling, or mitigating any form of plant or animal life or virus, bacteria, or other microorganism that the EPA Administrator declares to be a pest (except viruses, bacteria, or other microorganisms on or in living man or other living animals). Because preservatives such as mercury, captan, and hexachlorophene are used in

cosmetic products to inhibit the growth of microorganisms in the product rather than on the human body, the EPA Administrator could declare the microorganisms in cosmetics to be pests and regulate cosmetic preservatives as pesticides. FIFRA requires that pesticides be safe and effective and registered with EPA before they are marketed.

EPA, however, has not attempted to regulate cosmetic preservatives as pesticides. In July 1975 regulations (40 C.F.R. 162.14) declaring viruses and other microorganisms pests, the Administrator specifically excluded viruses and microorganisms in cosmetics from the declaration.

According to an EPA official, EPA excluded viruses and other microorganisms in cosmetics because it felt FDA had adequate authority to regulate cosmetic preservatives under the FD&C Act. Section 25(b) of FIFRA permits the EPA Administrator to exempt from the requirements of the act any pesticide which he determines to be adequately regulated by another Federal agency. The official pointed out that FDA had been given an opportunity to comment on the EPA regulations before they were finalized, but had not objected to the exemption granted to cosmetic preservatives.

Another EPA official told us that while he believes there should be some kind of preclearance for all ingredients used in products for human contact, such as cosmetics, he also believes that one agency--FDA--should be regulating all the ingredients in the products.

Furthermore, although EPA could require a preservative manufacturer to prove that its preservative could be safely and effectively used to prevent the growth of microorganisms in cosmetics, EPA could not require a cosmetic manufacturer to use a preservative in its products or to prove the effectiveness of the preservative as used.

CONCLUSIONS

The use of active drug ingredients, color additives, and preservatives in cosmetics is not being effectively regulated. Drugs can be used in a cosmetic without being subject to drug regulation if the product is not intended or understood to have a drug effect. FDA's control over the use of drugs in cosmetics could be strengthened if (1) FDA established regulations identifying drug ingredients that are intended or understood to have a drug effect when used in certain types of products, (2) FDA required inclusion of warning labels on cosmetic products containing active

drug ingredients consistent with label warnings on similarly administered drug products, and (3) additional legislative authority was given to FDA to require cosmetic manufacturers to prove the safety of ingredients used in their products. (See recommendation to the Congress on p. 48.)

The safety and effectiveness of preservatives used to prevent the growth of microorganisms in cosmetics could better be ensured if FDA were authorized to require manufacturers to submit data to FDA demonstrating the safety (see p. 48) and effectiveness of those preservatives.

Although FDA has adequate authority to regulate the use of color additives in cosmetics, it has not effectively used its authority to require color manufacturers or persons submitting color additive petitions to provide more timely evidence of the safety of their colors. About 25 additives have been available for use for over 15 years without their safety being fully established.

RECOMMENDATIONS TO THE SECRETARY, HEW

We recommend that the Secretary direct the FDA Commissioner to:

--Establish regulations identifying when drug ingredients are intended or understood to have a drug effect.

--Establish regulations requiring that labels of cosmetic products containing drugs bear warnings consistent with those required on drug products containing the same ingredients and given through the same routes of administration.

--Hasten the review of the safety of color additives provisionally listed for use in cosmetics and prevent the use in cosmetics of those colors not proven to be safe under the conditions of use.

AGENCY COMMENTS AND OUR EVALUATION

Regulations on use of drug ingredients

HEW said that FDA would have to approach the problem of whether a particular ingredient is a drug on a case-by-case basis. According to HEW, it would have to look at all the facts to determine if it can prove that the product was intended for use as a drug or a cosmetic.

HEW pointed out that the FD&C Act defines the term "cosmetic" to mean

> "(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles * * *."

while that act defines the term "drug" to mean

> "(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals."

HEW said that the distinction between a drug and a cosmetic therefore rests upon the intended use of the article.

Contrary to HEW's statement that the drug/cosmetic determination must be made on a case-by-case basis, FDA has, in fact, made such a determination on a product class basis in at least one instance. FDA treated all toothpastes containing sodium or stannous flouride as drugs, regardless of whether the labels contained drug claims (21 C.F.R. 310.201(a)(10) and (15)).

Similarly FDA has declared one suntan lotion a drug on the basis of the presence of a sunscreen which is understood to have a drug effect, without regard to its labeling claims. This would indicate that FDA could declare all suntan lotion containing the sunscreen drugs.

Warning labels

HEW said that it believes it is appropriate for FDA to examine the need for consistent warnings on drug and cosmetic products but that more study is needed to determine whether specific warnings should be required in each case. HEW also pointed out that under FDA regulations, the label of a cosmetic is required to bear a warning whenever necessary or appropriate to prevent a health hazard.

However, unless FDA establishes regulations identifying when specific warnings are necessary or appropriate,

the need for and wording of such warnings is determined by the manufacturer. Thus, before FDA could take regulatory action under its regulations, it must prove the need for a warning on a particular product. As stated by the Deputy Director of FDA's Division of Cosmetics Technology:

> "As a general rule * * * the most effective means to increase consumer safety with regard to a specific category of products is to promulgate an appropriate regulation. The regulation may * * * require the use of a specific warning statement on the label."

Review of color additives

HEW told us that FDA has already accelerated the review of color additives provisionally listed for use in cosmetics and that the speed of the review is dictated by agency resources, the availability of data from petitioners, and the time required to make sound scientific judgments in the public interest. HEW also said that FDA is taking action to prohibit the use of colors that pose safety problems.

RECOMMENDATION TO THE CONGRESS

We recommend that the Congress amend the FD&C Act to authorize FDA to require cosmetic manufacturers to submit data to FDA supporting the effectiveness of preservatives used.

CHAPTER 6

NEED TO REPEAL HAIR DYE EXEMPTIONS

Although coal tar hair dyes expose consumers to potentially serious hazards, FDA lacks adequate legislative authority to effectively regulate them. The FD&C Act requires cosmetics to be properly labeled and to be unadulterated. However, coal tar hair dyes whose labels contain a prescribed statutory warning concerning possible skin irritation and blindness are exempt from the adulteration provisions of the act. Because the labels of most such dyes bear this warning, they are generally exempt from FDA regulation under the adulteration provisions, even if they pose hazards, such as cancer, not covered by the warning.

Matters discussed in this chapter were discussed in our December 6, 1977, report to the Chairman, Subcommittee on Oversight and Investigations, House Committee on Interstate and Foreign Commerce, entitled "Cancer and Coal Tar Hair Dyes: An Unregulated Hazard to Consumers" (HRD-78-22).

BACKGROUND

According to a CTFA representative, about 33 million women use hair dyes to temporarily or permanently change their hair color. Most dyes marketed for use by women are known as coal tar hair dyes because initially coal tar was the only commercially practical source of material needed to synthesize the colors used in them. The remainder of the women's hair dye market is divided between metallic dyes, which are advertised to gradually cover gray hair, and the vegetable dye, henna. Although some men use coal tar hair dyes, the most popular dyes marketed for men are metallic dyes. Estimates on the number of men who use hair dyes were not readily available.

The Deputy Director of FDA's Division of Cosmetics Technology told us that most coal tar hair dyes contain colors derived from petroleum rather than coal tar. Because a color chemically identical to the petroleum-derived color could be derived from coal tar, FDA classifies petroleum-derived colors as coal tar colors and regulates hair dyes containing them accordingly. Throughout this report we refer to all hair dyes containing petroleum-derived and coal-tar-derived colors as coal tar hair dyes.

Coal tar hair dyes are divided into three groups--temporary, semipermanent, and permanent--depending on the permanence of the color.

Temporary hair dyes tone bleached hair, add highlights and brightness to natural color, improve shades of gray hair, and blend unevenly colored hair. The first temporary dyes were introduced in 1922 and were patterned after a similar product used to color curtains and other textiles. Commercial products generally contain a mixture of several colors to obtain a given shade. Temporary dyes are usually applied to the base of the hair and are combed through to the tip. The dyes are deposited on the surface of the hair fiber. Because they do not generally penetrate the hair, they are completely removable with one shampooing.

Semipermanent hair dyes penetrate the hair but wear off after two or three shampoos. They are often used to blend gray hair, to improve the coloring of white hair, or to add highlights to naturally blond hair. Semipermanent dyes are usually applied in a liquid base which is left on the hair for 20 to 40 minutes before being rinsed out. Because no chemical reaction takes place during application, semipermanent dyes do not significantly affect the structure and the color of hair as do permanent hair dyes. Like temporary hair dyes, semipermanent dyes generally contain a blend of several colors to obtain the desired shade.

Permanent, or oxidation, hair dyes account for about $3 out of every $4 spent on hair dyes. Such dyes work through a series of chemical reactions. The coal tar ingredients in permanent hair dyes are mostly colorless "intermediates" which produce color only after they are oxidized inside and on the hair by hydrogen peroxide or similar oxidants. 1/ Permanent hair dyes produce fast colors that are not readily removed by shampooing. The hydrogen peroxide also bleaches to some extent the natural color of the hair. Subsequent dyeing, perhaps monthly, is required to color new hair growth and restore the color of previously dyed hair.

POSSIBLE CANCER RISK TO CONSUMERS

There is increasing evidence that some coal tar hair dyes may pose a significant risk of cancer to users because

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1/The primary intermediates, such as para-phenylenediamine and para-aminophenol, are oxidized by hydrogen peroxide or another oxidant. The resulting products react with a coupler, such as 2,4-diaminoanisole, resorcinol, meta-aminophenol, and 1,5-dihydroxynaphthalene, or with another unoxidized "para" dye to give the desired shade.

known or suspected cancer-causing colors in these dyes may be absorbed through the skin and scalp. Specifically:

--Temporary hair dyes may contain coal tar colors shown to cause cancer in laboratory animals and banned by FDA for use in other cosmetic products.

--Temporary and semipermanent hair dyes may contain azo colors 1/ derived from benzidine, a known human carcinogen. Such colors contain benzidine as a contaminant, and the colors may break down in the body and release benzidine.

--Other coal tar colors available for use in temporary or semipermanent hair dyes have reportedly caused cancer in laboratory animals.

--Evidence from screening tests or animal studies indicates that several coal tar colors used in permanent hair dyes, including toluene-2,4-diamine and 2,4-diaminoanisole, 2/ may cause cancer.

Existing epidemiological studies provide limited and conflicting evidence about the incidence of cancer among coal tar hair dye users.

Skin absorption

In a study published in 1968 3/ three permanent hair dye ingredients--p-phenylenediamine, m-phenylenediamine, and toluene-2,5-diamine--were applied to the skin of dogs in gels and fluids, such as those used in hair dyes. The amount of dye absorbed through the skin was calculated

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1/Azo colors contain an "azo" group--two connected nitrogen atoms, each of which is usually linked to a carbon atom.

2/2,4-diaminoanisole is commonly referred to as 4-methoxy-m-phenylenediamine on hair dye labels.

3/M. Kiese, M. Rachor, and E. Rauscher, "The Absorption of Some Phenylenediamines Through the Skin of Dogs," Toxicology and Applied Pharmacology, vol. 12, 1968, pp. 495-507.

from the concentrations found in the blood or the urine. About 1 percent of the p-phenylenediamine applied was absorbed in 3 hours. The amount absorbed increased to about 7 percent if the gel was covered with aluminum foil immediately after application. Absorption decreased to about 0.1 percent if the dye was mixed with hydrogen peroxide before application. About 3 and 4 percent, respectively, were absorbed after applying toluene-2,5-diamine and m-phenylenediamine.

A second study 1/ demonstrated the absorption of toluene-2,5-diamine through human skin. The hair of five persons was dyed with a dye composed of toluene-2,5-diamine, resorcinol, and hydrogen peroxide. About 0.3 percent of the toluene-2,5-diamine was absorbed.

In a 1975 study report 2/ University of California researchers noted that many aromatic amines and diamines, such as benzidine, are absorbed through human skin. They estimated that women could absorb as much as 1 percent of the hair dye chemicals applied to the scalp.

Although we identified several reports stating that the colors in semipermanent hair dyes are absorbed, we could not find any studies identifying the extent to which they are absorbed.

FDA has received several reports of consumers experiencing brown or otherwise discolored urine following use of hair dyes.

Banned colors used in hair dyes

Coal tar hair dyes are exempt from the color additive provisions of the FD&C Act and, therefore, coal tar color additives banned from use in food, drugs, or other cosmetics may continue to be used in coal tar hair dyes.

1/M. Kiese and E. Rauscher, "The Absorption of p-Toluenediamine [toluene-2,5-diamine] Through Human Skin in Hair Dyeing," Toxicology and Applied Pharmacology, vol. 13, 1968, pp. 325-331.

2/B. Ames, H.O. Kammen, and E. Yamasaki, "Hair Dyes Are Mutagenic: Identification of a Variety of Mutagenic Ingredients," Proceedings of the National Academy of Sciences of the United States of America, vol. 72, no. 6., June 1975, pp. 2423-2427.

Nine color additives banned for use in cosmetics are listed in the 1977 edition of the CTFA Cosmetic Ingredient Dictionary as "available for use" in coal tar hair dyes. According to FDA officials, such colors would generally be used in temporary hair dyes. We found evidence that four of the nine colors--FD&C Green No. 2, FD&C Red No. 2, FD&C Violet No. 1, and FD&C Red No. 1--cause cancer in laboratory animals. The dictionary refers to these colors as Acid Green 5, Acid Red 27, Acid Violet 49, and HC Red No. 6, respectively. The remaining five colors (and their CTFA references) are: External D&C Red No. 11 (Acid Red 1), External D&C Red No. 13 (Acid Red 73), External D&C Red No. 8 (Acid Red 88), External D&C Yellow No. 3 (Acid Yellow 11), and External D&C Blue No. 1 (Basic Blue 9). We did not identify the toxic effects associated with these colors.

According to a November 1977 FDA printout of data submitted by manufacturers under the voluntary program for filing cosmetic product ingredient statements, manufacturers reported the use of FD&C Red No. 2 in three hair dyes, FD&C Red No. 1 in four hair dyes, and External D&C Blue No. 1 in thirteen hair dyes. A December 15, 1977, newspaper article on our report to the Subcommittee on Oversight and Investigations quoted an industry spokesperson as stating that no major hair dye manufacturer was currently using one of the banned colors shown to cause cancer in animals. The manufacturer of the four hair dyes reported to FDA as containing FD&C Red No.1 subsequently confirmed to us the use of the banned color in its products. However, the manufacturer that reported the use of FD&C Red No. 2 in hair dyes told us on December 21, 1977, that the banned color was no longer being used.

Because of the limited participation in the voluntary program and failure of participating manufacturers to update their submissions, the total number of products containing the nine colors could not be determined.

Benzidine-derived azo colors

Among the coal tar colors that may be used in temporary and semipermanent hair dyes are several azo colors derived from benzidine. According to EPA, benzidine-derived azo colors may contain up to 20 parts per million of benzidine. More significant, however, are data indicating that benzidine-derived azo colors may reconvert to benzidine in the body.

Benzidine was identified as a human carcinogen in the 1930s when factory workers exposed to benzidine developed an increased incidence of bladder cancer. Many scientists believe that cancer can result from ingestion, inhalation, or skin absorption of benzidine. In animal studies benzidine caused liver tumors in mice, rats, and hamsters and bladder cancer in dogs.

In a study report published in July 1975, 1/ two researchers from the New York University Medical Center reported on the metabolic reduction of benzidine-derived azo colors in the rhesus monkey. Monkeys were fed by stomach tube a single dose of benzidine or a benzidine-derived azo color dissolved in dimethyl sulfoxide. Four benzidine-derived azo colors were included in the study. Control urine was collected from each monkey before the test was begun.

The researchers analyzed urine collected from the monkeys over a 72-hour period and found benzidine and a benzidine metabolite (monoacetyl benzidine) in extracts of urine from both the monkeys fed benzidine and those fed benzidine-derived azo colors. They found that the metabolic reduction of the colors to benzidine was nearly total.

The researchers stated that the results of their work support the implication of an earlier study (one made in 1973) that an increased incidence of bladder cancer found in Japanese silk kimono painters had resulted from benzidine metabolically derived from ingested azo colors. The earlier study had demonstrated the reduction of benzidine-derived azo colors to benzidine in the presence of certain bacteria.

NIOSH began a study in 1977 to determine the degree of occupational risk to workers in the textile-dyeing and leather-tanning industries exposed to benzidine-derived colors. NIOSH notes that most dyestuffs are of a chemical class which offers the potential for rapid skin and lung absorption but that it is not known if the metabolites resulting from such occupational exposure differ from those reported in the New York University study.

1/E. Rinde and W. Troll, "Metabolic Reduction of Benzidine Azo Dyes to Benzidine in the Rhesus Monkey," Journal of the National Cancer Institute, vol. 55, no. 1, July 1975, pp. 181-182.

We could not locate any studies on the extent to which benzidine-derived azo colors are absorbed through the skin.

The 1977 edition of the CTFA Cosmetic Ingredient Dictionary lists eight benzidine-derived azo colors (Direct Black 38 and 131, Direct Blue 6, and Direct Brown 1, 1:2,2,31, and 154) as "available for use" in coal tar hair dyes.

By letter dated January 5, 1978, the National Cancer Institute's Associate Director for Carcinogenesis Testing Program notified the Chairman, Subcommittee on Oversight and Investigations, House Committee on Interstate and Foreign Commerce, that from inspection of preliminary test data on Direct Black 38 and Direct Blue 6, it appears that the colors are carcinogenic. NCI did not test the other benzidine-derived azo dyes.

In an interim report on the animal tests for carcinogenicity of Direct Black 38 and Direct Blue 6, NCI noted that:

> "* * * Ninety-day tests have been completed by the National Cancer Institute * * *.
>
> "In the short-term feeding studies, [the two] dyes produced liver toxicity in both species. Cancerous and precancerous conditions were found in rats, similar to the damage produced by known liver carcinogens. * * *
>
> "In addition, though the dyes were benzidine free when fed to the animals, benzidine was found in the urine of dosed rats and mice, an indication that animal systems break down the dyes and release benzidine.
>
> "Because the effects were so striking in the brief trial period and in comparatively young animals, NCI scientists resolved that findings should be reported, in order to expedite investigation of human exposures and the possible risks involved."

A December 15, 1977, newspaper article quoted CTFA as stating that no major hair dye manufacturers had used benzidine-derived azo colors in their products since 1973.

However, we subsequently purchased eight temporary hair dyes at Rockville, Maryland, drug stores containing one or more benzidine-derived azo colors.

Because the manufacturer--a CTFA member--does not participate in FDA's voluntary program for filing cosmetic product ingredient statements, FDA was unaware that the products contained benzidine-derived azo colors. FDA officials said benzidine-derived colors may also be used in semipermanent hair dyes.

Another manufacturer reported to FDA in April 1973 the use of benzidine-derived colors in 26 hair dyes but failed to notify FDA until December 1977 that manufacture of the products had been discontinued in December 1973.

The failure of participating manufacturers to update their submissions, coupled with the limited participation in the voluntary program, prevented us from determining the total number of products containing benzidine-derived azo colors.

Two of the eight colors available for use in coal tar hair dyes were included in the New York University study, and one of them, Direct Black 38, also reportedly was used by the Japanese kimono painters who developed an increased incidence of cancer.

The university researchers concluded that:

> "It is not our intent to imply that all azo dyes are biologicaly [sic] reduced to carcinogens, but those derived from carcinogenic aromatic amines should receive particular attention."

The CTFA dictionary lists other azo colors derived from toluene-2,4-diamine, toluene-2,4-diamine sulfate, and o-tolidine, each of which is a known or a suspected animal carcinogen.

Other suspected carcinogens in temporary and semipermanent hair dyes

Eleven other colors listed as suspected carcinogens in the 1976 NIOSH Registry of Toxic Effects of Chemical Substances were listed in the 1977 edition of the CTFA dictionary as "available for use" in coal tar hair dyes. The

NIOSH registry lists the studies upon which the list is based. Neither we nor NIOSH, however, has reviewed the adequacy of the studies or the appropriateness of the studies as a basis for determining the safety of the colors for use in hair dyes.

The table below lists the 11 colors, the animal species in which the studies were made, and the routes by which the colors were administered to the animals.

Color	Test animal	Route of administration
Acid Blue 9	Rat	Subcutaneous
	Rat	Parenteral
Acid Blue 9 ammonium salt	Rat	Subcutaneous
	Rat	Parenteral
Acid Blue 74	Rat	Subcutaneous
Acid Red 18	Rat	Oral
Acid Red 87	Rat	Subcutaneous
Acid Yellow 73 sodium salt	Rat	Subcutaneous
Basic Orange 2	Mouse	Oral
Basic Violet 10	Rat	Subcutaneous
Disperse Yellow 3 (note a)	Not identified	Not identified
Pigment Red 53 (note a)	Not identified	Not identified
Pigment Red 53:1 (note a)	Not identified	Not identified

a/Reviewed by the World Health Organization's International Agency for Research on Cancer. Available data were indefinite with respect to carcinogenicity.

Although the CTFA dictionary indicates that these 11 colors are "available for use" in coal tar hair dyes, we could not readily identify individual products that contain them.

Possible carcinogenicity of permanent hair dyes

Screening tests and animal-feeding studies provide additional evidence that some widely used permanent hair dye ingredients may be carcinogenic or mutagenic. CTFA has questioned the appropriateness of such studies for

determining the safety of hair dyes and has cited certain animal-skin-painting studies to support their safety. However, some scientists have questioned the adequacy of these studies.

We reviewed some of the more significant studies, which are briefly discussed below.

Screening tests

University of California researchers have developed a very sensitive and simple bacterial screening test for detecting chemical mutagens. The test is also believed to offer strong evidence of possible carcinogenicity. The researchers reported that 85 percent of the chemicals found carcinogenic in animal studies had been detected as mutagens in the bacterial test. By contrast, less than 10 percent of the chemicals classified as noncarcinogenic in animal studies showed mutagenic potential in the bacterial tests.

The researchers tested 169 marketed permanent hair dyes. The dyes were tested both before and after mixing with hydrogen peroxide. Of the 169 dyes, 150 (89 percent) were found to be mutagenic. Most of the dyes retained their mutagenic activity after being mixed with hydrogen peroxide. The researchers also tested 25 semipermanent hair dyes and found most to be mutagenic.

In addition, the researchers obtained from industry representatives 18 chemicals used in permanent hair dyes and tested them for mutagenic properties. Nine of the 18 showed various degrees of mutagenicity. 1/ Oxidation by hydrogen peroxide caused three of the chemicals to become strongly mutagenic.

An official from FDA's Division of Cosmetics Technology told us that although screening tests offer strong indications of possible carcinogenicity and mutagenicity, they alone do not provide sufficient evidence to conclude that a substance is harmful to humans. The official stated that such tests need corroboration by tests on animals.

1/The nine ingredients were 2,4-diaminoanisole, 4-nitro-o-phenylenediamine, 2-nitro-p-phenylenediamine, 2,5-diaminoanisole, 2-amino-5-nitrophenol, m-phenylenediamine, o-phenylenediamine, 2-amino-4-nitrophenol, and toluene-2,5-diamine.

NCI studies

NCI has contracted for animal studies on the carcinogenicity of 16 coal tar hair dye ingredients. The studies involve feeding the ingredients to rats and mice or applying the ingredients to the skin of rabbits and mice.

As of October 1977 NCI had not completed the analysis of any of the studies. Because it is impossible to assign priorities to chemicals in different use categories and because chemicals (including hair dye ingredients) appear in more than one use category, NCI had elected to analyze and report the results of experiments in the order that was most expeditious (usually chronological). NCI's Associate Director for Carcinogenesis Testing Program said, however, that because of the structural similarity of the coal tar colors being tested to known carcinogens, he expects many of them to be found carcinogenic. He said that analysis probably would not be completed before the spring of 1978.

On September 2, 1977, the FDA Commissioner wrote to the NCI Director requesting that priority be given to completion of the evaluations of 2,4-diaminoanisole, toluene-2,4-diamine, and any other ingredients which show positive effects. The letter stated:

> "Possible positive results with respect to two of the compounds studied, in particular, 2,4-diaminoanisole (2,4 DAA) and toluene-2,4-diamine (2,4 TDA) 1/ have attracted our attention. In addition, there is evidence that compounds such as these do penetrate intact skin.
>
> "In light of this and the extensive use of hair dyes * * * the need to confirm the conclusions suggested by preliminary reviews in an orderly scientific manner is obvious."

By letter dated October 18, 1977, NCI's Associate Director for Carcinogenesis Testing Program advised the FDA Commissioner that NCI had found both 2,4-diaminoanisole and toluene-2,4-diamine carcinogenic in animals. The

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1/Most cosmetic manufacturers stopped using toluene-2,4-diamine in hair dyes after it was found to cause cancer in laboratory animals. However, data submitted to FDA under its voluntary program for filing cosmetic product ingredient statements indicates that it is still used in at least seven permanent hair dyes.

Associate Director gave FDA a draft of a technical report on 2,4-diaminoanisole and advised FDA that results of the other study would be submitted to the Journal of the National Cancer Institute for publication.

By letter dated October 21, 1977, the Acting Director of FDA's Bureau of Foods notified NCI that FDA was beginning an immediate evaluation of the draft technical report on 2,4-diaminoanisole.

On October 17, 1977, the Environmental Defense Fund, Inc. (EDF), a private nonprofit national consumer organization, petitioned FDA to require all hair dyes containing 2,4-diaminoanisole or 2,4-diaminoanisole sulfate to bear a cancer warning label. EDF stated that its evaluation of the data on 2,4-diaminoanisole compiled, but not yet released, by NCI showed the dye to be carcinogenic in both rats and mice following oral ingestion. EDF noted that the dye caused a statistically significant increase in certain types of tumors in male and female rats and mice.

2,4-diaminoanisole is a basic component of most permanent hair dyes. We identified, from data submitted by manufacturers to FDA, 407 hair dyes containing 2,4-diaminoanisole or 2,4-diaminoanisole sulfate.

By letter dated January 5, 1978, NCI's Associate Director for Carcinogenesis Testing Program notified the Chairman, Subcommittee on Oversight and Investigations, House Committee on Interstate and Foreign Commerce, that from inspection of preliminary test data on four other permanent hair dye ingredients (4-amino-2-nitrophenol, 2-nitro-p-phenylenediamine, o-anisidine, and o-phenylenediamine), it appears that they also are carcinogenic in animals.

Skin-painting studies

These studies involve applying a chemical or a chemical mixture to the skin of the test animal. Because topical application more closely approximates the actual conditions of hair dye use and permits testing the actual mixture of compounds produced during oxidation, CTFA believes that only skin-painting studies can offer meaningful results on hair dye carcinogenicity.

CTFA noted that 2,4-diaminoanisole and toluene-2,4-diamine had been included in five skin-painting studies in which no problems had been found. While some researchers recognize

the usefulness of skin-painting studies, they have questioned the adequacy of the studies performed. Two of these studies are discussed below.

The first study 1/ involved the twice weekly application of toluene-2,5-diamine, either alone in a vehicle (a carboxymethylcellulose gel) or in a mixture with two other hair dye ingredients (resorcinol and 2,4-diaminoanisole) to the shaved dorsal (back) skin of Sprague-Dawley rats for 2 years. Two control groups were used; one group was treated with the vehicle only and the other group remained untreated. No positive control group was used (i.e., no group received a known carcinogen). All rats surviving the 2-year application period were observed for another 6 months.

The researchers reported:

--There was no evidence that the hair dye ingredients caused any adverse effects.

--There was no difference between the control and treated rats with respect to lifespan or the type and the incidence of tumors.

--There were no tumors or other skin reactions at the site of application.

--Histopathological studies of the liver, kidney, and lungs provided no evidence of degenerative change or functional disturbance.

However, University of California researchers questioned the usefulness of the study in evaluating the safety of hair dyes, because of the small number of animals and low dosages used. They noted that the experiment could not detect a chemical that increased the incidence of cancer in the population by 5 percent.

1/H. J. Kinkel and S. Holzmann, "Study of Long-term Percutaneous Toxicity and Carcinogenicity of Hair Dyes (Oxidizing dyes) in Rats," Food Cosmetic Toxicology, vol. 11, Pergamon Press, 1973, pp. 641-648.

The second study 1/ involved applying one of three different hair dye formulations 2/ to the skin of mice. Each formulation and a control formulation without a dye intermediate were administered, after mixing with hydrogen peroxide, to two groups of mice--one weekly and one every 2 weeks for 18 months. A positive control group and an untreated control group were also used.

The researchers reported that no evidence of toxicity or carcinogenicity had been noted. They noted that one ingredient used, toluene-2,4-diamine, had previously been shown to cause liver cancer when fed to rats.

The University of California researchers, however, believed that this study was also inadequate for evaluating safety for humans. They noted that, compared with the previous study, smaller doses had been used, the dyeings had been done weekly or every 2 weeks rather than twice a week, and the animals had been sacrificed after only 18 months.

Epidemiological studies

Epidemiology is a science that deals with the incidence, distribution, and control of disease in a given population. Epidemiological studies compare the incidence of a disease, such as bladder cancer, in a population exposed to a particular chemical with the incidence of the disease in an unexposed population in order to identify causes for the disease. The two populations should be closely matched according to such factors as age, sex, and smoking habits.

Although extensive epidemiological studies have not been performed for users of coal tar hair dyes, two studies on breast cancer patients have been performed with conflicting results. However, deficiencies have been noted in both studies.

1/C. Burnett, B. Lanman, R. Giovacchini, G. Wolcott, R. Scala, and M. Keplinger, "Long-Term Toxicity Studies on Oxidation Hair Dyes," Food Cosmetic Toxicology, vol. 13, Pergamon Press, 1975, pp. 353-357.

2/Each formulation contained oleic acid, isopropanol, sodium sulphite, ammonia, toluene-2,5-diamine sulphate, p-phenylenediamine, resorcinol, and deionized water. In addition, each formulation contained one of the following: toluene-2,4-diamine base, 2,4-diaminoanisole sulphate, or m-phenylenediamine base.

In one study 1/ a New York physician compared the use of coal tar hair dyes among his women breast cancer patients with use of the dyes by women of the same age who did not have breast cancer. The study showed that 87 of 100 breast cancer patients had been longtime (over 5 years) users of coal tar hair dyes whereas only 26 percent of the women without breast cancer were longtime users. The women were apparently matched by age, but not by other factors which could affect the incidence of cancer, such as smoking habits.

In the second study 2/ 191 women with breast cancer and 561 women without breast cancer were matched according to age, marital status, and social class. Although data on factors known to affect the incidence of breast cancer were obtained from the women, the women were not matched according to those factors. The study showed no relationship between breast cancer and use of hair dyes.

According to the October 17, 1977, EDF petition to FDA, the second study is inadequate because of the short followup period. EDF maintains that the latent period for development of cancer after exposure to hair dye use will probably be over 15 years, but too few women in the study had used hair dyes for more than 14 or 15 years before cancer diagnosis to make the data useful.

EXEMPTIONS HINDER EFFECTIVE REGULATION

Ordinarily FDA could ban the use of an ingredient in a cosmetic under the adulteration provisions of the FD&C Act if the substance may cause cancer under the conditions of use of the cosmetic. However, the exemptions granted to coal tar hair dyes prevent FDA from effectively regulating the dyes.

Section 601(a) of the act states that a cosmetic shall be deemed to be adulterated if it bears or contains any

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1/N. Shafer and R. W. Shafer, "Potential of Carcinogenic Effects of Hair Dyes," New York State Journal of Medicine, March 1976, pp. 394-396.

2/L. J. Kinlen, R. Harris, A. Garrod, and K. Rodriguez, "Use of Hair Dyes by Patients with Breast Cancer: A Case Control Study," British Medical Journal, vol. 2, 1977, pp. 366-368.

poisonous or deleterious substance that may render it injurious to users under normal use. It further states, however, that:

> "* * * this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: 'Caution--This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.', and the labeling of which bears adequate directions for such preliminary testing."

According to the November 1974 issue of the FDA Consumer, an agency periodical, the coal tar hair dye exemption was granted because industry persuasively argued that while the dyes could not meet safety standards of the FD&C Act, they should nonetheless be sold to meet popular demand.

Although the Color Additive Amendments to the FD&C Act have required establishment of regulations listing color additives that are safe for use in food, drugs, and cosmetics, coal tar hair dyes were exempted from these provisions. Under section 601(e), a cosmetic is considered adulterated:

> "If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706(a)."

The U.S. Court of Appeals, Second Circuit, ruled in the 1969 case of Toilet Goods Association v. Finch (419 F. 2d 21 (1969)) that the exemption does not apply to coloring ingredients in hair dyes not derived from coal tar, such as the metallic and vegetable dyes. The court noted that the legislative history of the Color Additive Amendments contained no indication that the Congress intended to broaden the 601(a) exemption.

Under section 602 a cosmetic is considered misbranded if its labeling is false or misleading in any particular. Coal tar hair dyes are not exempt from the misbranding provisions.

Many coal tar hair dyes contain ingredients that have been shown to cause cancer in humans or animals. Because of the exemptions, however, FDA cannot ban the use of a cancer-causing coal tar hair dye even if the evidence suggests that the dye is a human carcinogen, such as a hair dye containing a benzidine-derived azo color.

In recognition of this problem, FDA in 1963 issued regulations defining when the exemption applied. The regulation excluded from the exemption any coal tar hair dyes which posed a hazard that was different from those covered by the statutory warning (28 F.R. 6439, June 22, 1963). According to the regulation,

> "If the poisonous or deleterious substance in the 'hair dye' is one to which the caution is inapplicable and for which patch-testing provides no safeguard, the exemption does not apply * * *."

A patch test is a test on the forearm, on the bend of the elbow, or behind the ear to detect allergic sensitivity.

However, in the 1969 case the U.S. Court of Appeals upheld a district court ruling (278 F. Supp. 786) invalidating that portion of the regulation. The court of appeals found that:

> "The Government's argument should indeed be appealing to a legislator--what good is the warning to make a patch test if the test will not disclose the danger? But a court must take the statute as it is, and Congress wrote with great specificity. Whether it relied solely on the patch test warning because it was unaware in 1938 that coal-tar dyes might have damaging effects not detectable by such a test, as the Government asserts but the industry denies, or because it thought such instances so rare as not to warrant indentation of the exemption, the language is too clear for us to read it as meaning something different from what it so plainly says, at least in the absence of persuasive legislative history." (419 F. 2d 21, 29 (1969))

Thus the court ruled that even if a coal tar hair dye were found to cause cancer or some other adverse effect which would not be detected by a patch test, the dye could

not be removed from the market under the adulteration provisions of the FD&C Act if the label bore the statutory warning. In 1971 FDA revised the regulation to delete the objectionable statement (36 F.R. 16902, Aug. 26, 1971).

In the opinion of an FDA attorney, FDA could probably require, under the misbranding provisions of the act, that an additional warning be placed on the label of coal tar hair dyes posing hazards under conditions of use, such as cancer not covered by the statutory warnings.

However, because section 601(e) exempts coal tar hair dyes from the color additives provisions of the act, FDA cannot require manufacturers to prove the safety of their products under the color additive requirements and, therefore, FDA has the burden of proof for any additional label warnings it may require. By contrast, FDA can require the manufacturers of colors used in metallic and vegetable hair dyes to prove the safety of their colors because the law does not similarly exempt these products from the color additive requirements.

In its October 17, 1977, petition to FDA, EDF asked the agency to require the following warning on labels of coal tar hair dyes containing 2,4-diaminoanisole.

> "This product contains the chemical 2,4 DAA [2,4-diaminoanisole], which can enter your bloodstream through your scalp and has been shown to cause cancer in animals."

In our report to the Subcommittee on Oversight and Investigations, we recommended that the Secretary, HEW, direct the FDA Commissioner to evaluate safety data on coal tar hair dye ingredients and require, where applicable, cancer or other appropriate warnings on product labels.

On January 6, 1978, FDA published in the Federal Register a proposal to require that labels of hair dyes containing 2,4-diaminoanisole contain a cancer warning statement. FDA also proposed that hairdressers be required to post signs suggesting that their customers request to see the labeling of a hair dye before it is used.

FDA is still considering the need for cancer warnings on labels of hair dyes containing other suspected carcinogens.

Our report also recommended that the Congress repeal the coal tar hair dye exemptions.

Pending legislation

Under Senate bill 2365, introduced during the 95th Congress, the exemption granted to coal tar hair dyes under section 601(a) of the FD&C Act would be repealed. However, Senate bill 2365 would not repeal the exemption from the color additive provisions granted to coal tar hair dyes under section 601(e).

Several other bills have been introduced during the 95th Congress to repeal both the 601(a) and 601(e) exemptions, including House bill 10512.

CONCLUSIONS

Many coal tar hair dyes contain known or suspected carcinogens that pose potential hazards because they may be absorbed through the skin and scalp. However, the exemptions in the FD&C Act bar FDA from banning or restricting the use of coal tar hair dyes that may cause cancer under the conditions of use.

Although coal tar hair dyes are subject to FDA labeling requirements, FDA has not issued final regulations requiring a cancer warning on labels of coal tar hair dyes containing known human or animal carcinogens. Such regulations have been proposed only for hair dyes containing 2,4-diaminoanisole or 2,4-diaminoanisole sulfate. The issuance of such regulations is made difficult by the fact that the burden of proof for their need rests with FDA, rather than the manufacturers.

If the exemptions were repealed, the color ingredients used in these dyes would be subject, similar to other color additives, to premarket approval by FDA for safety and manufacturers would have to prove the safety of the colors.

In February 1974 testimony before the Subcommittee on Health, Senate Committee on Labor and Public Welfare, FDA supported elimination of the exemptions. FDA testified that:

> "coal tar hair dyes should not receive privileged treatment but should be subject to the same regulation and safety appraisal as other cosmetics."

RECOMMENDATION TO THE SECRETARY, HEW

We recommend that the Secretary direct the FDA Commissioner to evaluate safety data on coal tar hair dye ingredients

and require, where applicable, a cancer or other appropriate warning on product labels.

AGENCY COMMENTS

HEW said that FDA is evaluating safety data on coal tar hair dyes. According to HEW, FDA intends to take action similar to that which it has proposed against hair dyes containing 2,4-diaminoanisole (see p. 89) against any other chemical used in coal tar hair dyes that poses a cancer risk on the basis of FDA's review of appropriate tests.

FDA officials advised us that their evaluation of NCI's data on 2,4-diaminoanisole is continuing and that final reports on five other suspected carcinogens submitted to FDA by NCI are awaiting review.

HEW pointed out, however, that the ability of FDA to protect the public from risks associated with long-term use of hair dyes will continue to be severely limited until the Congress repeals the coal tar hair dye exemption in the FD&C Act.

RECOMMENDATION TO THE CONGRESS

To permit FDA to better regulate coal tar hair dyes, we recommend that the Congress repeal exemptions in sections 601(a) and 601(e) of the FD&C Act concerning these dyes.

CHAPTER 7

NEED TO ESTABLISH AN EFFECTIVE MARKET SURVEILLANCE AND ENFORCEMENT PROGRAM

Because FDA cannot test cosmetics for safety before they are marketed or require manufacturers to do so, its success in insuring cosmetics' safety depends largely upon the effectiveness of its market surveillance and enforcement efforts. However, such efforts have not been effective because:

--FDA has not inspected most manufacturers' plants nor sampled most of their products for compliance with the FD&C Act.

--FDA has not established good manufacturing practice (GMP) regulations for cosmetics.

--FDA has not always taken effective enforcement actions when violations of the FD&C Act were discovered.

The lack of adequate legislative authority and interpretative regulations also limits the effectiveness of the market surveillance and enforcement program.

LIMITED MARKET SURVEILLANCE

FDA has the same basic authority to conduct inspections and collect samples to enforce the cosmetic provisions of the FD&C Act as it has to enforce the food, drug, and medical devices provisions of the act. FDA is authorized to visually inspect any factory, warehouse, or establishment in which cosmetics are manufactured, processed, packed, or held for introduction into interstate commerce and to collect product samples for analysis. However, most cosmetic plants have never been inspected and most products have never been sampled.

FDA officials told us that an effective market surveillance program should provide for every firm to be inspected every 2 years but that under the current rate of inspection--about 500 inspections per year--that would be impossible.

An FDA printout of inspection and sampling history of cosmetic plants between fiscal years 1969 and 1975 listed about 2,200 plants operated by the approximately 1,200 cosmetic manufacturers known to FDA at that time. Although

FDA conducted about 3,800 inspections during the 7-year period, about half of the 2,200 plants were never inspected, while others were inspected several times. We were not able to readily determine how many of the 1,200 manufacturers had one or more of their plants inspected.

Many other plants were not inspected because they were operating without FDA's knowledge. In 1976 FDA contracted with a market research consultant to identify cosmetic firms previously unknown to FDA. FDA simultaneously undertook an in-house project to identify new firms. As a result of these efforts, FDA identified about 1,000 additional manufacturers which it had never inspected because they had been unknown to the agency, increasing the total number of known cosmetic manufacturers from 1,200 to 2,200.

FDA's testing of cosmetics is even more limited. FDA collected about 3,000 samples between 1968 and 1976. According to FDA, many of these were not analyzed because of lack of personnel and higher priority programs. Because more than one sample was often collected for an individual product, we could not determine the total number of products sampled during this period. However, it represents only a fraction of the more than 50,000 different brand name products.

Testing of cosmetics was generally limited to chemical analysis to identify some of the ingredients in them. Tests to identify microbial contamination and tests to identify products that are skin and eye irritants were performed much less frequently. Almost three-fourths of the tests run were for chemical analysis.

FDA has had to devote considerable resources to chemical analysis because manufacturers have not registered their products or product formulations with FDA. Effective implementation of FDA's ingredient-labeling regulations, which became effective in April 1977, should decrease the need for chemical analyses and make resources available for other tests.

However, because FDA has not established product and ingredient standards, it has no criteria for using the results of tests for eye and skin irritation or microbial contamination for regulatory purposes. (See p. 34.)

NEED FOR GMP REGULATIONS

Although FDA has established specific criteria, known as GMPs, for determining whether adequate methods, facilities,

and controls are used in all phases of food and drug manufacture and distribution, it has not established such criteria for cosmetics. FDA uses such criteria in inspections of equipment, finished and unfinished materials, containers, manufacturing records, and laboratory controls.

Under the FD&C Act, a cosmetic is deemed to be adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or rendered injurious to health. Court decisions have established that it is unnecessary for the Government to prove that any product was actually contaminated. The courts have interpreted the term "insanitary conditions" to refer to conditions of manufacture or storage that would result, with reasonable possibility, in product contamination.

GMP regulations would identify such conditions. Failure to manufacture or store cosmetics in accordance with GMP regulations would cause them to be deemed adulterated.

According to the Director of the Bureau of Foods' Office of Technology, although FDA has not established GMP regulations specifically applicable to cosmetics, it generally uses the food or drug GMP regulations as guidelines during inspections of cosmetic manufacturers. The drug GMP regulations state that manufacturers shall establish specifications for raw materials, test equipment for microbial contamination, establish specifications for finished products, test the effectiveness of preservative systems used in their products, and maintain batch records and an inventory control system adequate to facilitate a recall. According to a summary in its March 1975 Compliance Program Guidance Manual, FDA inspectors found during inspections that:

--Less than 33 percent of the establishments had raw material specifications.

--Less than 50 percent kept adequate batch records.

--Less than 15 percent tested equipment for microbial contamination.

--Only 30 percent had established finished product specifications (chemical, microbial, physical, etc.).

--Only 20 percent tested the effectiveness of preservative systems.

--Only 25 percent maintained inventory control systems adequate to facilitate a recall.

Appendix V compares the conditions noted during cosmetic inspections to drug GMP regulations. According to an FDA official, about 75 percent of a sample of over 300 firms inspected since 1976 had deficiencies in their manufacturing practices.

An attorney from FDA's Office of General Counsel told us that the food and drug GMP regulations cannot be applied to cosmetic inspections for enforcement purposes as regulations binding on cosmetics with the force of law. Although FDA has drafted GMP regulations for cosmetics, they had not been published in the Federal Register for comments as of March 1, 1978. Because FDA has not established GMP regulations for cosmetics, it has enforced the adulteration provisions of the act only when contamination could be proved.

NEED FOR EFFECTIVE ENFORCEMENT

FDA has not always used its authority to enforce compliance by manufacturers with the cosmetic provisions of the FD&C Act. FDA's failure to effectively use its enforcement authority in cases of serious or repeated violations could indicate to the cosmetics industry that major violations of the law will be treated with minimum consequence.

Between fiscal years 1974 and 1976, FDA inspectors and laboratory personnel found deficiencies which they believed warranted some form of regulatory action in 188, or 11 percent, of the 1,658 cosmetic plants inspected and in 218, or 23 percent, of the 952 samples analyzed. In addition, minor deficiencies not warranting regulatory action were noted in 109, or 7 percent, of the plants inspected and 123, or 13 percent, of the samples analyzed.

Although FDA identified over 400 deficiencies which its inspectors or laboratory personnel classified as warranting some form of regulatory action, as shown below only 141 regulatory actions were taken during the 3-year period.

Seizures attempted	74
Injunctions obtained	2
Regulatory letters issued	28
Information letters issued	37
Total	141

FDA did not issue any citations or refer any cases to the Department of Justice for prosecution. Furthermore, 54 (53 seizures and 1 injunction) of the 141 regulatory actions were taken in an effort to prevent the marketing of one violative product, a fingernail lengthener containing methyl methacrylate monomer. Thus regulatory action was actually taken for about 20 percent of the violations FDA determined warranted such action.

In addition, FDA requested the recall of 52 products during the 3-year period. Although recall is a voluntary action on the part of the manufacturer, FDA has found it to be the most efficient means to remove a hazardous product from the market.

As shown by the following examples, FDA has not always taken effective regulatory action even in cases of serious or repeated violations of the act. Nor has FDA always conducted timely followup inspections to assure that corrective action has been taken.

Firm A manufactures hair care and bath products and has estimated annual sales of between $500,000 and $1 million. FDA made three compliance inspections of this firm's manufacturing practices between August 1970 and March 1973. In each case the inspector found what he believed were major deficiencies in the firm's manufacturing practices. FDA has not inspected the firm's manufacturing practices since March 1973.

A summary of the August 1970 inspection stated that the firm was:

> "* * * operating under conditions which may cause bacterial contamination of the finished product (Egg Shampoo). Poor housekeeping conditions such as pools of stagnant water, dirt, and debris on the floor in the manufacturing area and paint peeling from the ceiling directly over the mixing tank were found during the inspection. In addition, open unscreened doors off the street to the manufacturing area could cause bacterial contamination of the finished product."

Inspection observations were discussed with the president of the firm, but no enforcement action was taken by FDA. Although the president promised to correct the deficiencies, FDA did not make another inspection of the firm's manufacturing practices until January 1973.

During the January 1973 inspection, the firm was again found to be operating under poor sanitary conditions. A 41-point list was given to management pointing out conditions which could lead to bacterial or filth contamination of the firm's products, especially baby shampoo. The list of conditions included:

--Rodent excreta at several locations in the plant.

--A dead mouse in a storage closet; a live mouse in the firm's office.

--A "filthy, inadequate toilet facility" adjacent to the men's lunchroom with no wash basin and inoperable plumbing.

--Waste on the floor not confined to drain areas.

--Foreign material in the "window" of the pipe feeding baby shampoo to the filler.

A postinspection letter was sent to the manufacturer, and reinspection was scheduled for March 1973. Management replied to the letter and promised that corrections would be made.

However, the followup inspection revealed that the firm was still operating under unsanitary conditions. Many of the 59 deficiencies observed during this inspection were problems that had also been noted during the prior inspection. These conditions included:

--A dead, decomposed mouse on the storage room floor (according to the inspection report, "the same mouse noted in the January 1973 inspection").

--Rodent harborage areas throughout the plant.

--Potential pest entry ways throughout the plant.

--Sewers throughout the manufacturing areas left uncovered when not in use.

--A large accumulation of wash water and product waste on the floor.

--Equipment leaks allowing the product to seep out on the floor.

--An accumulation of a jelly-like substance in a crack in the floor near the product storage area.

All three inspections identified major deficiencies which the FDA inspector believed warranted regulatory action. Corrective action was again promised by the management after a discussion with FDA of the deficiencies. As of April 1978 no FDA followup had been made and no regulatory action taken.

Firm B manufactures hair products and other cosmetics and has estimated annual sales of between $100,000 and $500,000. FDA made five inspections of this firm's manufacturing practices between February 1965 and December 1973. Four inspections revealed illegal use of coal tar color additives in the firm's cosmetics. In addition, all five inspections revealed that the firm had an inadequate quality control system for production and packaging.

In the February 1965 inspection, FDA found the firm using a banned coal tar color additive, FD&C Yellow No. 4, in two products. Management stated that it did not know that use of FD&C Yellow No. 4 was illegal and voluntarily agreed to destroy the remaining supply of the color and stocks of the two products containing it. A followup inspection in March 1966 showed the firm had discontinued the use of FD&C Yellow No. 4.

An April 1970 inspection showed that the firm was using three different color additives--Burnt Sienna, Umber, and D&C Brown No. 1--no longer approved for use. The inspection also revealed that the equipment used in cosmetic manufacture was not cleaned or sanitized between production runs. At management's request the inspector gave it a copy of FDA regulations listing the color additives that can legally be used in cosmetics.

During a January 1973 inspection, FDA found quantities of four color additives on hand, Burnt Sienna, Umber, D&C Brown No. 1, and External D&C Red No. 15, which were no longer approved for use. The firm had been notified during the April 1970 inspection that three of the colors were no longer approved for use in cosmetics. Management informed the inspector that Umber, Burnt Sienna, and External D&C Red No. 15 were being used in makeup products and that D&C Brown No. 1 had been used in a mascara which was no longer manufactured. On January 4, 1973, the firm notified FDA that it would remove all disapproved color additives from its plant and would not manufacture makeup products until it had substitute colors approved by FDA.

In December 1973 FDA found the firm still had D&C Brown No. 1 in stock. Management said that it was aware D&C Brown No. 1 no longer had a legal status and that it had discontinued manufacturing the product containing it. All remaining stock of the color was voluntarily disposed of by the firm.

Several inspection reports revealed that manufacturing operations were lax since no written specifications, batch recordings, tests, or codes were available.

The FDA district office proposed issuance of a regulatory letter to the firm on the basis of serious violations of the FD&C Act and FPLA found during the December 1973 inspection. The proposed letter cited several alleged violations but did not mention either the firm's use of illegal color additives or the lax manufacturing operations.

FDA's Division of Regulatory Guidance denied the district office's request for issuance of a regulatory letter in May 1974 because of a lack of adequate evidence concerning the alleged violations and insufficient FDA guidelines for determining when a product is an eye irritant. As of March 1978, no regulatory action had been taken against this firm and no further establishment inspections had been made.

Firm C is a nationally known cosmetic manufacturer having annual sales of between $5 million and $10 million. FDA inspected this firm's manufacturing practices twice between fiscal years 1969 and 1975. Both inspections revealed major deficiencies, including poor manufacturing practices, use of hazardous ingredients, and microbial contamination in finished products. In addition, FDA examined 27 samples of the firm's products during the 7-year period. Only seven were found by FDA laboratories to be in compliance with the FD&C Act and FPLA. Of the 20 samples the laboratories found were not in compliance, 13 had major deficiencies warranting regulatory action. Minor violations not requiring regulatory action were noted in the remaining samples.

In a June 1970 inspection, FDA noted several objectionable conditions, including deficiencies in manufacturing practices. Among the deficiencies were opened windows in the compounding area and lack of a sanitizing solution along the production lines. The need to correct the deficiencies was especially important in this case because samples collected at the time of the inspection revealed the presence of pathogenic Pseudomonas bacteria. The conditions noted could have contributed to the bacterial contamination of the firm's products.

In October 1973 the firm voluntarily recalled a shampoo containing bacterial contamination. FDA conducted a limited inspection to obtain information pertaining to the recall but did not inspect the firm's manufacturing practices.

However, during an October 1973 tour of the firm's plant, the Director and Deputy Director of the Division of Cosmetics Technology noticed what they considered deficiencies in the firm's manufacturing practices. They noted that:

> "Microbiological control facilities were essentially non-existant [sic] and demonstrated poor housekeeping. Control specifications were minimal at best. Based on remarks made by * * * [company officials] guidelines for proper preservation of products were inadequate, and microbiological testing appeared to be minimal."

During a November 1975 inspection, many objectionable conditions were again noted in the manufacturing area. The inspection disclosed that not all raw materials were identified, some raw materials were stored under conditions whereby they may become contaminated, and manufacturing equipment was uncovered in an area having open unscreened windows. A list of 18 deficiencies was discussed with the manufacturer. Management promised corrections for most of the deficiencies, but in other cases when the deficiencies would result in the product being exposed to unsanitary conditions, management felt that the deficiencies were not significant and did not agree to take corrective action.

No deficiencies were noted in manufacturing practices during a followup inspection in October 1976. However, when the inspector asked to review the firm's microbiological test data, the firm denied FDA access to the data until the request was considered by the firm's lawyers. Consent was never received and FDA made no further attempts to obtain the test data. As of March 1978 no further action had been taken by FDA.

LACK OF AUTHORITY LIMITS ENFORCEMENT

FDA's market surveillance and enforcement efforts are further limited because FDA lacks adequate legislative authority to (1) obtain access to a manufacturer's production and other records and (2) assess civil penalties for violations of the cosmetic provisions of the FD&C Act.

Access to manufacturers' records

Although the FD&C Act authorizes FDA inspection of cosmetic-manufacturing plants, it does not require manufacturers to permit FDA inspectors to examine their consumer complaint files, safety data, formulation data, shipping records, or other manufacturing records. As a result, manufacturers frequently refuse FDA access to such records. In some cases, FDA inspectors were even refused access to the plants. The following table summarizes the types and numbers of refusals that occurred between fiscal years 1968 and 1976.

Type of refusal	Number of refusals
Access to qualitative or quantitative formulas	464
Access to sales or shipping records	75
Access to complaint files	61
Permit photographing of plant	33
Access to quality control records	32
Access to plant except by appointment or other condition	19
Access to plant	5
Permit observation of manufacturing procedures	4
Permit collection of official samples	4

In several cases, FDA inspectors were denied access to complaint files, product formulation, and/or safety data when they were conducting a followup to a consumer complaint.

Civil penalties

The FD&C Act provides for criminal penalties for violations of its cosmetics provisions. However, it may be difficult for FDA to assess criminal penalties for many such violations. FDA has established informal criteria to be used in determining whether to prosecute a manufacturer for violations of the FD&C Act. Among the conditions to be met before prosecution is considered are:

--Prior warning must be given to the firm.

--An individual officer(s) must be identified as responsible for the violation.

--A responsible officer(s) must be given notice of the impending charges.

--The violation must be a continuing or flagrant violation, not a first offense.

However, as shown earlier in this chapter, it is unlikely that FDA will inspect most manufacturers' plants or sample their products frequently enough to develop a case history supporting prosecution. One alternative that could help FDA enforce the act's provisions would be the authority to assess civil money penalties for violations of the cosmetic provisions.

In a 1972 recommendation, the Administrative Conference of the United States--established to study the efficiency, adequacy, and fairness of Federal agencies' administrative procedures--expressed the desirability of regulatory agencies making greater use of civil money penalties. The conference stated that civil penalties are an important and useful tool that should enable agencies to (1) obtain quicker corrective action for violations and (2) demonstrate greater consistency in their judicial reviews. Criminal penalties would remain available for use when appropriate.

The conference said that use of civil penalties would not reduce or eliminate the due process protection now provided under criminal penalty situations. Civil penalties would be assessed in accordance with the Administrative Procedure Act (5 U.S.C. 551 et seq.), which provides for review, on appeal, by the U.S. Court of Appeals (5 U.S.C. 701, et seq.). Also the conference suggested that agencies be allowed to compromise or mitigate any civil penalty settlement either before or after assessment.

Subseq ently, the 1972 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act authorized the Environmental Protection Agency to assess civil penalties for violations of its provisions. Since then EPA has used civil penalties extensively in enforcing the act. An EPA official said the agency often assesses civil penalties for pesticide violations rather than attempting to institute criminal action against first-time offenders.

PENDING LEGISLATION

Several provisions of Senate bill 2365 would provide FDA additional authority to enforce the cosmetics provisions of the FD&C Act. Specifically Senate bill 2365 would:

--Broaden FDA's inspection powers to include records bearing on whether a cosmetic may be adulterated or misbranded.

--Give FDA clear authority to establish and enforce compliance with GMPs.

--Authorize FDA to levy civil money penalties for violations of the FD&C Act.

CONCLUSIONS

Because of the low priority of the cosmetics program, it is essential that FDA effectively use the limited resources available for market surveillance and enforcement. By establishing GMPs for cosmetics, FDA could provide guidance to FDA inspectors and manufacturers in identifying conditions which might result in a product becoming contaminated and form a firm basis for enforcement action. However, establishment of GMPs will not have a significant effect unless FDA insures that prompt and effective enforcement action is taken when violations are identified.

If the voluntary programs discussed in chapter 3 are made mandatory, the data provided to FDA should enable FDA to establish a more effective market surveillance program based on such factors as

--past sampling and enforcement history of the firm,

--the type and volume of products it makes,

--the number and severity of adverse reactions reported for its products, and

--the degree of potential hazard of the products and ingredients.

In addition, FDA could shift emphasis in analyzing cosmetic samples from tests for chemical composition to tests for product safety, such as tests for microbial contamination and skin and eye irritation.

Authority to obtain access to manufacturers' production records, including shipping records, quality control records, and formulation data, would enable FDA to more effectively evaluate a manufacturer's compliance with GMPs. Authority to levy civil penalties would enable it to take quicker corrective action for violations.

RECOMMENDATIONS TO THE SECRETARY, HEW

We recommend that the Secretary direct the FDA Commissioner to:

--Devise a more effective program to insure that all cosmetic manufacturers are periodically inspected.

--Establish GMPs specifically applicable to cosmetics.

--Expand the collection and testing of cosmetic samples for such factors as microbial contamination and eye and skin irritation.

--Insure that prompt and effective enforcement action is taken when violations are found in plant inspections or sample analyses.

AGENCY COMMENTS AND OUR EVALUATION

HEW said that during the past 2 years, FDA has instituted more effective (1) manufacturing establishment and product inspection programs, (2) information systems, and (3) evaluation of the compliance activities. HEW said that the lack of legal authority to require cosmetic firms to register their manufacturing sites, coupled with resources constraints, continues to restrict the inspection program for cosmetic manufacturers. However, the rate of inspection continues at about 500 per year, which FDA officials agreed is insufficient for an effective market surveillance program.

HEW agreed that GMP regulations are needed for cosmetics and said that FDA is reviewing a draft of proposed GMP regulations and considering a GMP petition submitted by the cosmetic industry. HEW said that work on the GMP regulations will be done as expeditiously as possible, given the limited resources available and competing activities.

With respect to product testing, HEW said that surveillance programs to determine if cosmetics are contaminated with harmful microorganisms were conducted during fiscal years 1975 and 1977. According to HEW, FDA concluded in both surveys that contamination with harmful microorganisms did not constitute a problem among either domestic or imported products for sale in this country. HEW said that similar surveys will be conducted in the future, as resources permit and the need arises.

However, HEW pointed out that there is evidence that some mascara and other eye area products may not be adequately preserved to prevent the growth of harmful microorganisms under conditions of use. HEW said that a notice of intent to propose rules designed to correct this problem had been printed in the October 11, 1977, Federal Register.

According to HEW, collection and testing of cosmetic samples to determine eye and skin irritation potential would far exceed budgeted resources. Because additional data are required to make safety determinations, e.g., product composition, ingredient purity, intended use, and toxicological data on individual ingredients, collection and testing of products for irritation are directed to those instances when adverse experience or other reliable data indicates that a particular product or an ingredient may be harmful under conditions of use. As FDA does not have enough data on cosmetic-related safety problems (see ch. 4), collection and testing of cosmetic samples remains an important source of information.

HEW agreed that prompt and effective enforcement action should be taken when violations are found in plant inspections or sample analyses and said that FDA's present policy is consistent with our recommendations. HEW said that when violations of the statute are found, FDA takes the most appropriate regulatory action. According to HEW, many of the conditions discussed in this report are not actionable because of a lack of adequate evidence to prove that there was a violation of the FD&C Act.

Taking prompt and effective enforcement action depends on many factors, including development of adequate supporting evidence. As noted on pages 95 to 100, FDA inspectors have identified conditions at manufacturing plants which they consider to be major violations of the FD&C Act but apparently have not obtained sufficient supporting evidence. FDA should ensure that inspectors obtain adequate supporting evidence during inspections.

RECOMMENDATIONS TO THE CONGRESS

To improve FDA's ability to enforce the cosmetic provisions of the FD&C Act, we recommend that the Congress authorize FDA to:

--Obtain access to cosmetic manufacturers' production and control records.

--Assess civil penalties for violations of the FD&C Act.

CHAPTER 8

SCOPE OF REVIEW

Our review included:

--Reviewing FDA's regulation of cosmetic products at FDA headquarters in Rockville, Maryland, and Washington, D.C.

--Analyzing reports and publications prepared by FDA and other experts and reviewing legislation and FDA regulations, policies, and procedures.

--Reviewing cosmetic complaint reports received from the public and manufacturing plant inspection files prepared by FDA regional offices.

--Comparing the lists of ingredients available for use in cosmetics with NIOSH's Registry of Toxic Effects of Chemical Substances and NCI's list of substances under test.

--Interviewing officials and reviewing records at FDA, EPA, CPSC, NCI, and the Federal Trade Commission.

--Interviewing CTFA officials.

APPENDIX I

REPORTED TOXIC EFFECTS OF CERTAIN COSMETIC INGREDIENTS

The toxic effect attributed to a substance in the following list is based primarily on test data reported in the 1976 NIOSH Registry of Toxic Effects of Chemical Substances. Neither we nor NIOSH has reviewed the adequacy of the tests performed or the applicability of the results to exposure to the ingredients through use of cosmetics.

The list also contains data obtained from FDA, EPA, the International Agency for Research on Cancer (IARC) of the World Health Organization, and published articles.

The listing was obtained from the 1977 edition of the CTFA Cosmetic Ingredient Dictionary--a list of ingredients "available for use" in cosmetic products--and from ingredient lists voluntarily submitted to FDA by the industry. We did not determine whether all these ingredients are currently being used in cosmetics.

Carcinogenic (note a)

	Ingredient	Comments
1.	Acacia	-
2.	Acid Blue 9	-
3.	Acid Blue 9 ammonium salt	-
4.	Acid Blue 74	-
5.	Acid Green 5	-
6.	Acid Red 18	-
7.	Acid Red 27	FDA determination: animal carcinogen; formerly FD&C Red No. 2
8.	Acid Red 87	-
9.	Acid Violet 49	Formerly FD&C Violet No. 1
10.	Acid Yellow 73 sodium salt	-
11.	Alcohol	-
12.	4-Amino-2-nitrophenol	NCI determination: animal carcinogen
13.	o-Anisidine	NCI determination: animal carcinogen
14.	Asbestos	Contaminant of talc; NCI determination: human carcinogen

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	Ingredient	Comments
15.	Basic Orange 2	IARC determination: animal carcinogen
16.	Basic Violet 1	Also known as Gentian Violet
17.	Basic Violet 3	Also known as Gentian Violet
18.	Basic Violet 10	-
19.	Boric acid	-
20.	Butyrolactone	IARC determination: indefinite
21.	Calcium carrageenan	IARC determination: animal suspect
22.	Calcium saccharin -	FDA determination: animal carcinogen, suspect human carcinogen
23.	Captan	EPA determination: animal suspect
24.	Carrageenan	IARC determination: animal suspect
25.	Chloramine-T	-
26.	Chloroacetic acid	-
27.	Cholesterol	IARC determination: indefinite
28.	Chromium oxide greens	IARC determination: animal suspect
29.	Coal tar	NCI determination: human carcinogen
30.	Coumarin	IARC determination: animal carcinogen
31.	Creosote	NCI determination: human carcinogen
32.	D&C Blue No. 1 Aluminum Lake	-
33.	D&C Blue No. 2 Aluminum Lake	-
34.	D&C Blue No. 4	-
35.	D&C Green No. 3 Aluminum Lake	-
36.	D&C Red No. 4 Aluminum Lake	-
37.	D&C Red No. 9	IARC determination: indefinite
38.	D&C Red No. 9 Barium Lake	IARC determination: indefinite
39.	D&C Red No. 9 Barium/ Strontium Lake	IARC determination: indefinite
40.	D&C Red No. 9 Zirconium Lake	IARC determination: indefinite
41.	D&C Red No. 17	IARC determination: indefinite
42.	D&C Red No. 19	-

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	Ingredient	Comments
43.	D&C Red No. 19 Aluminum Lake	-
44.	D&C Red No. 19 Barium Lake	-
45.	D&C Red No. 19 Zirconium Lake	-
46.	D&C Red No. 22	-
47.	D&C Yellow No. 6 Aluminum Lake	-
48.	D&C Yellow No. 8	-
49.	Dehydroacetic acid	-
50.	Dimethoxane	-
51.	Dimethyl sulfate	IARC determination: human suspect
52.	Direct Black 38	NCI determination: animal carcinogen Contains benzidine, a human carcinogen May be converted to benzidine in the body
53.	Direct Black 131	Contains benzidine, a human carcinogen May be converted to benzidine in the body
54.	Direct Blue 6	NCI determination: animal carcinogen Contains benzidine, a human carcinogen May be converted to benzidine in the body
55.	Direct Brown 1	See comments under 53
56.	Direct Brown 1:2	See comments under 53
57.	Direct Brown 2	See comments under 53
58.	Direct Brown 31	See comments under 53
59.	Direct Brown 154	See comments under 53
60.	Disperse Yellow 3	IARC determination: indefinite
61.	Estrone	NCI determination: human carcinogen
62.	Ethyl carbonate	-
63.	Ethylene oxide	IARC determination: indefinite
64.	Ethylene urea	-
65.	Ethynylestradiol	IARC determination: animal carcinogen
66.	FD&C Blue No. 1	-
67.	FD&C Blue No. 1 Aluminum Lake	-

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	Ingredient	Comments
68.	FD&C Blue No. 2	-
69.	FD&C Blue No. 2 Aluminum Lake	-
70.	FD&C Green No. 3	-
71.	FD&C Red No. 4	IARC determination: negative FDA determination: animal suspect
72.	FD&C Red No. 40	FDA determination: animal suspect
73.	FD&C Yellow No. 6	IARC determination: indefinite
74.	FD&C Yellow No. 6 Aluminum Lake	IARC determination: indefinite
75.	Formaldehyde	-
76.	HC Red No. 6	Formerly FD&C Red No. 1 IARC determination: animal carcinogen
77.	Hydroquinone	-
78.	Hydroxystearic acid	-
79.	Iron oxides	IARC determination: indefinite
80.	Krameria extract	-
81.	Lactose	-
82.	Lead acetate	IARC determination: animal carcinogen
83.	Maleic anhydride	-
84.	Methenamine	-
85.	4-Methoxy-m-phenylenediamine	NCI determination: animal carcinogen
86.	4-Methoxy-m-phenylenediamine sulfate	NCI determination: animal carcinogen
87.	Methyl hydroxystearate	-
88.	Methyl methacrylate	-
89.	Methyl oleate	-
90.	Methyl stearate	-
91.	2-Nitro-p-phenylenediamine	NCI determination: animal carcinogen
92.	N-nitrosodiethanolamine	FDA determination: animal carcinogen Unintentional contaminant
93.	Nylon	-
94.	Oleic acid	-
95.	Oxyquinoline	-
96.	Oxyquinoline sulfate	-
97.	Paraffin	-
98.	PEG-8	-
99.	Phenol	EPA determination: animal suspect

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	Ingredient	Comments
100.	Phenylalanine, L-	IARC determination: human suspect
101.	o-Phenylenediamine	NCI determination: animal carcinogen
102.	Phenyl mercuric acetate	-
103.	Pigment Red 53:1	IARC determination: indefinite
104.	Pigment Red 53	IARC determination: indefinite
105.	Polyethylene	-
106.	Polysorbate 80	-
107.	Polyvinyl alcohol	-
108.	Propyl alcohol	-
109.	Propylene oxide	IARC determination: animal suspect
110.	PVP	-
111.	Ricinoleic acid	-
112.	Saccharin	FDA determination: animal carcinogen, human suspect
113.	Silver	-
114.	Sodium saccharin	FDA determination: animal carcinogen, human suspect
115.	Solvent Red 23	IARC determination: indefinite
116.	Sorbic acid	-
117.	Succinic anhydride	-
118.	Thiourea	IARC determination: animal carcinogen
119.	Toluene	-
120.	Toluene-2,4-diamine	NCI determination: animal carcinogen
121.	Trichloroethylene	IARC determination: animal suspect
122.	Tristearin	-
123.	Ultramarine green	IARC determination: animal suspect
124.	Zinc chloride	-
125.	Zinc sulfate	-

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Teratogenic (note b)

	Ingredient	Comments
1.	Acid Red 27	-
2.	6-Aminocaproic acid	-
3.	BHT	-
4.	Butyl methacrylate	-
5.	Captan	-
6.	Carbon dioxide	-
7.	Cetrimonium bromide	-
8.	Dibutyl phthalate	-
9.	Dimethyl phthalate	-
10.	Dioctyl phthalate	-
11.	EDTA	-
12.	Estrone	-
13.	Ethyl methacrylate	-
14.	Ethyl phthalate	-
15.	Hexachlorophene	-
16.	Lead acetate	-
17.	Lithium chloride	-
18.	MEK	-
19.	Nitrous oxide	-
20.	Phenyl mercuric acetate	-
21.	Retinol	-
22.	Retinyl palmitate	-
23.	Salicylamide	-
24.	Sodium chloride	-
25.	Sodium salicylate	-
26.	Theophylline	-

Nervous system effects (note c)

	Ingredient	Comments
1.	Acetone	Based on human exposure
2.	Boric acid	Based on human exposure
3.	p-Cymene	Based on human exposure
4.	Dibutyl phthalate	Based on human exposure
5.	Ethylene dichloride	Based on human exposure
6.	Hexachlorophene	Based on human exposure
7.	MEK	Based on human exposure
8.	Methoxyethanol	Based on human exposure
9.	Methyl alcohol	Based on human exposure
10.	Methylene chloride	Based on human exposure
11.	Methyl methacrylate	Based on human exposure
12.	Phenacetin	Based on human exposure
13.	Sodium fluoride	Based on human exposure

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	Ingredient	Comments
14.	Sodium Salicylate	Based on human exposure
15.	Sodium Sulfite	Based on human exposure
16.	Tetrachloroethylene	Based on human exposure
17.	Theophylline	Based on human exposure
18.	Toluene	Based on human exposure
19.	Trichloroethane	Based on human exposure
20.	Trichloroethylene	Based on human exposure

Irritant effects (note d)

	Ingredient	Comments
1.	Acetaldehyde	Based on human exposure
2.	Acetic acid	Based on human exposure
3.	Ammonia	Based on human exposure
4.	Amyl acetate	Based on human exposure
5.	Butyl acetate	Based on human exposure
6.	n-Butyl alcohol	Based on human exposure
7.	Ether	Based on human exposure
8.	Ethyl acetate	Based on human exposure
9.	Formaldehyde	Based on human exposure
10.	Isopropyl acetate	Based on human exposure
11.	Isopropyl alcohol	Based on human exposure
12.	MEK	Based on human exposure
13.	Methyl methacrylate	Based on human exposure
14.	Phosphoric acid	Based on human exposure
15.	Sodium salicylate	Based on human exposure
16.	Trichloroethylene	Based on human exposure
17.	Xylene	Based on human exposure

Eye effects (note e)

	Ingredient	Comments
1.	Ammonium hydroxide	Based on human exposure
2.	Boric acid	Based on human exposure
3.	Furfural	Based on human exposure
4.	Isopropyl acetate	Based on human exposure
5.	Methyl alcohol	Based on human exposure
6.	Tetrachloroethylene	Based on human exposure

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Skin effects (note f)

	Ingredient	Comments
1.	Benzoic acid	Based on human exposure
2.	Boric acid	Based on human exposure
3.	N,N-Dimethyl-p phenylenediamine	Based on human exposure
4.	Silver	Based on human exposure

Gastrointestinal tract effects (note g)

	Ingredient	Comments
1.	Alcohol	Based on human exposure
2.	Dioctyl phthalate	Based on human exposure
3.	Phenol	Based on human exposure

Blood effects (note h)

	Ingredient	Comments
1.	Methylene chloride	Based on human exposure
2.	Sodium thiosulfate	Based on human exposure
3.	Thiourea	Based on human exposure

Mutagenic effects (note i)

	Ingredient	Comments
1.	Bis (2-Ethylhexyl) adipate	-
2.	Ethylene oxide	-
3.	Captan	-

Pulmonary effects (note j)

	Ingredient	Comments
1.	Sulfur dioxide	Based on human exposure
2.	Zinc chloride	Based on human exposure

Psychotropic effects (note k)

	Ingredient	Comments
1.	Toluene	Based on human exposure
2.	Trichloroethane	Based on human exposure

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Systemic effects (note l)

	Ingredient	Comments
1.	Tetrachloroethylene	Based on human exposure

Blood pressure effects (note m)

	Ingredient	Comments
1.	Sodium chloride	Based on human exposure

a/Carcinogenic substances produce cancer, a cellular tumor, the nature of which is fatal or is associated with the formation of secondary tumors.

b/Teratogenic substances produce birth defects or nontransmissible changes in the offspring.

c/Nervous system effects include headaches, tremors, drowsiness, convulsions, hypnosis, and anesthesia.

d/Irritant effects include any irritant effect on the skin, eye, or mucous membrane.

e/Eye effects include irritation, diplopia, cataracts, eye ground, and blindness.

f/Skin effects include erythema, rash, sensitization of the skin, and petechial hemorrhage.

g/Gastrointestinal tract effects include diarrhea, constipation, and ulceration.

h/Blood effects include effects on all blood elements, electrolytes, pH, protein, and oxygen carrying or releasing capacity.

i/Mutagenic substances produce mutations or transmissible changes in the offspring.

j/Pulmonary effects are effects on respiration and respiratory pathology.

k/Psychotropic substances affect the mind and can modify mental activity.

APPENDIX I

l/Systemic effects are effects on the metabolic and excretory function of the liver or kidneys.

m/Blood pressure effects are those which increase or decrease blood pressure from normal.

LISTING BY INTENDED DRUG FUNCTION OF DRUG INGREDIENTS AVAILABLE FOR USE IN COSMETICS

The following ingredients were either (1) listed in the second edition of the CTFA Cosmetic Ingredient Dictionary as available for use in cosmetic products or (2) reported by manufacturers as being used in cosmetics under FDA's voluntary program for filing cosmetic product ingredient statements. The intended effects of these ingredients were obtained from the U.S. Pharmacopeia, the National Formulary, or the Physician's Desk Reference.

Diagnostic aids; vitamins; and pharmaceutic aids, such as colors, flavors, and solvents, are not included.

We have not attempted to evaluate the potential of the ingredients to cause drug effects as they are used in cosmetics. Such a determination would depend on factors such as (1) the normal route of administration of the ingredient and the route of administration during cosmetic usage and (2) the extent to which the ingredient is absorbed through the skin.

Drug function/ingredient:

Abrasive (dental) (a substance used to polish, grind, or wear away the teeth): pumice.

Acidifier (a substance used to cause acidity): ammonium chloride, sodium biphosphate.

Alkalizer (a substance that causes alkalinization): sodium acetate, sodium bicarbonate, tromethamine.

Analgesic (an agent that alleviates pain): chlorobutanol, clove oil, eugenol, phenacetin, salicylamide, sodium salicylate.

Androgenic (an agent which produces masculine characteristics): testosterone propionate.

Anesthetic (an agent used to eliminate pain): benzocaine (local), ether (general), lidocaine (topical), nitrous oxide (general).

Antacid (a substance that neutralizes acidity): alumina, aluminum hydroxide, bismuth subnitrate, calcium carbonate, magnesium carbonate, magnesium hydroxide, magnesium phosphate, magnesium trisilicate, sodium bicarbonate.

APPENDIX II

Drug function/ingredient:

Antihelminitic (an agent that is destructive to worms): tetrachloroethylene.

Antibacterial (a substance which destroys bacteria or suppresses their growth): methenamine.

Anticonvulsant (an agent that prevents or relieves convulsions): magnesium sulfate.

Antieczematic (an agent used to treat an inflammatory skin disease): coal tar, juniper tar.

Antifungal (an agent destructive to fungi or suppressive of their growth): sodium propionate, undecylenic acid, zinc undecylenate.

Antiinfective (an agent that fights infection): alcohol, benzalkonium chloride, cetylpyridinium chloride, Gentian Violet, hydrogen peroxide, ichthammol, methylbenzethonium chloride, silver nitrate, thimerosal.

Antipruritic (an agent which relieves or prevents itching): camphor, menthol, phenol.

Antischistosomal (an agent which destroys a type of blood parasite): antimony potassium tartrate.

Antiseborrheic (an agent used in treating seborrhea, a disturbance of the sebaceous glands marked by greasy scales on the body): resorcinol monoacetate.

Astringent (an agent which stops bodily discharges): alum, aluminum acetate, aluminum chloride, calcium hydroxide, zinc chloride, zinc oxide, zinc sulfate.

Cathartic (an agent which quickens and increases evacuation from the bowels): castor oil, magnesium hydroxide, magnesium sulfate, mineral oil, sodium carboxymethylcellulose, sodium phosphate.

Caustic (an agent which is burning or corrosive and destructive to living tissue): silver nitrate.

Contraceptive (an agent which prevents conception): nonoxynol-9, octoxynol.

APPENDIX II

Drug function/ingredient:

Dental caries prophylactic (an agent which prevents tooth decay): sodium fluoride, stannous fluoride.

Depigmenting agent (a substance which removes pigmentation from the skin): hydroquinone.

Diuretic (an agent which promotes the secretion of urine): mannitol, theophylline, urea.

Emetic (an agent which causes vomiting): ipecac.

Estrogens (compounds which produce estrus, the cycle of changes in the genital tract which are produced as a result of ovarian hormonal activity): estradiol benzoate, estrogen, estrone.

Expectorant (an agent which promotes the clearing of mucus from the lungs, nose, and throat): potassium iodide.

Irritant, local (an agent that produces irritation): camphor.

Keratolytic (an agent which causes peeling of the outer layer of the skin): resorcinol, resorcinol monoacetate, salicylic acid.

Lipotropic (an agent which acts on fat metabolism to speed the removal of fat in the liver): methionine.

Protectant (an agent that provides a defense against a harmful influence, such as a substance applied to the skin to avoid the effects of the sun's rays): benzoin, calamine, collodion, pectin, Peruvian balsam, petrolatum (white), titanium dioxide, zinc oxide.

Relaxant (an agent that reduces tension): theophylline (smooth muscle relaxant).

Rubefacient (an agent that reddens the skin by increasing the blood flow): isopropyl alcohol, Peruvian balsam.

Scabicide (an agent used to destroy an itch mite which bo es beneath the skin): benzyl benzoate.

APPENDIX III

STATUS OF COLOR ADDITIVES USED IN COSMETICS

Permanently listed

1. Aluminum powder
2. Annatto
3. Azulene
4. Bismuth oxychloride
5. Bronze powder
6. Carmine
7. Carotene
8. Chromium hydroxide green
9. Chromium oxide greens
10. Copper (metallic powder)
11. D&C Blue No. 4
12. D&C Brown No. 1
13. D&C Green No. 8
14. D&C Orange No. 4
15. D&C Orange No. 10
16. D&C Orange No. 11
17. D&C Red No. 17
18. D&C Red No. 31
19. D&C Red No. 34
20. D&C Violet No. 2
21. D&C Yellow No. 7
22. D&C Yellow No. 8
23. D&C Yellow No. 11
24. Dihydroxyacetone
25. Disodium EDTA - copper
26. External D&C Violet No. 2
27. External D&C Yellow No. 7
28. FD&C Red No. 40
29. Ferric ferrocyanide
30. Guanine (pearl essence)
31. Henna
32. Iron oxides
33. Manganese violet
34. Mica
35. Potassium sodium copper chlorophyllin
36. Pyrophyllite
37. Titanium dioxide
38. Ultramarine blue
39. Ultramarine green
40. Ultramarine pink
41. Ultramarine red
42. Zinc oxide

Provisionally listed

1. Caramel
2. D&C Green No. 5
3. D&C Green No. 6
4. D&C Orange No. 17
5. D&C Red No. 6
6. D&C Red No. 7
7. D&C Red No. 8
8. D&C Red No. 9
9. D&C Red No. 19
10. D&C Red No. 21
11. D&C Red No. 22
12. D&C Red No. 27
13. D&C Red No. 28
14. D&C Red No. 30
15. D&C Red No. 33
16. D&C Red No. 36
17. D&C Red No. 37
18. D&C Yellow No. 10
19. D&C Orange No. 5
20. FD&C Blue No. 1
21. FD&C Blue No. 2
22. FD&C Green No. 3
23. FD&C Red No. 3
24. FD&C Yellow No. 5
25. FD&C Yellow No. 6
26. Lead acetate

COMPARISON OF RESTRICTIONS ON THE USE OF COSMETIC INGREDIENTS BY THE PROPOSED EEC DIRECTIVE AND BY FDA REGULATIONS

(Based on Ingredients Listed in the 1977 Edition of the CTFA Cosmetic Ingredient Dictionary)

Ingredient	EEC restrictions	EEC required labeling	FDA restrictions	FDA required labeling	Reported uses (note a)	Maximum reported concentrations
Antimony potassium tartrate	Banned	N/A	None	None	Hair preparations.	0.1% or less
Barium sulfide	Banned	N/A	None	None	Shaving preparations.	10% to 25%
Brucine	Banned	N/A	None	None	Shaving lotions, feminine sprays, hair preparations.	0.1% or less
Cantharides (Spanish fly)	Banned	N/A	None	None	Hair preparations.	0.1% or less
2,5-Dinitrophenol	Banned	N/A	None	None	None	N/A
Iodine	Banned	N/A	None	None	Personal cleanliness products.	1% to 5%
2-Naphthol	Banned	N/A	None	None	None	N/A
Phenol	Banned	N/A	None	None	Hair preparations, skin care preparations, douches.	0.1% to 1%
Tricresyl phosphate	Banned	N/A	None	None	Nail polish	5% to 10%
Stramonium	Banned	N/A	None	None	None	N/A
Tetracholoroethylene	Banned	N/A	None	None	Eye makeup	25% to 50%
Vitamin D	Banned	N/A	None	None	None	N/A
Chlorobutanol	Use as an antiseptic; maximum concentration, 0.5%; banned in aerosols.	"Contains chlorobutanol."	None	None	Makeup preparations.	0.1% to 1%
Ammonia	Maximum concentration, 6% calculated as free ammonia gas.	"Contains ammonia" if above 2%.	None	None	Hair bleaches.	.4% to 2.8%

APPENDIX IV

APPENDIX IV

Ingredient	EEC restrictions	EEC required labeling	FDA restrictions	FDA required labeling	Reported uses (note a)	Maximum reported concentrations
Chloramine T	Maximum concentration, 0.2%.	None	None	None	None	N/A
Methylene chloride	Maximum concentration, 35%; impurity content, 0.2%.	For preparations in aerosol packages, "Must not be used near a flame or electrical equipment with glowing elements."	None	"Warning - Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperatures above 120°F. Keep out of reach of children."	Hairsprays.	25% to 50%
Hydrogen peroxide	Maximum concentration, 12%.	Actual concentration must be stated on label.	None	None	Hair preparations, hair-coloring preparations.	over 17%
Formaldehyde	Banned except for use (1) in nail hardeners at maximum concentration of 5% and (2) as a preservative at maximum concentration of 0.2%.	Nail hardeners must warn to protect the cuticles with grease or oil.	None	None	Hair conditioners, mouthwashes, nail hardeners.	0.1% to 1%
Hydroquinone	Maximum concentration, 2%.	"Do not use to dye eyelashes or eyebrows. Rinse the eyes immediately if the product comes into contact with them."	None	None except when used in coal tar hair dyes.	Hair coloring preparations, skin lighteners.	1% to 5%
1-Naphthol	Limited to use in hair dyes at maximum concentration, 0.5%.	Requires a patch test 24 hours before application. Label must contain directions for patch testing.	None	None	None	N/A
Pyrogallol	Maximum concentration, 5%.	None	None	None	Hair coloring preparations	0.1% to 1%

Ingredient	EEC restrictions	EEC required labeling	FDA restrictions	FDA required labeling	Reported uses (note a)	Maximum reported concentrations
Resorcine	Maximum concentration, 5% in hair dyes.	Can cause an allergic reaction; requires patch test at least 24 hours before application; rinse the hair after application; do not use to dye eyelashes or eyebrows; rinse eyes immediately if product comes in contact with them; directions for patch testing.	None	Sec. 601(a) warning if used in coal tar hair dyes.	Hair dyes.	10% to 25%
	Maximum concentration, 0.5% in hair lotions and shampoos.	Can cause an allergic reaction; requires a patch test at least 24 hours before application; rinse hair well after application; directions for patch testing.	None	None	Face, body, and hand lotions.	1% to 5%
Tyrothricin	Maximum concentration, 0.05%; may not be used in products for intimate hygiene.	None	None	None	Skin fresheners, paste masks.	0.1% to 1%
Zinc chloride	Maximum concentration, 1% calculated as zinc.	None	None	None	Mouthwashes, breath fresheners.	0.1% to 1%
Zinc sulfate	Maximum concentration, 1% calculated as zinc.	None	None	None	Bath preparations, douches, skin care preparations.	25% to 50%
Zinc phenolsulphonate	Maximum concentration, 6% as an astringent in lotions or as a deodorant in aerosols.	"Keep away from eyes during use; do not spray into the eyes."	None	Aerosol warning when used in aerosol deodorants.	Fragrance preparations, aftershave lotions, skin fresheners, underarm deodorants.	1% to 5%

APPENDIX IV

APPENDIX IV

Ingredient	EEC restrictions	EEC required labeling	FDA restrictions	FDA required labeling	Reported uses (note a)	Maximum reported concentrations
Hexachlorophene	Maximum concentration, 1% in soaps, 0.1% in aerosol packs, 0.5% in other uses.	None	Maximum concentration, 0.1%; not for use in products which may come in contact with mucous membranes.	None	Aftershave lotions; skin care preparations; face, body, hand lotions.	0.1% to 1%
Lead acetate	Maximum concentration, 1.75% calculated as lead.	"Contains lead acetate."	None	None	Hair coloring preparations.	10% to 25%
Methyl alcohol	Maximum concentration, 5% as a denaturant.	None	None	None	Personal cleanliness products, nail polish and enamel.	1% to 5%
1,1,1-trichloroethane	Maximum concentration, 35%.	For preparations in aerosol packs. "Do not use in the vicinity of a flame or an electric appliance with exposed elements."	None	Aerosol warning.	None	N/A

a/Reported to FDA by manufacturers under the voluntary program for filing of cosmetic product ingredient statements as of August 1977.

COMPARISON OF MANUFACTURING PRACTICES OBSERVED IN FDA INSPECTIONS OF COSMETIC PLANTS WITH DRUG GMPs

Drug GMPs	Conditions noted during cosmetic plant inspections
Buildings shall be maintained in a clean and orderly manner and shall be of suitable size, construction, and location to facilitate maintenance, adequate cleaning, and proper operations.	Open doors and windows and inadequately monitored or equipped ventilation systems made possible airborne contamination.
Equipment shall be maintained in a clean and orderly manner and shall be of suitable design, size, construction, and location to facilitate cleaning, maintenance, and operation for its intended purpose.	Firms were observed using equipment that could not be dismantled for thorough cleaning and that contained unnecessary pipelines, bypasses, dead ends, and unused valves.
Personnel shall have a background of appropriate education and/or experience for assuming responsibility to insure that the drug has the safety, identity, strength, quality, and purity that it purports to possess.	Need for an adequate training program for new maintenance personnel or a refresher course for others to instill the proper attitude toward the necessary manufacturing precautions needed to produce quality products.
Components shall be stored and handled in a safe, sanitary, and orderly manner. Components shall be withheld from use until they have been identified, sampled, and tested for conformance with established specifications. Adequate measure shall be taken to prevent mixups and cross-contamination of components.	Over 67 percent of the firms inspected had not established raw material specifications and had not kept records of raw material testing and use. Few firms conducted bacteriological tests on raw materials, and 10 to 20 percent did not store raw materials under adequate conditions. About 30 percent of the firms did not properly identify components to prevent mixups or misuses.
batch production and control records shall be prepared and shall be numbered to permit the identification of all production and control documents relating to the history of the batch and all lot or control numbers appearing on the labels of drugs from the batch.	Less than 50 percent of the firms inspected kept adequate batch records to determine the production and analytical history of cosmetics or conducted tests to insure product homogeneity.

APPENDIX V

Drug GMPs	Conditions noted during cosmetic plant inspections
Production and control procedures shall include all reasonable precautions to insure that the drugs produced have the identity, strength, quality, and purity they purport to possess.	Over 67 percent of the firms inspected did not conduct pharmacological or chemical studies on new or reformulated products to determine product safety before distribution.
1. Master records containing a description of sampling procedures and appropriate specifications for finished products shall be established.	About 70 percent of the firms inspected had not established finished product specifications (microbiological, chemical, physical, etc.) and had not withheld from distribution any batch not meeting the specifications. Less than 50 percent of the firms inspected conducted tests to insure product homogeneity.
2. Appropriate precautions shall be taken to minimize microbiological and other contamination.	More than 85 percent of the firms inspected did not test equipment for microbial contamination. Extensive use of uncovered containers for temporary storage that could result in product contamination was noted. Airborne contamination was made possible via open doors and windows and improperly monitored or equipped ventilation systems. Manufacturers may be using preservatives improperly to cover up contamination with microorganisms resulting from poor manufacturing practices. Less than 20 percent of the firms inspected tested the effectiveness of preservative systems.
3. Appropriate precautions shall be taken to minimize the hazard of cross-contamination of drugs while being manufactured or stored.	Additional study is needed by firms to assure that the method of dispensing does not increase the possibility of product contamination.
Packaging and labeling operations shall be adequately controlled to insure that correct labeling is employed for the drug.	About 30 percent of the firms inspected failed to label their products with adequate directions for use.
Distribution records shall be maintained for each batch of drug in a manner that will facilitate its recall if necessary.	About 75 percent of the firms failed to maintain adequate inventory control systems that would facilitate a product recall.

APPENDIX V

APPENDIX VI

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

June 12, 1978

Mr. Gregory J. Ahart
Director, Human Resources
Division
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Ahart:

The Secretary asked that I respond to your request for our comments on your draft report entitled, "Lack of Authority Hampers Efforts to Ensure Cosmetic Safety." The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

Thomas D. Morris
Inspector General

Enclosure

APPENDIX VI

COMMENTS OF THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE
ON THE COMPTROLLER GENERAL'S DRAFT REPORT ENTITLED
"LACK OF AUTHORITY HAMPERS EFFORTS
TO ENSURE COSMETIC SAFETY"

General Comments: As the Commissioner of Food and Drugs stated in testimony before the Subcommittee on Oversight and Investigations Committee on Interstate and Foreign Commerce of the House of Representatives, "As the law stands, cosmetics are the only products for which the legal burden rests on the Food and Drug Administration (FDA) to prove a hazard to the public, rather than on the industry to demonstrate that their product has been tested in accordance with currently accepted methodology and that it is safe."

Although we agree in principle with many of the recommendations in this report, we do not necessarily agree that these steps can be taken under the present statute. Nor do we believe that, under current statutory authority, an extensive expenditure of resources toward the regulation of cosmetics is a wise investment of public funds. As the Commissioner also stated, ". . .if you have important public health responsibilities in three different areas, and if each of them lays compelling claims to your resources, and in one of those areas you have manifestly inadequate statutory authority, and in the other two it is at least better, then a wise man is going to allocate (resources) more heavily to where he is going to get a return."

GAO Recommendation

That the Secretary, HEW, direct the FDA Commissioner to strengthen FDA's program for insuring the safety of cosmetic products. Specifically FDA should:

-- Require a listing of fragrance and flavoring ingredients on cosmetic labels when those ingredients are known allergens.

Department Comment

We do not concur. There is a lack of adequate scientific information to classify a fragrance or flavor ingredient as a "known allergen." Any ingredient can give rise to allergic contact dermatitis in some susceptible individuals. The question that remains to be resolved is the frequency of such reactions which would permit an unambiguous classification of the ingredient as a "known allergen." This matter is further complicated by the fact that the rate of allergic responses is related to the exposure concentration and that some allergens can be safely used in some products and not others. Furthermore, if a substance produces allergic reactions to a significant extent, FDA may take regulatory action to restrict its use as a cosmetic ingredient as it has done in the case of bithionol and halogenated salicylanilides. (21 CFR 700.11 and 700.15.) The listing of all ingredients in a fragrance or flavor would in many instances require the declaration of over a hundred chemical names on a product label and may raise trade secret issues.

APPENDIX VI

GAO Recommendation

-- Hasten the development of ingredient and product-class standards.

Department Comment

We do not concur. The FDA does not have the authority to require the data submissions from industry that would be required before such standards could be developed. For FDA to collect the data necessary for the development of ingredient and product-class standards would require resources that are not available to the program at this time. Furthermore, FDA can issue regulations establishing standards only if it can show that a cosmetic violating the standards may be injurious under the condition of use or otherwise in conflict with the existing law.

GAO Recommendation

-- Establish a specific definition of "adequate substantiation of safety" including specific testing criteria.

Department Comment

The FDA has already clarified the meaning of "adequate substantiation of safety" in relation to cosmetics with respect to the warning requirement of 21 CFR 740.10. In the Federal Register of March 3, 1975 (40 FR 8916) the Commissioner advised:

> ". . .that the safety of a product can be adequately substantiated through (a) reliance on already available toxicological test data on individual ingredients and on product formulations that are similar in composition to particular cosmetics, and (b) performance of any additional toxicological and other tests that are appropriate in the light of such existing data and information. Although satisfactory toxicological data may exist for each ingredient of a cosmetic, it will still be necessary to conduct some toxicological testing with the complete formulation to assure adequately the safety of the finished cosmetic."

Furthermore, FDA does not have the authority to require that cosmetic manufacturers substantiate the safety of their products nor the authority to establish specific testing criteria. FDA also does not have the authority to require submission of data to support development of such criteria at this time.

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GAO Recommendation

-- Take steps, in coordination with CPSC, to ensure that toxic cosmetics are packaged in child-proof containers.

Department Comment

We agree that requiring child-proof packaging for those cosmetics that are revealed to be the cause of poison ingestions leading to injury would be worthwhile. At the present time, however, the FDA is not aware of any hazard associated with cosmetic products that would warrant such packaging. The FDA will continue to evaluate data received from the Consumer Product Safety Commission's (CPSC) National Electronic Injury Surveillance System (NEISS) and take appropriate action as the need arises.

GAO Recommendation

That the Secretary, HEW, direct the FDA Commissioner to:

-- Obtain and evaluate data from the published literature on the safety of cosmetic products and ingredients.

Department Comment

We concur with this recommendation. FDA scientists continuously review new scientific information both from the published literature and other sources.

GAO Recommendation

-- Obtain and evaluate the basis for restrictions on the use of certain ingredients in cosmetics in other countries, and, where appropriate, adopt similar restrictions on the use of the ingredients in U.S. cosmetics.

Department Comment

We agree that evaluating the basis for restrictions placed on the use of ingredients in cosmetics by other countries is appropriate when the conditions of the use of such ingredients in cosmetics marketed in the United States warrant such action. The FDA is already familiar with the restrictions imposed by many countries and continues to review the basis for new restrictions as the need arises. However, under current statutes, use of cosmetic ingredients in the United States can be prohibited or restricted only if proven to be harmful to users under the conditions of their use. This requirement would preclude the FDA from taking action on the basis of foreign regulatory restrictions alone. It would be necessary to show that the ingredient in question posed a hazard as it is used.

GAO Recommendation

-- Establish an adverse reaction reporting system to (1) develop additional sources of information on cosmetic-related injuries and (2) ensure effective follow up on consumer complaints.

Department Comment

Monitoring adverse reactions to cosmetic products is an important activity which has resulted in the removal of unsafe cosmetic products from the market. The FDA is using and has used a substantial portion of its cosmetic resources for this type of activity. This includes a program for evaluating adverse reactions reported directly to FDA, monitoring reactions at selected hospital emergency rooms under the NEISS program, evaluating voluntarily submitted product experience reports from the cosmetic industry, conducting a comprehensive consumer survey, and contracting with dermatologists to evaluate and report cosmetic adverse reactions from patients. To further improve efforts in this area, the statute would have to be changed to require mandatory reporting by industry.

Effective follow ups on consumer adverse reaction complaints about cosmetics is conducted when facts available to the FDA indicate a possibility that a significant health hazard is involved and that such follow up could lead to an action on the part of the FDA which would improve the safety of a specific product or cosmetic products in general. FDA's ability to follow up in every instance is limited by the lack of resources, cooperation of the complainant or the treating physician, lack of reliable information to relate the product to the alleged injury, and lack of authority to review complaint files of cosmetic firms and the safety data used to substantiate the safety of the product. Where consumer or physician information indicates serious injury, reports of adverse reactions are currently investigated to the fullest extent possible.

GAO Recommendation

That the Secretary, HEW, direct the FDA Commissioner to:

-- Establish regulations indentifying the conditions of use of drug ingredients under which the ingredient is "intended or understood" to have a drug effect.

Department Comment

We do not concur. The Food, Drug and Cosmetic (FD&C) Act defines the term "cosmetic" to mean "(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; . . ." (emphasis added)

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The term "drug" is defined in the FD&C Act as "(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals, " (emphasis added). Thus, the distinction between a drug and a cosmetic rests upon the intended use of the article. We would have to approach the problem of whether a particular ingredient is a drug on a case by case basis. In each case we have to look at all the facts to determine if we can prove that the product was intended for use as a drug or a cosmetic.

GAO Recommendation

-- Establish regulations requiring that labels of cosmetic products containing drug ingredients bear warning statements consistent with those required on drug products containing the same ingredient and given through the same route of administration.

Department Comment

We do not concur. We believe that it is appropriate for FDA to examine the need for consistent statements, but more study is needed to determine whether specific warnings should be required in each case. Furthermore, under 21 CFR Section 740.1, the label of a cosmetic product is required to bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product.

GAO Recommendation

-- Hasten the review of the safety of color additives provisionally listed for use in cosmetics and take appropriate regulatory action to prevent the conditions of use.

Department Comment

We do not concur that the review should be further accelerated. The FDA is already engaged in an accelerated review of the safety of color additives provisionally listed for cosmetics and is taking action to prohibit the use of colors that pose safety problems. The speed of the review is dictated by agency resources, the availability of data from petitioners and the time required to make sound scientific judgements in the public interest.

GAO Recommendation

That the Secretary, HEW, direct the FDA Commissioner to evaluate safety data on coal tar hair dye ingredients and require, where applicable, a cancer or other appropriate warning on product labels.

Department Comment

The FDA is already evaluating safety data on coal tar hair dyes and published a notice in the Federal Register of January 6, 1978 (43 FR 1101-1106) proposing a warning statement on hair dye labels about the risk of cancer that may result from the use of hair dyes containing these ingredients. Also proposed is the placement of an information poster in beauty salons advising consumers to review the labels of the products intended for their hair to determine if they contain an ingredient found to cause cancer in animals. These proposals concern coal tar hair dyes containing 4-methoxy-m-phenylenediamine and its sulfate (also known as 2,4-diaminoanisole and its sulfate).

On February 3, 1978, the FDA testified before Congress that it intends to take similar action in regard to any other chemical used in coal tar hair dyes that poses a cancer risk based on FDA's review of appropriate tests. A review of toxicological data on additional coal tar hair dye ingredients is presently underway.

The ability of FDA to protect the public from risks associated with long-term use of hair dyes will continue to be severely limited until Congress repeals the coal tar hair dye exemption in the FD&C Act.

GAO Recommendation

That the Secretary, HEW, direct the FDA Commissioner to:

-- Devise a more effective inspection program to ensure that all cosmetic manufacturers are periodically inspected.

Department Comment

During the past two years, the FDA has instituted more effective manufacturing establishment and product inspection programs, information systems, and evaluation of the compliance activities. FDA has also identified some 1,000 cosmetic manufacturing establishments that were previously unknown, bringing the total number identified to about 2,200. However, lack of legal authority to require cosmetic firms to register their manufacturing sites, coupled with the resource constraints previously discussed, continues to restrict the inspection program for cosmetic manufacturers.

GAO Recommendation

-- Establish GMP's specifically applicable to cosmetic manufacture.

Department Comment

We concur with the need for Good Manufacturing Practices (GMP) regulations for cosmetics. Currently, the FDA is reviewing a draft of proposed GMP regulations and is concurrently considering a GMP petition submitted by the cosmetic industry. Work on the GMP regulations will be done as expeditiously as possible, given the limited resources available and competing activities.

GAO Recommendation

-- Expand the collection and testing of cosmetic samples for such factors as microbial contamination and eye and skin irritation.

Department Comment

Surveillance programs to determine if cosmetic products are contaminated with harmful microorganisms were conducted during fiscal years 1975 and 1977. In both surveys it was concluded that contamination with harmful microorganisms did not constitute a problem among either domestic or imported products for sale in this country. Similar surveys will be conducted in the future, as resources permit and the need arises. However, there is evidence that some mascara and other eye area products may not be adequately preserved to prevent the growth of harmful microorganisms under conditions of use. A notice of intent to propose rules, designed to correct this problem, was initiated in the October 11, 1977, Federal Register.

Collection and testing of cosmetic samples to determine eye and skin irritation potential would far exceed budgeted resources. Furthermore, additional data are required to make safety determinations; e.g., product composition, ingredient purity, intended use, toxicological data on individual ingredients. Collection and testing of products for irritation are, therefore, directed to those instances where adverse experience, or other reliable data, indicate that a particular product or ingredient may be harmful under conditions of use.

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GAO Recommendation

-- Take appropriate steps to ensure that prompt and effective enforcement action is taken when violations are found in plant inspections or sample analyses.

Department Comment

We concur. The present policy of the FDA is consistent with this recommendation. In those situations where violations of the statute are found, FDA takes the most appropriate regulatory action. However, many of the conditions discussed in this report were not actionable because of a lack of adequate evidence to prove that there was a violation of the FD&C Act.

Technical Comments

GAO note: These technical comments have been incorporated into the final report and are not included here.

PRINCIPAL HEW OFFICIALS

RESPONSIBLE FOR ADMINISTERING ACTIVITIES

DISCUSSED IN THIS REPORT

	Tenure of office	
	From	To
SECRETARY OF HEALTH, EDUCATION, AND WELFARE:		
Joseph A. Califano, Jr.	Jan. 1977	Present
David Mathews	Aug. 1975	Jan. 1977
Caspar W. Weinberger	Feb. 1973	Aug. 1975
Frank C. Carlucci (acting)	Jan. 1973	Feb. 1973
Elliot L. Richardson	June 1970	Jan. 1973
Robert H. Finch	Jan. 1969	June 1970
Wilbur J. Cohen	Mar. 1968	Jan. 1969
John W. Gardner	Aug. 1965	Mar. 1968
ASSISTANT SECRETARY FOR HEALTH (note a):		
Julius B. Richmond	July 1977	Present
James F. Dickson (acting)	Jan. 1977	July 1977
Theodore Cooper	May 1975	Jan. 1977
Theodore Cooper (acting)	Feb. 1975	Apr. 1975
Charles C. Edwards	Mar. 1973	Jan. 1975
Richard L. Seggel (acting)	Dec. 1972	Mar. 1973
Merlin K. Duval, Jr.	July 1971	Dec. 1972
Roger O. Egeberg	July 1969	July 1971
Phillip R. Lee	Nov. 1965	Feb. 1969
COMMISSIONER, FOOD AND DRUG ADMINISTRATION:		
Donald Kennedy	Apr. 1977	Present
Sherwin Gardner (acting)	Dec. 1976	Apr. 1977
Alexander M. Schmidt	July 1973	Dec. 1976
Sherwin Gardner (acting)	Mar. 1973	July 1973
Charles C. Edwards	Feb. 1970	Mar. 1973
Herbert L. Ley, Jr.	July 1968	Dec. 1969
James L. Goddard	Jan. 1966	June 1968

a/Until December 1972 the title of this position was Assistant Secretary (Health and Scientific Affairs).

(10859)

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