I. Background

In a notice published in the **Federal Register** of December 18, 2001 (66 FR 65214), FDA announced the availability of a draft CPG entitled ''Filth from Insects, Rodents, and Other Pests in Food.'' FDA has finalized the draft CPG after receiving no comments on the document. The CPG revises and clarifies existing guidance on foods that contain filth from insects, rodents, and other pests to reflect recent advances in science. The purpose of this CPG is to provide clear policy to FDA's field and headquarters staff with regard to filth from insects, rodents, and other pests in foods. It also contains information that may be useful to the regulated industry and to the public.

The CPG supersedes the current CPG and represents the agency's current thinking on the subject. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of applicable statutes or regulations.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115).

II. Comments

Interested persons may submit to the Docket Management Branch (*see* **ADDRESSES**) written or electronic comments on the CPG entitled ''Filth from Insects, Rodents, and Other Pests in Food'' at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the CPG and received comments may be seen in the Dockets Management Branch (*see* **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Copies of the CPG also may be downloaded to a personal computer with access to the Internet. The Office of Regulatory Affairs home page includes the CPG and may be accessed at *http://www.fda.gov/ora* under ''Compliance References.''

Dated: November 4, 2002.

John M. Taylor,

Senior Associate Commissioner for Regulatory Affairs.

[FR Doc. 02–30403 Filed 11–29–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00P–1378]

Draft Guidance for Industry on Labeling for Topically Applied Cosmetic Products Containing Alpha Hydroxy Acids as Ingredients; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance for Industry: Labeling for Topically Applied Cosmetic Products Containing Alpha Hydroxy Acids as Ingredients.'' FDA has considered evidence that suggests that topically applied cosmetic products containing alpha hydroxy acids (AHAs) may increase the sensitivity of skin to the sun while the products are used and for up to a week after use is stopped and that this increased skin sensitivity to the sun may increase the possibility of sunburn. The purpose of this draft guidance is to educate manufacturers to help ensure that their labeling for AHA-containing cosmetic products is not false or misleading. The draft guidance suggests content for a labeling statement for AHA-containing cosmetic products. This action was prompted by a citizen petition filed by the Cosmetic, Toiletry, and Fragrance Association (CTFA), which requested that FDA issue a regulation establishing sun alert labeling on AHA-containing products.

DATES: Submit written or electronic comments by January 31, 2003, to ensure their adequate consideration in preparation of the final document. Comments on this draft guidance may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Cosmetics and Colors (HFS–100), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Submit electronic comments on the draft guidance to *http://www.fda.gov/dockets/ecomments.* Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance may be sent. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Julie N. Barrows, Center for Food Safety and Applied Nutrition (HFS–105), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3412.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Guidance for Industry: Labeling for Topically Applied Cosmetic Products Containing Alpha Hydroxy Acids as Ingredients.'' This draft guidance explains FDA's suggested labeling of topically applied cosmetic products that contain AHAs to alert consumers of the need to use sun protection when using these products. The guidance will educate manufacturers to help ensure that their labeling for AHA-containing cosmetic products is not false or misleading under 21 U.S.C. 362(a) and 321(n).

AHAs are organic acids with a hydroxyl group on the carbon adjacent to the carboxylic acid group. The predominant AHAs present in cosmetic products are glycolic acid and lactic acid. Other AHAs that are found in cosmetic products include citric acid, -hydroxyoctanoic acid, and -hydroxydecanoic acid (Ref. 1). Since the early 1990s, there has been a proliferation of AHA-containing cosmetic and salon products (Ref. 2). AHAs have been formulated into skin products, make-up, hair products, nail products, bath products, colognes, and suntan preparations. Most AHA-containing products are ''leave on'' products that are intended for daily use on the skin or mucous membrane or are ''discontinuous use'' products that are intended to be applied to the skin for a short period of time (*e.g.*, less than an hour) followed by thorough rinsing. Salon products are usually discontinuous use products.

FDA received a total of 107 adverse dermatologic experience reports for AHA-containing skin care products between 1992 and 2000, with the maximum number (32) in 1994 (Ref. 2). The reported adverse experiences include: Burning (43), dermatitis or rash (33), swelling (26), pigmentary changes (15), blisters or welts (13), skin peeling (12), itching (12), irritation or tenderness (6), chemical burns (6), and increased sunburn (3).

Starting in 1994, CTFA's Cosmetic Ingredient Review (CIR) Expert Panel, FDA's AHA Review Committee, and FDA reviewed the safety of topically applied AHAs in cosmetic products

(Refs. 2 through 4). The reviewers evaluated human clinical studies that investigated the effects of ultraviolet (UV) radiation on the skin after exposure to AHAs. The studies demonstrated that topically applied AHAs increase skin sensitivity to UV radiation during application and that this increased skin sensitivity to UV radiation diminishes after discontinuing application for a week.

Sensitivity to UV radiation is the main reason for the skin's sensitivity to the sun (Ref. 5). Short-term exposure to the sun may cause sunburn, and chronic long-term exposure to the sun may increase the risk of premature skin aging (Ref. 5). Experimental and epidemiological studies have demonstrated that prolonged exposure to the UV radiation in sunlight is a primary risk factor for certain types of skin cancer (Refs. 6 through 8).

The human clinical studies provided data for the effects of UV radiation on the skin after short-term (up to 12 weeks) topical exposure to AHAs. The evidence from the clinical studies suggests that increased skin sensitivity to UV radiation may increase the possibility of sunburn for consumers. Adverse experience reports of increased sunburn after AHA use support this conclusion (Ref. 2). The increased skin sensitivity to UV radiation also may result in other harmful effects to the skin, but the data available to FDA's Center for Food Safety and Applied Nutrition (CFSAN) are still inconclusive on this point.

FDA's National Center for Toxicological Research (NCTR) currently is investigating the effects of long-term exposure to AHAs in a photocarcinogenicity study by the National Toxicology Program's Center for Phototoxicology (Ref. 2). The purpose of the NCTR study is to allow quantitative determination of the effect AHA treatment (glycolic acid) has on the induction of mouse skin cancer (SKH–1 hairless mouse) by simulated solar radiation.

FDA believes that increased skin sensitivity to the sun, and particularly the possibility of sunburn following AHA use, may be material facts that manufacturers should disclose to users under 21 U.S.C. 362(a) and 321(n) and 21 CFR 1.21. Accordingly, FDA believes that if manufacturers inform users of AHA-containing products about the potential for increased skin sensitivity to the sun and particularly the possibility of sunburn, and what steps a user may take to avoid such consequences, this will help avoid the potential that the products are misbranded under 21 U.S.C. 362(a) and 321(n).

In the draft guidance, FDA suggests that the following statement appear on the label of AHA-containing cosmetic products:

> ''Sunburn Alert: This product contains an alpha hydroxy acid (AHA) that may increase your skin's sensitivity to the sun and particularly the possibility of sunburn. Use a sunscreen and limit sun exposure while using this product and for a week afterwards.''

FDA expects that a label statement such as the recommended ''Sunburn Alert'' will be a source of new information about sun protection for most consumers, as well as a reminder about sun protection for consumers who already are aware of the need to use sun protection when using these products (Ref. 2).

CTFA submitted a citizen petition (dated June 29, 2000, and assigned FDA Docket No. 00P–1378/CP1), which requested that under 21 U.S.C. 362(a), FDA issue a regulation on cosmetic labeling in 21 CFR part 701 establishing labeling requirements related to sun protection with use of cosmetics containing AHAs. FDA is issuing this draft guidance entitled ''Guidance for Industry: Labeling for Topically Applied Cosmetic Products Containing Alpha Hydroxy Acids as Ingredients'' rather than a proposed regulation.

FDA is announcing the availability of this draft guidance at this time pending the results of the NCTR study because the agency believes interim action is warranted to recommend that manufacturers label topically applied cosmetic products that contain AHAs to alert consumers of the need to use sun protection when using these products. After assessing the results of the photocarcinogenicity study and the effectiveness of any final guidance, the agency intends to determine if additional agency action is appropriate.

This draft guidance is a level 1 guidance issued consistent with FDA's regulation on good guidance practices (21 CFR 10.115). The draft guidance represents the agency's current thinking on the labeling of topically applied cosmetic products that contain an AHA as an ingredient. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of applicable statutes and regulations.

II. Comments

Interested persons may, at any time, submit written comments on the draft guidance to the Dockets Management Branch (*see* **ADDRESSES**). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

An electronic version of this draft guidance is available on the Internet at *http://www.cfsan.fda.gov/~dms/guidance.html*.

IV. References

The following references are on display in the Dockets Management Branch (*see* **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Yates, R. L., and D. C. Havery, ''Determination of Phenol, Resorcinol, Salicylic Acid and -Hydroxy Acids in Cosmetic Products and Salon Preparations,'' *Journal of Cosmetic Science*, vol. 50, pp. 315–325, 1999.

2. Barrows, Julie N., memorandum to the administrative file, ''Guidance for Industry: Labeling for Topically Applied Cosmetic Products Containing Alpha Hydroxy Acids as Ingredients,'' Office of Cosmetics and Colors, CFSAN, FDA, September 12, 2002.

3. Andersen, F. A., Ed., ''Final Report on the Safety Assessment of Glycolic Acid, Ammonium, Calcium, Potassium, and Sodium Glycolates, Methyl, Ethyl, Propyl, and Butyl Glycolates, and Lactic Acid, Ammonium, Calcium, Potassium, Sodium, and TEA-Lactates, Methyl, Ethyl, Isopropyl, and Butyl Lactates, and Lauryl, Myristyl, and Cetyl Lactates,'' *International Journal of Toxicology*, vol. 17, supplement 1, pp. 1–241, 1998.

4. FDA, memoranda of meetings of AHA Review Committee, May 6, 1997, and February 12, 1997, and index of reviewed information.

5. Hawk, J. L. M., Ed., ''*Photodermatology*,'' Arnold Publishers, chapters 4, 6, and 7, pp. 43–52 and 69–102, 1999.

6. DeGruijl, F. R., J. B. VanDerMeer, and J. C. VanDerLeun, ''Dose-Time Dependency of Tumor Formation by Chronic UV Exposure,'' *Photochemistry and Photobiology*, vol. 37, pp. 53–62, 1983.

7. Strickland, P. T., et al., ''Quantitative Carcinogenesis in Man: Solar Ultraviolet B Dose Dependence of Skin Cancer in Maryland Watermen,'' *Journal of the National Cancer Institute*, vol. 81, pp. 1910–1913, 1989.

8. Forbes, P. D., et al., ''Simulated Stratospheric Ozone Depletion and Increased Ultraviolet Radiation: Effects on Photocarcinogenesis in Hairless Mice,'' *Cancer Research*, vol. 42, pp. 2796–2803, 1982.

Dated: November 15, 2002.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 02–30340 Filed 11–29–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: National Treatment Outcomes Monitoring System (NTOMS)—New—NTOMS is an extension and expansion of two pilot projects funded by the Office of National Drug Control Policy (ONDCP), the Drug Evaluation Network System (DENS) and Random Access Monitoring of Narcotics Addicts (RAMONA). NTOMS will be a surveillance system that will provide periodic reporting on access to and effectiveness of drug abuse treatment using a nationally representative sample of patients receiving treatment for psychoactive substance dependence in a sample of specialty treatment providers throughout the United States. NTOMS will collect information from and about clients, and limited information about treatment facilities. A sample of 250 facilities and 84,000 clients is planned. The clients will be sampled over a period of four years. NTOMS will permit SAMHSA's Center for Substance Abuse Treatment (CSAT) to enhance its ability to carry out statutory responsibilities to determine the quality and appropriateness of treatment, as required by Sections 507(b)(13) and (14) of the Public Health Service Act [42 U.S.C. 290bb].

Specialized substance abuse treatment facilities will be sampled as clusters of service delivery units (SDU's). Facilities will be asked to complete a single instrument, the Addiction Treatment Inventory once per year to track changes in facility treatment programs and activities. Some facilities will thus complete this instrument four times; those that are recruited late in the beginning stages of the system will complete it less often. Replacements for dropouts and closures, or for the purpose of adjusting the facility sample to changes in the facility population, will also have fewer administrations.

Upon admission, a baseline battery consisting of several different instruments will be administered to a sample of clients. The principal questionnaire will include the content of the Addiction Severity Index, an intake assessment instrument already widely used at treatment facilities. This content will impose no marginal burden on clients beyond the normal intake process. However, the Addiction Severity Index will be supplemented by additional items that are required for CSAT to meet its obligations under the Government Performance Results Act of 1993 (GPRA) (31 U.S.C. 101) and by items concerning entering patients collected at publicly-funded treatment facilities as part of the Treatment Episode Data Set, a component of the Drug and Alcohol Services Information System. At admission, three other questionnaires will be administered. The Life History Interview (LHI) will obtain information about patterns of substance use over the past five years. The Waiting List Module will ask about access to treatment and how long entering patients have waited for admission since seeking treatment. The Locator/Tracking Form will request information needed to find clients six months after discharge to determine the outcome of their treatment. Clients will also be asked to read and sign a consent form for participation in subsequent stages of the study.

During treatment, sampled clients who are still in treatment will be contacted periodically by telephone and asked the questions in the Treatment Services Review, an extant instrument used to determine the treatment services and activities actually delivered to clients. This instrument will be administered periodically. Therefore, clients who spend more than 30 days in treatment will be asked to complete it more than once. Because of high initial drop-out rates, it is estimated that only 60 percent of clients will be asked to complete at least one Treatment Services Review.

Selected items from the expanded ASI will be administered to a sample of the original clients again shortly after they leave treatment and the sampled clients will be asked to confirm or update the locating information. Six months after discharge, a sample of 20 percent of the clients who left treatment will be interviewed in person or by telephone. The expanded ASI will be administered for a third time, and the LHI for a second time. Approximately one-third of this sample of clients, all interviewed in person, will also be asked to provide a urine sample for analysis.

To obtain a response rate at both the institutional and client levels that will support estimates in larger populations, CSAT plans to offer incentives for participation in NTOMS to both facilities and clients. Estimated annual burden for NTOMS is shown below:

Type of respondent and activity	Number of respondents	Responses/ respondent	Hours/response	Total burden hours
Treatment Facilities				
Addiction Treatment Inventory	250	1	0.33	83
Facility Subtotal	250			83
Clients				
Instruments administered at admission or during treatment:				
Expanded ASI at admission [1]	21,000	1	0.17	3,500
LHI at admission	21,000	1	0.50	10,500