receive on this working draft with the copy available for inspection at the above address.

Copies of the working draft are available and may be obtained by interested individuals or organizations by writing to the Commissioner of Social Security, Department of Health and Human Services, P.O. Box 1585, Baltimore, Maryland 21203.

We wish to point out that this is a working draft. Neither SSA nor the Department of Health and Human Services has approved these draft regulations.

FOR FURTHER INFORMATION CONTACT: Armand Esposito, Room 4234, West High Rise Building, 6401 Security Boulevard, Baltimore, Maryland 21235, (301) 594–7455.

Dated: September 12, 1980.

William J. Driver,

Commissioner of Social Security.

[FR Doc. 80–29903 Filed 9–25–80; 8:45 am]

BILLING CODE 4110–07–M

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20 CFR Parts 404 and 416

Disability Insurance and Supplemental Security Income Determinations of Disability

AGENCY: Social Security Administration, HHS.

ACTION: Notice of decision to develop regulations.

SUMMARY: The Social Security Administration plans to recommend to the Secretary proposed regulations establishing standards of performance and administrative requirements and procedures for States making disability determinations for the Secretary under titles II and XVI of the Social Security Act. These new regulations for administering the disability program are being developed to implement a provision of Pub. L. 96–265 (the "Social Security Disability Amendments of 1980") which amends section 221 of the Social Security Act.

The disability determination function is now carried out by the States and the Federal Government under negotiated agreements between the Social Security Administration and designated State agencies. The law provides that, effective June 1, 1981, disability determinations will be made by the State agencies in compliance with regulations containing performance standards and other administrative requirements and procedures relating to the disability determination function. States will have the option of turning the function over to the Federal Government if they do not wish to make disability determinations.

The proposed regulations will specify the responsibilities of the Secretary and the States in administering the disability program. They will prescribe State agency performance standards for accuracy and processing time in making disability determinations, and provide the administrative requirements and procedures the Social Security Administration and the State agencies will follow in carrying out the disability determination function. Provisions will be included specifying how the Secretary or a State may terminate the State's performance of this function.

The primary purpose of these regulations is to improve the quality and timeliness of disability determinations and to insure nationally uniform standards and procedures. At the same time, every effort will be made to preserve the Federal-State relationship and to allow States to perform their function with maximum management flexibility and a minimum of regulation.

The proposed administrative regulations will require revisions to parts 404 and 416 of Title 20 CFR. The Department has classified the proposed regulations as policy significant.

FOR FURTHER INFORMATION CONTACT: David B. Smith, Social Security Administration, Office of Disability Programs, Room 3–A–12, Operations Building, 6401 Security Boulevard, Baltimore, Maryland 21235, Telephone 301–594–7108.

Dated: September 4, 1980.

Approved.

William J. Driver,

Commissioner of Social Security.

[FR Doc. 80–29844 Filed 9–25–80; 8:45 am]

BILLING CODE 4110–07–M

Food and Drug Administration

21 CFR Part 310

[Docket No. 80N–0227]

Camphorated Oil and Camphor-Containing Drug Products for Over-the-Counter Human Use; Notice of Proposed Rulemaking

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) proposes that drug products labeled as "camphorated oil" or "camphor liniment" and drug products containing camphor in excess of 11 percent be classified in Category II as not generally recognized as safe and effective and as misbranded. This document, based on the recommendations of the Advisory Review Panel on OTC Miscellaneous External Drug Products and the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products, is part of the ongoing review of OTC drug products conducted by the FDA. The agency, having reviewed the Panels' reports, has determined that any drug product labeled as "camphorated oil" or "camphor liniment" or any drug product containing camphor in excess of 11 percent is misbranded and is a new drug for which an approved new drug application is required for marketing. The agency has also decided that action to remove camphorated oil drug products and any drug product containing camphor in excess of 11 percent from the market should be implemented expeditiously and not await the full procedural review that has been established for OTC drug products.

DATE: Comments by November 25, 1980.

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Bureau of Drugs (HFD–510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4960.

SUPPLEMENTARY INFORMATION: In accordance with Part 330 (21 CFR Part 330), FDA received on March 7, 1980, a report of the Advisory Review Panel on OTC Miscellaneous External Drug Products. Under § 330.10(a)(6) (21 CFR 330.10(a)(6)), the agency issues (1) a proposed regulation containing the monograph recommended by the Panel, which establishes conditions under which OTC drugs are generally recognized as safe and effective and not misbranded (i.e., Category I); (2) a statement of the conditions excluded from the monograph because the Panel determined that they would result in the drugs not being generally recognized as safe and effective or would result in misbranding (i.e., Category II); (3) a statement of the conditions excluded from the monograph because the Panel determined that the available data are insufficient to classify such conditions under either (1) or (2) above (i.e., Category III); and (4) the conclusions and recommendations of the Panel. Because the Panel's recommendations on camphorated oil contain no Category I or Category III conditions, FDA is issuing a notice, containing the Panel's recommendations, which proposes

Category II classification for camphorated oil.

The Panel's report has been prepared independently of FDA, and represents the best scientific judgment of the Panel members. Because the Panel strongly recommended that FDA act swiftly to remove camphorated oil from the market, the agency has reviewed the Panel's report at this time. The Panel concluded, and FDA concurs, that camphorated oil is not generally recognized as safe for OTC use because of the large number of harmful accidental ingestions of camphorated oil, often mistaken for castor oil, cod liver oil, mineral oil, olive oil, cough medicine, or other products. Moreover, because the risk of poisoning in infants and young children upon accidental ingestion greatly outweighs any questionable benefits to be derived from the medicinal use of this drug, the agency has determined that marketing of any camphorated oil drug products should cease.

Historically, camphorated oil has been a recognized synonym for camphor liniment. Camphor liniment, which was officially recognized in the National Formulary (NF), was deleted from the official compendia with publication of NF XIII (September 1, 1970). "Camphorated oil" or "camphor liniment," or any similar name such as "camphor oil" or "camphorated liniment," as previously recognized in the official NF and as presently formulated, is a solution of 20 percent camphor in cottonseed oil. Although no longer recognized in an official compendia, the product continues to be marketed under both names.

The agency has determined that any drug product labeled as "camphorated oil" or "camphor liniment," or any similar name such as "camphor oil" or "camphorated liniment," represents a potential health hazard because of the possibility of accidental ingestion and subsequent toxic effects.

The agency, therefore, is proposing that any drug product containing camphor which is labeled as "camphorated oil" or "camphor liniment," or any similar name such as "camphor oil" or "camphorated liniment," and which is offered for any use in interstate commerce after the effective date of this regulation is misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) and is a new drug within the meaning of section 201(p) of the act for which an approved new drug application under section 505 of the act (21 U.S.C. 355) and Part 314 of the regulations (21 CFR Part 314) is required for marketing. In the absence of an approved new drug application such products in interstate commerce after the effective date of this regulation will be subject to regulatory action.

Although the Miscellaneous External Panel's report was concerned only with camphorated oil drug products, the Panel noted that the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products (hereinafter referred to as the Topical Analgesic Panel) discussed the safety of camphor in its report on external analgesic drug products published in the **Federal Register** on December 4, 1979 (44 FR 69768). That Panel concluded that camphor as an ingredient was safe and effective for use in OTC drug products as a topical analgesic, anesthetic, and antipruritic in a concentration of 0.1 to 3.0 percent and as a topical counterirritant in a 3- to 11-percent concentration.

The agency has reviewed the Topical Analgesic Panel's recommendations concerning camphor. Because of the potential toxicity problems which the Miscellaneous External Panel has identified, the agency has determined at this time that no product containing camphor in excess of 11 percent can be generally recognized as safe for OTC use. Moreover, because of the risk of poisoning in infants and young children upon accidental ingestion, the agency has determined that marketing of any drug product containing camphor in excess of 11 percent should cease. The agency, therefore, is also proposing that any drug product containing camphor in excess of 11 percent offered for any use in interstate commerce after the effective date of the final regulation is misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) and is a new drug within the meaning of section 201(p) of the act for which an approved new drug application under section 505 of the act (21 U.S.C. 355) and Part 314 of the regulations (21 CFR Part 314) is required for marketing. In the absence of an approved new drug application such products in interstate commerce after the effective date of this regulation will be subject to regulatory action.

The agency advises that the Topical Analgesic Panel's recommendations on drug products other than those either containing camphor and labeled as "camphorated oil" or "camphor liniment," or any similar name such as "camphor oil" or "camphorated liniment," or containing camphor in excess of 11 percent are not affected by this proposed rule. The recommendations of the Topical Analgesic Panel on camphor and the safety and effectiveness of products containing camphor in concentrations less than 11 percent will be addressed in the rulemaking proceeding for external analgesic drug products.

Elsewhere in this issue of the **Federal Register**, the agency has published a notice reopening the administrative record for OTC external analgesic drug products to consider the Miscellaneous External Panel's recommendation. Two other OTC advisory review panels—the Advisory Review Panel on OTC Hemorrhoidal Drug Products and the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products—also reviewed the safety and effectiveness of camphor. Elsewhere in this issue of the **Federal Register**, the agency has published notices reopening the administrative record for OTC anorectal drug products and for OTC cold, cough, allergy, bronchodilator, and antiasthmatic drug products to consider the Miscellaneous External Panel's recommendation.

By the action proposed in this document, the agency does not wish to give the impression that it has made a final determination that 11 percent is the upper safe limit for camphor-containing products for OTC use. This determination will be made at a later date in a future issue of the **Federal Register**.

The agency has determined that action to remove all camphorated oil drug products and all drug products containing camphor in excess of 11 percent from the market should be implemented expeditiously. Accordingly, the agency advises that it will not follow the full OTC rulemaking procedure set forth in § 330.10 (21 CFR 330.10). FDA will not publish a tentative final order, but will publish a final order soon after the receipt and consideration of comments on this proposal. It is the agency's intention that the final order will become effective upon publication in the **Federal Register**. Interested persons have until November 25, 1980 to submit comments on this proposal.

Upon the effective date of the regulation, because of the risk associated with use of camphorated oil drug products and drug products containing camphor in excess of 11 percent, the agency will request firms to recall to the retail level all drug products containing camphor which purport to be or are representd as camphorated oil or camphor liniment and all drug products containing camphor in excess of 11 percent. In the interim manufacturers are requested voluntarily to discontinue marketing of these products. Any

manufacturer wishing to ascertain whether its product purports to be or is represented as camphorated oil or camphor liniment should submit the product's formulation and labeling to the Division of Drug Labeling Compliance, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

The products affected by the proposed action pose an unwarranted risk of harm, in the agency's judgment, because some or all of the following factors are found in these products: a high concentration of a potentially toxic ingredient; little or no data to show that the ingredient at these concentration levels has any benefit or any benefit commensurate with the risk; a name or appearance that confusingly suggests a product intended for ingestion; and a number of reported incidents of accidental ingestion and harm. Thus, it is particularly important to take action with respect to products with high concentrations of camphor because in these products the ingestion of even a small quantity of the drug poses a serious risk.

A proposed review of the safety, effectiveness, and labeling of all OTC drugs by independent advisory review Panels was announced in the **Federal Register** of January 5, 1972 (37 FR 85). The final regulations providing for this TC drug review under § 330.10 were published and made effective in the **Federal Register** of May 11, 1972 (37 FR 9464).

In accordance with these regulations, a request for data and information on all active ingredients used in OTC miscellaneous external drug products was issued in the **Federal Register** of November 16, 1973 (38 FR 31697). In the **Federal Register** of August 27, 1975 (40 FR 38179), a further notice supplemented the initial notice with a detailed list of ingredients. However, camphorated oil was not specifically included in either notice.

The Commissioner appointed the following Panel to review the information submitted and to prepare a report under § 330.10(a) (1) and (5) on the safety, effectiveness, and labeling of the ingredients in those products:

William E. Lotterhos, M.D., Chairman
Rose Dagirmanjian, Ph. D.
Vincent J. Derbes, M.D. (resigned July 1976)
George C. Cypress, M.D. (resigned November 1978)
Yelva L. Lynfield, M.D. (appointed October 1977)
Harry E. Morton, Sc. D.
Marianne N. O'Donoghue, M.D.
Chester L. Rossi, D.P.M.
Robert Hewson, M.D. (appointed September 1978)

Representatives of consumer and industry interests served as nonvoting members of the Panel. Marvin M. Lipman, M.D., nominated by Consumers Union, served as the consumer liaison. Gavin Hildick-Smith, M.D., served as industry liaison from January until August 1975, followed by Bruce Semple, M.D., until February 1970. Both were nominated by the Proprietary Association. Saul A. Bell, Pharm. D., nominated by the Cosmetic, Toiletry, and Fragrance Association, also served as an industry liaison since June 1975.

Two nonvoting consultants, Albert A. Belmonte, Ph. D. and Jon J. Tanja, R.Ph., M.S., have provided assistance to the Panel since February 1977.

The following FDA employees assisted the Panel: John M. Davitt served as Executive Secretary until August 1977, followed by Arthur Auer until September 1978, followed by John T. McElroy, J.D. Thomas D. DeCillis, R.Ph., served as Panel Administrator until April 1976, followed by Michael D. Kennedy until January 1978, followed by John T. McElroy, J.D. Joseph Hussion, R.Ph., served as Drug Information Analyst until April 1976, followed by Victor H. Lindmark, Pharm. D., until March 1978, followed by Thomas J. McGinnis, R.Ph.

The Advisory Review Panel on OTC Miscellaneous External Drug Products was charged with the review of many categories of drugs, but due to the large number of ingredients and varied labeling claims, the Panel decided to review and publish its findings separately for several drug categories and individual drug products. The Panel presents its conclusions and recommendations for camphorated oil in this document. The review of other categories of miscellaneous external drug products will be continued by the Panel, and its findings will be published in future issues of the **Federal Register** as the Panel completes its deliberations on each category of drugs.

The Panel was first convened on January 13, 1975 in an organizational meeting. Working meetings which dealt with the topic of this document were held on January 14 and 15, February 27 and 28, 1977; October 29 and 30, 1978; January 27 and 28, and March 7, 1980.

The minutes of the Panel meetings are on public display in the Hearing Clerk's Office (HFA–305), Food and Drug Administration (address given above).

No submissions were made for camphorated oil. However, camphorated oil came to the attention of the Panel By Mr. Carmine Varano, a New Jersey pharmacist, who reported a number of accidental ingestions of camphorated oil to FDA. In many of these cases, consumers had mistaken camphorated oil for castor oil or code liver oil (Ref. 1).

At the Panel's request, Mr. Varano appeared before the Panel at its January 28, 1980 meeting to provide information and to express his views on camphorated oil. (See *Safety* below.) No other person requested an opportunity to appear before the Panel on this subject; however, the American Pharmaceutical Association filed a written statement on camphorated oil with the Panel recommending that the Panel classify camphorated oil as Category II for both safety and effectiveness (Ref. 2). The Panel has thoroughly reviewed the literature and considered all pertinent data and information through March 7, 1980 in arriving at its conclusions and recommendations on camphorated oil.

In accordance with the OTC drug review regulations (21 CFR 330.10), the Panel considered camphorated oil with respect to the following three categories:

Category I. Conditions under which camphorated oil is generally recognized as safe and effective and is not misbranded.

Category II. Conditions under which camphorated oil is not generally recognized as safe and effective or is misbranded.

Category III. Conditions for which the available data are insufficient to permit final classification at this time.

The Panel concludes that camphorated oil is not safe (Category II) for any OTC external use.

Camphorated Oil

Camphorated oil, also known as camphor liniment, is a simple solution of 20 percent camphor in cottonseed oil. It was officially recognized in the first edition of "The United States Pharmacopeia," published in 1820. It has been used mainly in the past as a counterirritant, rubefacient, and liniment for treating sprains, bruises, rheumatism, and other inflammatory conditions. Historically, camphorated oil has been the official synonym for camphor liniment when camphor liniment was recognized in the official NF. It remained the officially recognized synonym in NF XI (October 1, 1960), but was deleted as the officially recognized synonym in NF XII (September 1, 1965). Ultimately, camphor liniment was deleted from the official compendia with publication of NF XIII (September 1, 1970). Although no longer recognized in an official compendia, the product continues to be marketed under both names and has fallen into disuse to some degree in recent years.

(1) *Safety.* In its report on external analgesic drug products, which was published in the **Federal Register** of December 4, 1979 (44 FR 69768), the Topical Analgesic Panel discussed the safety of camphor. That Panel stated that cases of systemic poisoning from topical application of camphor have not been reported. In his presentation to the Miscellaneous External Panel on January 28, 1980, Mr. Varano pointed out that three cases have been reported in the medical literature (Ref. 1). In one case, camphorated oil was applied continually for about 80 hours to the chest of a 2-year-old child. The resulting diagnosis was camphor poisoning (Ref. 3). In another case, a 15-month-old boy became progressively ataxic and had some brief generalized major motor seizures after he crawled through spirits of camphor (a 10-percent solution of camphor in alcohol) spilled by a sibling. No further seizures occurred until 1 year later when the child was exposed to a camphorated vaporizer preparation containing about 5 percent camphor. Concurrent with this inhalant exposure, the child had a brief major motor seizure. The authors concluded that the occurrence of seizures with only two camphor exposures, a year apart, indicates a specific sensitivity to this agent (Ref. 4). The third case was a near-fatal incident in a 6-week-old infant after an ointment containing camphor, menthol, and thymol had been rubbed on the chest (Ref. 5).

The Topical Analgesic Panel noted in its report that the estimated minimal lethal dose of camphor in humans is 2 grams (g) (for a 150 lb. man) when ingested orally and that one adult survived ingestion of 15 g camphor. The Panel calculates that the minimal lethal dose is thus 30 milligrams/kilograms (mg/kg) body weight. However, ingesting 0.7 to 1.0 g camphorated oil proved fatal to a child (Ref. 6).

The Panel noted that accidental poisoning has occurred from ingestion of camphorated oil when it has been administered erroneously for castor oil and that cases continue to be reported. In information Mr. Varano submitted to the FDA (Ref. 1), which he obtained from Regine Aronow, M.D., Director, Children's Hospital Poison Center, Detroit, MI, Mr. Varano presented data on hospital admissions at Children's Hospital due to ingestion of camphorated oil. Between 1975 and the first 6 months of 1979, there were 26 hospital admissions involving ingestion of camphorated oil. Of these 26, 16 were due to accidental ingestion, 5 were due to ingestion of camphorated oil mistaken for castor oil, 1 was due to an ingestion of camphorated oil mistaken for cod liver oil, and 4 were due to ingestion of camphorated oil mistaken for cough medicine. Mr. Varano also presented information which he received from the Provincial Drug and Poison Information Center of Vancouver, BC, concerning an ingestion of camphorated oil by a 2-year-old child which proved fatal (Ref. 1).

Jacobziner and Raybin (Ref. 7) reported a case in which an 18-month-old girl ingested camphorated oil, had a convulsion soon thereafter, and was hospitalized several hours later. At the hospital, the patient had generalized convulsions, right facial twitchings, and twitchings of the right leg. The infant soon became comatose and died 4 hours after admission to the hospital. Death was attributed to respiratory failure.

Phelan (Ref. 8) reported a case of a 3-year-old girl who ingested an estimated 0.7 g of camphor (of a product containing about 5 percent camphor) and had a convulsion soon thereafter. An electroencephalogram 18 hours after the seizure showed some abnormalities. A repeat electroencephalogram 15 days after discharge from the hospital was unchanged from the earlier one. An electroencephalogram 3 months later was normal.

The American Academy of Pediatrics Committee on Drugs (Ref. 9) has presented a progressive symptomatology of severe camphor intoxication. The onset of symptoms of camphorated oil poisoning may occur within 5 to 15 minutes after ingestion, although they may be delayed up to several hours if food is present in the stomach to interfere with absorption. Nausea and vomiting are usually the first symptoms to appear, followed by a feeling of warmth, headache, vertigo, mental confusion, restlessness, delirium, and hallucinations. Increased muscular excitability, tremors and jerky movements, and convulsions followed by central nervous system depression and coma may occur. In cases of severe poisoning, death occurs from respiratory failure or from status epilepticus. If death does not occur, mental retardation can be an aftereffect (Ref. 10). If the patient lives, recovery is usually complete within 48 hours (Ref. 11); however, a 19-month-old infant died 5 days after the ingestion of 1 teaspoonful of camphorated oil (Ref. 5).

Camphor is readily absorbed through mucous membranes, subcutaneous tissue, and the gastrointestinal tract. In small doses, camphor combines with glucuronic acid and is excreted via the kidneys (Ref 12). This mechanism accounts for its unusually high toxicity in fetuses and newborn infants because neither has developed the process of glucuronidation and, therefore, cannot detoxify camphor (Ref. 13). Camphor has been shown to pass through the placenta and has been implicated in the deaths of newborn infants (Ref. 14). In one case a newborn infant died 30 minutes after delivery when the mother had ingested compahorated oil 36 hours before giving birth. Camphor was detected in maternal blood 15 minutes after ingestion, gastric lavage was performed, and camphor was not found 8 hours later. At delievery, 36 hours after ingestion, camphor was found in amniotic fluid, umbilical cord blood, and fetal blood, as well as in the liver, brain, and kidney of the infant. Cause of death was failure to initiate respiration (Ref. 15). In a second case (Ref. 16) a healthy baby was delivered 20 hours after ingestion of camphorated oil. While high levels of camphor were measured in maternal blood 24 hours after ingestion and the amniotic fluid had a distinct odor of camphor, only very low levels were found in the infant's blood. In both cases (Ref. 9) the mothers mistakingly took camphorated oil, believing it to be castor oil, to induce labor.

The treatment of camphorated oil poisoning is by no means simple. Most toxicology texts recommend symptomatic and supportive treatment. Treatment is complicated by the fact that camphorated oil is highly soluble lipid deposits. Lipid hemodialysis (Ref. 11) and resin hemoperfusion (Ref. 17) have been proven to be effective treatments, but the value of these procedures is constrained by their limited availability.

Reports of camphor poisonings have appeared in the literature for decades, with a large number of the cases involving the accidental ingestion of camphorated oil, often mistaken for such items as castor oil, cod liver oil, mineral oil, olive oil, and cough medicine (Refs. 6, 9, 14, 18, 19, 20, 21, 22, and 23). The Panel concludes that camphorated oil is the worst offender of all camphor preparations that are accidentally ingested because it is mistaken for a variety of other OTC products. The Panel further concludes that camphorated oil is unsafe because of the large number of accidental ingestions by children and the potential toxicity in infants and young children including death (Refs. 1, 6, 7, 19, 20, and 22). Statistics compiled by the National Clearinghouse for Poison Control Centers record 706 ingestions of camphorated oil, 421 occurring in children less than 5 years of age, from 1974 to 1978 (Ref. 18). The risk of poisoning in infants and young children,

as evidenced by the numerous reports in the literature and by the National Clearinghouse for Poison Control Centers, is a major factor in the Panel's assessment that camphorated oil is not safe for OTC use. Additionally, in reviewing toxicity in mice, rats, and rabbits, it appears that human beings may be 50 to 100 times more susceptible to camphor poisoning than the usual laboratory animals. The Panel strongly recommends that the FDA act swiftly to remove camphorated oil from the market.

(2) *Effectiveness.* The Topical Analgesic Panel, in its report published in the **Federal Register** of December 4, 1979 (44 FR 69768), discussed the mechanism of action of camphor as a counterirritant and stated that it was unable to find any acceptable reasons for the continued employment of camphor alone as a topical counterirritant at the concentration (20 percent) present in camphorated oil. In a statement on camphorated oil presented to the Miscellaneous External Panel on September 27, 1978, the American Pharmaceutical Association (Ref. 2) stated:

> Considering the length of its existence (camphorated oil was officially recognized in the first edition of the U.S.P., published in 1820), and its widespread use, it is surprising that a search of the literature failed to yield a single reference concerning the efficacy of camphorated oil.

The Panel was not able to locate, nor is it aware of any significant body of data demonstrating, the effectiveness of camphorated oil when used as a counterirritant.

(3) *Evaluation.* The Panel believes the hazards (i.e., the dangers of poisoning) associated with the use of camphorated oil far outweigh any questionable benefits to be derived from the medicinal use of this product. The Panel has serious concerns about the potential for poisonings resulting from the accidental ingestion of camphorated oil, often mistaken for other proprietary medications; therefore, the Panel places camphorated oil in Category II for safety.

References

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(8) Phelan, W. J., III, "Camphor Poisoning: Over-the-Counter Dangers," *Pediatrics,* 57:428–431, 1976.

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(16) Weiss, J., and P. Catalano, "Camphorated Oil Intoxication During Pregnancy," *Pediatics,* 52:713, 1973.

(17) Kopelman, R. et. al, "Camphor Intoxication Treated by Resin Hemoperfusion," *Journal of the American Medical Association,* 241:727–728, 1979.

(18) Poison Control Statistics, Food and Drug Administration, 1974–1978.

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(21) Haft, H. H., "Camphor Liniment Poisoning," *Journal of the American Medical Association,* 84:1571, 1925.

(22) Barker, F., "A Case of Poisoning by Camphorated Oil," *The British Medical Journal,* 1:921, 1910.

(23) Bellman, M. H., "Camphor Poisoning in Children," *British Medical Journal,* 2:177, 1973.

All references are on display in the office of the Hearing Clerk, Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

The agency has determined that under 21 CFR 25:24(d)(9) (proposed in the **Federal Register** of December 11, 1979; 44 FR 71742) that this proposal is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 505, 701, 52 Stat. 1040–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321, 352, 355, 371)) and the Administrative Procedure Act (secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704)) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations be amended in Part 310 by adding new § 310.526, to read as follows:

§ 310.526 Camphorated oil and camphor-containing drug products.

(a) Historically, comphorated oil (also known as camphor liniment), a solution of 20 percent camphor in cottonseed oil, has been marketed as an over-the-counter (OTC) drug product for various uses, primarily as a counterirritant or liniment. A large number of accidental ingestions of camphorted oil, often mistaken for castor oil, cod liver oil, mineral oil, olive oil, cough medicine, or other products, have been reported and toxicity has often resulted, primarily in infants and young children. Because of the potential hazard for poisoning to occur, the benefit from using any drug products containing camphor and labeled as "camphorated oil" or "camphor liniment," or any similar name such as "camphor oil" or "camphorated liniment," for any use, is insignificant when compared to the risk. Based upon the adverse benefit-to-risk ratio, any drug product containing camphor which is labeled as "camphorated oil" or "camphor liniment," or any similar name such as "camphor oil" or "camphor liniment," cannot be considered generally recognized as safe. Also, based upon lack of safety and effectiveness data and the adverse benefit-to-risk ratio, any drug product containing camphor in excess of 11 percent cannot be considered generally recognized as safe.

(b) Any drug product containing camphor and labeled as "camphorated oil" or "camphor liniment," or any similar name such as "camphor oil" or "camphorated liniment," or any drug product containing camphor in excess of 11 percent offered for any use is misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act and is a new drug within the meaning of

section 201(p) of the Act for which an approved new drug application under section 505 of the act and Part 314 of this chapter is required for marketing.

(c) A completed and signed "Notice of Claimed Investigational Exemption for a New Drug" (Form FD–1571), as set forth in § 312.1 of this chapter, is required to cover clinical investigations designed to obtain evidence that any preparation containing camphor which purports to be or is represented as camphorated oil or camphor liniment or any preparation containing camphor in excess of 11 percent for any use is safe and effective for the purpose intended.

(d) Any such drug product in interstate commerce after the effective date of the final regulation that is not in compliance with this section is subject to regulatory action.

Interested persons are invited to submit their comments in writing (preferably in four copies and identified with the Hearing Clerk docket number found in brackets in the heading of this document) regarding this proposal on or before November 25, 1980. Comments should be addressed to the Hearing Clerk, Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, and may be accompanied by a supporting memorandum or brief. Comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration

Dated: September 15, 1980.

Jere E. Goyan,

Commissioner of Food and Drugs.

[FR Doc. 80–29964 Filed 9–25–80; 8:45 am]

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21 CFR Part 341

[Docket No. 76–N–52]

Cold, Cough Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Reopening of the Administrative Record

AGENCY: Food and Drug Administration.

ACTION: Reopening of administrative record

SUMMARY: This notice advises that the Food and Drug Administration (FDA) is reopening the administrative record for over–the–counter (OTC) cold, cough, allergy, bronchodilator, and antiasthmatic drug products to allow for consideration of recommendations on camphor–containing drug products that have been received from the Advisory Review Panel on OTC Miscellaneous External Drug Products.

DATES: Comments by November 25, 1980; and reply comments by December 26, 1980.

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Bureau of Drugs (HFD–510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4960.

SUPPLEMENTARY INFORMATION: The Food and Drug Administration (FDA) published the report and proposed monograph of the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products (CCABA Panel) on OTC cold, cough, allergy, bronchodilator, and antiasthmatic drug products for human use on September 9, 1976 (41 FR 38312). Interested persons could have filed written comments regarding this proposal by December 8, 1976, and comments replying to comments by January 7, 1977. After the closing of the comment period following publication of the panel report, new data and information may be submitted for inclusion into the administrative record only through a petition to reopen the administrative record.

In a notice published in the **Federal Register** of March 21, 1980 (45 FR 18400), the agency advised that it had reopened the administrative record for OTC cold, cough, allergy, bronchodilator, and antiasthmatic drug products to allow for consideration of data and information that had been filed with the Hearing Clerk's Office after the date the administrative record officially closed. The agency concluded that any new data and information filed prior to March 21, 1980 should be available to the agency in developing a tentative final order.

The CCABA Panel concluded that camphor is safe but the available data were insufficient to determine whether it is effective when labeled for use as an OTC expectorant, antitussive, and nasal decongestant. The Panel placed camphor in Category III (available data are insufficient to classify the ingredient as Category I or Category II) for different uses at different concentrations: expectorant (topical-5 percent ointment, steam inhalation-7 percent solution, lozenge-0.02 to 15 milligrams (mg)); antitussive (topical-5 percent ointment, steam inhalation-7 percent solution, lozenge-0.02 to 15 mg); and nasal decongestant (topical-5 percent ointment, steam inhalation-7 percent solution lozenge-0.02 to 15 mg). Following the publication of this panel's recommendation on camphor, the Advisory Review Panel on OTC Miscellaneous External Drug Products (Miscellaneous External Panel) also reviewed camphor. The Miscellaneous External Panel, however, concluded that OTC products containing greater than 2.5 percent camphor have a low benefit-to-risk ratio and recommended that camphor be limited in OTC drug products for external use to less than 2.5 percent. The Miscellaneous External Panel also recommended that the quantity of camphor in a package be limited to a total of 360 mg per package, preferably in a child-proof container.

Because of the conflicting recommendations on camphor-containing drug products, FDA has concluded that resolution of this issue would be in the public's best interest. Therefore, the agency has concluded that the Miscellaneous External Panel's recommendations should be available to the agency in developing a tentative final order on cold, cough, allergy, bronchodilator, and antiasthmatic drug products. By this notice, FDA announces that it is treating the data and information on camphor received from the Miscellaneous External Panel as a petition to reopen the administrative record on cold, cough, allergy, bronchodilator, and antiasthmatic drug products. FDA is granting the petition by allowing the data and information contained therein to be included in the administrative record for OTC cold, cough, allergy, bronchodilator, and antiasthmatic drug products. This notice serves to inform interested persons of these recommendations, which appear below. This reopening of the administrative record relates only to the ingredient camphor in OTC drug products. Comments relating to portions of the Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Proposed Monograph (41 FR 38312) other than on camphor will not be accepted at this time.

Statement of the Advisory Review Panel on OTC Miscellaneous External Drug Products Concerning OTC Drug Products Containing Camphor

The Advisory Review Panel on OTC Miscellaneous External Drug Products has reviewed the product camphorated oil as well as numerous other camphor-