DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. 80N-0227]

New Drugs; Camphorated Oil Drug Products for Human Use

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing this final rule establishing that any camphorated oil drug product or any similar drug product for human use is misbranded and a new drug, and is subject to regulatory action unless it is the subject of an approved new drug application. FDA is issuing this final rule after considering public comments on the proposed rule. This final rule is part of FDA's ongoing review of OTC drug products.

EFFECTIVE DATE: September 21, 1982.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, National Center for Drugs and Biologics (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 26, 1980 (45 FR 63869), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), a proposal to establish a regulation for camphorated oil drug products and drug products containing in excess of 11 percent camphor, together with the conclusions and recommendations of the Advisory Review Panel on OTC Miscellaneous External Drug Products.

In accordance with § 330.10(a)(2), the data and information considered by the Panel were put on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857, after deletion of information considered confidential.

Interested persons were invited to file, by November 25, 1980, written comments regarding the proposed rule. Twenty-two comments were received, including comments from individual consumers, groups of consumers, physicians, pharmacists, drug manufacturers, a drug manufacturer association, a pharmaceutical association, and State departments of health.

Although the proposal would have established conditions for both camphorated oil and other drug products containing camphor in excess of 11 percent, the final rule is limited, for reasons discussed later in this document, to camphorated oil and similar drug products (i.e., any drug product containing camphor in oil and any drug product containing camphor that is represented, suggested, or purported to be camphorated oil).

The agency's conclusions on other camphor-containing drug products, including those that contain camphor in excess of 11 percent, will be made as part of the agency's conclusions on the recommendations of the various advisory review panels that have reviewed camphor for specific uses, i.e., antimicrobial, anorectal, cough/cold, and external analgesic. Those conclusions will be published in future issues of the **Federal Register.**

In the preamble to the proposed regulation, FDA advised that it would not follow the full OTC rulemaking procedure set forth in § 330.10, but would proceed directly to a final order after consideration of comments to the proposal. The agency also advised in the proposal that a final order would become effective on the date of its publication in the **Federal Register.**

Because of the risk to pubic health in the potential for accidental ingestion and toxicity to occur from the continued availability of camphorated oil drug products, the Secretary of Health and Human Services and the Commissioner of Food and Drugs have found that there is good cause to have this final rule become effective on the date of publication, as authorized by 5 U.S.C. 553(d)(3) and by 21 CFR 10.40(c)(4)(ii). This final rule containing the agency's final decision on camphorated oil drug products is, therefore, effective immediately.

I. The Agency's Conclusions on the Comments

1. A number of comments concurred with the agency's proposal to remove camphorated oil and other drug products containing more than 11 percent camphor from the OTC market, stating that such action would be beneficial in reducing the number of toxic responses attributed to camphor preparations.

2. A number of comments objected to the Panel's recommendation to remove camphorated oil drug products from the OTC market. The comments argued that the continued marketing of camphorated oil is warranted based on its long history of widespread use and consumer acceptance. The comments also maintained that marketing camphorated oil in child-resistant containers and with distinct and specific labeling would minimize the potential for poisoning. One comment recommended that the confusion surrounding "camphorated oil" could be eliminated by recognizing "camphor liniment" as the product's established name. The comment argued that the name "camphor liniment" indicates the purpose for which the product is intended and eliminates the word "oil," which may have contributed to the confusion of this product with other products that are intended for internal use.

The agency believes that the continued marketing of camphorated oil products is not warranted. The Miscellaneous External Panel reported that statistics compiled by the National Clearinghouse for Poison Control Centers show 706 ingestions of camphorated oil from 1974 to 1978 (Ref. 1) (45 FR 63872). The latest statistics available from the National Clearinghouse for Poison Control Centers show 130 ingestions of camphorated oil in 1979, of which 38 were considered toxic cases (Ref. 2). As the Miscellaneous External Panel also pointed out, some infants and young children have died from ingesting camphorated oil. If death does not occur, mental retardation can be an after effect of camphorated oil ingestion. Even in less serious cases, convulsions followed by central nervous system depression and coma may occur (45 FR 63872).

Accidental ingestions of camphorated oil occur under various circumstances. Sometimes adults confuse camphorated oil for other products and ingest it themselves; sometimes adults mistakenly administer it to other adults; sometimes adults mistakenly administer it to children; and sometimes children drink it themselves. In most cases, the accidental ingestion is attributable to confusion of the camphorated oil product with another product. Most frequently the confusion occurs in the home; sometimes it happens in the store at the time of purchase.

The agency has identified 32 poisoning incidents in which the cause of the ingestion is reported (Ref. 3). In 28 cases, the cause was confusion with another product. In 20 cases, that product was castor oil; in three cases, cough medicine; in one case, acetaminophen. In four cases, the identity of the drug for which camphorated oil was mistaken could not be determined. Of the 28 cases in which confusion occurred, 15 cases involved ingestion of the product by the person who made the mistake, 12 cases involved administration of the product to another person, often a child, and in one case the person who took the

product could not be determined from the information available.

The agency has considered various possible alternatives to removing camphorated oil from the market in order to prevent these accidental ingestions. The alternatives primarily involve either requiring physical changes in the product or limiting the product's availability through a requirement that it be sold by prescription only. These alternatives were rejected for the following reasons.

One way to try to prevent confusion of camphorated oil with other products is to give it a distinctive appearance. Because camphorated oil is often mistaken for castor oil, which has a similar physical appearance (an amber colored, slightly viscous liquid), changes could be required in the color of camphorated oil products and in the appearance of the containers. However, even if camphorated oil were required to be of a non-amber color in an opaque and distinctively-shaped container, it cannot reliably be concluded that the confusion which leads to ingestion would cease. The Panel identified several products other than castor oil—including cod liver oil, mineral oil, olive oil, and cough medicine—for which camphorated oil also has been mistaken. Because these products have various physical appearances, it is unlikely that color and container changes would prevent accidental ingestions of camphorated oil.

Child-resistant containers also have been suggested as a possible solution to the problem. Although this measure could substantially reduce or eliminate the number of accidental ingestions by very young children who drink the product on their own, it would not affect the mistaken administrations by adults. Of the 32 poisoning incidents identified by the agency in which the cause of the ingestion was reported, only four were cases of young unattended children drinking the camphorated oil.

As the comment argues, it might be possible to reduce the confusion surrounding "camphorated oil" if "camphor liniment" were recognized as the product's established name. The argument is that use of the word "oil" has contributed to the confusion of this product with other products that are intended for internal use.

The word "oil" in the product name may well have contributed to the confusion. Yet "camphor liniment" historically has been the established name for this product. "Camphorated oil" was the official synonym for camphor liniment for most of the time that camphor liniment was recognized in the official compendia. Camphorated oil remained the officially recognized synonym in the National Formulary (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 compendium with publication of NF XIII (September 1, 1970). Although camphor liniment was the last established name for the product, it has been marketed under both names since the product was deleted from the official compendium. It is unlikely that reinstating "camphor liniment" as the established name would eliminate the confusion surrounding this product. Through custom and usage, many people could be expected to continue to refer to the product as "camphorated oil," even if it were labeled "camphor liniment. Furthermore, because camphorated oil has been confused with various products that do not have "oil" in the product name, such as cough medicines and analgesics, it is clear that the name is not the only cause of the confusion. Therefore, changing the name would not eliminate the confusion.

Another possible alternative for eliminating the confusion and the resultant accidental ingestions is to have strong warnings on the labeling. Camphorated oil products have for years borne specific label warnings that these products are for external use and not for ingestion; yet confusion with products for internal use has persisted. It is possible that bolder warnings, combined with changes in the physical appearance and name of the product, would reduce the number of accidental ingestions. The risk of mistaking camphorated oil for other products, however, would not necessarily be reduced by such changes. Because of the long history of use of camphorated oil products and concomitant confusion with products intended for ingestion, the agency believes that adequate directions and warnings to protect against unsafe use of camphorated oil products cannot be written. Given the questionable therapeutic benefits from camphorated oil, FDA does not believe that it is worth the risk of additional poisonings to test the possible effectiveness of stronger labeling and other physical changes in preventing confusion of the product with ingestible products.

Requiring camphorated oil products to be sold by prescription only is another possible way to deal with the hazards posed by the drug. If camphorated oil were sold only by prescription, purchasers could be more aware of the product's toxicity through communications with the physician and the pharmacist and through the very fact of prescription status. However, this alternative also does not provide adequate assurance that accidental ingestions would be substantially eliminated. Among the poisoning incidents in which the cause of ingestion was reported were several poisonings that resulted from confusion by older children or teen-agers. Persons in this age group, unlike very young children, make a conscious, but mistaken, decision to take the product, thinking it is something else. Limiting camphorated oil to prescription distribution is unlikely to alert these persons to the toxicity of the product and the need to avoid confusing it with other products, because these persons probably do not purchase the product themselves. Furthermore, they may not share in the communications with the physician, either because they are too young or because the prescription was intended for another member of the household.

Oral communications by health professionals often can significantly reduce the risks involved with toxic drug products. However, given the long history of camphorated oil use, as well as the persistence of the confusion with other products, the risk of confusion and mistaken ingestion could remain significant. Other members of the household would not have received the physician's oral warnings; even the person for whom the prescription was intended might confuse the product with others, especially if some time had passed since the oral warnings had been communicated.

The agency cannot definitively demonstrate that physical alterations, stronger warnings, prescription status, or some combination of these changes would not eliminate the possibility of confusion between camphorated oil and other products and of accidental ingestion for other reasons. Unless these changes are made, the effectiveness of these measures cannot be determined with certainty. The agency believes, however, that there is a sufficient factual basis to conclude that an appreciable risk of poisonings (which might include deaths) will remain even if these measures are instituted, and that the risk is unacceptable in light of the marginal therapeutic value of the product.

References

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

(2) Poison Control Statistics, Food and Drug Administration, 1979.

(3) Fow, M. L., Food and Drug Administration, "Analysis of Camphorated Oil Ingestion and Poisoning," Docket No. 80N–0227, Dockets Management Branch.

3. Several comments requested that the agency permit the continued marketing of camphorated oil preparations containing 3 to 11 percent camphor. In support of this request, the comments pointed out that the Advisory Review Panel on OTC Topical Analgesic Drug Products concluded that preparations containing 3 to 11 percent camphor are safe and effective for use as counterirritants (44 FR 69802; December 4, 1979).

As discussed more fully in comment 2 above, the agency's decision on camphorated oil is based on the large number of accidental ingestions of camphorated oil products that have occurred. The Advisory Review Panel on OTC Topical Analgesic Drug Products (hereinafter referred to as the Topical Analgesic Panel), in its report on external analgesic drug products (44 FR 69768; December 4, 1979) concluded that 3 to 11 percent camphor products were safe and effective for external use as counterirritants. The Panel stated that it was unaware of any case of poisoning that had occurred from topical administration of a camphor product. However, that Panel also pointed out that ingesting 0.7 to 1 gram (g) camphorated oil proved fatal to a child and that poisonings from accidental ingestions continue to occur (44 FR 69803). The Miscellaneous External Panel noted that a 3-year-old girl had a convulsion after ingesting an estimated 0.7 g of camphor from a product containing about 5 percent camphor (45 FR 63872). It is clear that toxic amounts of camphor can be ingested accidentally from products containing 3 to 11 percent camphor.

The confusion surrounding camphorated oil products appears to stem from various factors, including the products' appearance and readily ingestible form. The 3 to 11 percent camphorated oil products have the same features contributing to accidental ingestions that the higher concentration camphorated oil products have. Because all of the camphorated oil products pose an unacceptable risk of poisoning in light of their marginal therapeutic value, the agency concludes that camphorated oil products at all concentrations are not generally recognized as safe for human use and are misbranded.

4. Numerous comments objected to the agency's proposal to remove from the OTC market dosage forms, other than camphorated oil, of drug products containing more than 11 percent camphor. The comments contended that, although there was evidence available to demonstrate a potential for toxicity to occur from accidentally ingesting camphorated oil, such evidence was not available for other dosage forms of camphor-containing drug products. The comments pointed out that cream and ointment dosage forms would not be mistaken for castor oil or other internally ingested medicinal products and are unlikely to be accidentally ingested by children. One comment further stated that the potential for toxicity to occur is minimized because of the difficulty in swallowing a sufficiently large amount to cause harm.

One comment urged that the final regulation specifically exempt from enforcement products containing more than 11 percent camphor in combination (chemical complex) with metacresol in a ratio of 3 to 1 respectively. The comment stated that data previously submitted to the agency demonstrate that this combination is unique in that it is far less toxic than pure camphor. The comment argued that these data, plus a 50-year marketing history without one report of adverse reaction from topical use of products containing this combination of ingredients, are sufficient to exempt these products from the final regulation.

The agency points out that the basis for including drug products that contain greater than 11 percent camphor in the proposed rule was the recommendation of the Topical Analgesic Panel in its report on external analgesic drug products (44 FR 69768; December 4, 1979) that OTC counterirritant drug products should not contain more than 11 percent camphor. The agency has not yet evaluated comments on the Topical Analgesic Panel's report. Camphor was reviewed by various OTC advisory review panels for use in cough/cold, anorectal, topical analgesic, anesthetic, and antipuritic products. On September 26, 1980, the administrative records for the rulemakings on these OTC drug products were reopened to allow for consideration of the Miscellaneous External Panel's recommendations on camphor-containing drug products (45 FR 63874–79). That Panel recommended that camphor be limited in OTC drug products for external use to less than 2.5 percent and that the quantity of camphor in a package be limited to 360 mg. Interested persons were invited to comment on the Miscellaneous External Panel's recommendations for camphor products in the respective rulemakings. At a future time, interested persons will also be given an opportunity to comment on this Panel's recommendations with respect to camphor in OTC antimicrobial drug products.

The name, appearance, and readily ingestible form appear to be significant elements contributing to the accidental ingestion of camphorated oil. As the comments pointed out, other dosage forms of camphor-containing products do not necessarily share these characteristics leading to consumer confusion. Because these other camphor-containing products are substantially distinct from camphorated oil products, and because the agency has not yet fully evaluated the comments regarding these other products, the agency has decided not to include other camphor-containing products in this final rule on camphorated oil products. Instead, the agency's final decisions on other camphor-containing products, including those with camphor in excess of 11 percent and including those with camphor complexed with metacresol, will be made in the context of the individual rulemakings in which the other products are being considered. These decisions will be published in future issues of the **Federal Register.**

5. Several comments objected to the proposed recall of camphorated oil to the retail level. The comments contended that recalls to the retail level should be reserved for removing products which present a significant hazard to the public health and not for products that are safe when used as directed and unsafe only when misused. The comments urged the agency to allow these products to be phased off the market instead of being recalled to the retail level.

Another comment urged that any recall be limited to products marketed after one of the following dates: (1) The date of the recall order; (2) the final date for offering comments to the proposed rulemaking (November 25, 1980); (3) 1 month after the proposed rulemaking was published in the **Federal Register** (October 26, 1980).

The agency stated in the preamble to the Panel's report (45 FR 63870) that "* * * because the risk of poisoning in infants and young children upon accidental ingestion [of camphorated oil] 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," and that, upon the effective date of this regulation, "the agency will request firms to recall to the retail level all drug products containing camphor which purport to be or are represented as camphorated oil or camphor liniment * * *" The agency reaffirms this recall at this time. Because of the risk to the public health from harmful accidental ingestions of camphorated oil drug

products, the agency has found that there is good cause to have this final rule become effective on the date of publication, as authorized by 5 U.S.C. 553(d)(3) and by 21 CFR 10.40(c)(4)(ii). A phase-out of existing stocks would allow these products to remain on the market for a substantial period of time, with the continuous risk of accidental ingestion. Limiting the recall to products marketed after a certain date would also allow the risk to the public health to continue for an unacceptably long period of time. This final rule, which contains the agency's final decision on camphorated oil drug products, is effective immediately. The agency is currently initiating a recall of all of these products to the retail level.

6. One comment contended that FDA is without authority to remove camphorated oil drug products from the market under the new drug and misbranding provisions (sections 201(p) and 502) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(p) and 352). The comment stated that the proposal failed to state why these products were new drugs or misbranded and that this inadequacy violated the requirements of *Rutherford* v. *United States,* 542 F. 2d 1137 (10th Cir. 1976), that FDA have an administrative record to support its determination that a drug is a new drug. The comment concluded that the agency is without authority to remove camphorated oil drug products from the market on the basis of their toxicity if used other than according to their labeling directions, such as in the case of accidental ingestions. The comment suggested that, rather than removing these products from the market, a proper course of action would be to submit any information on accidental ingestion of these products to the Consumer Product Safety Commission (CPSC), which has express authority to regulate products causing injury resulting from misuse, for whatever action it deems appropriate.

The agency points out that section 502(f) of the act declares a drug to be misbranded unless its labeling bears adequate directions for use and adequate warnings against use "by children where its use may be dangerous to health" and against "unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users." As discussed in comment 2 above, although camphorated oil drug products for years have borne label statements that these products are for external use and not for ingestion, poisonings resulting from accidental ingestion continue to occur from confusing these products with other products that are intended to be ingested. The agency concludes that because consumers continue to confuse camphorated oil with other products, directions and warnings are not adequate to protect against dangerous use by children or to protect the user from an unsafe method of administration. Moreover, because of the long history of use of camphorated oil products and persistent confusion with products intended for ingestion, the agency believes that adequate directions and warnings to protect against unsafe use of camphorated oil products cannot be written. Therefore, the agency concludes that camphorated oil or any drug product which is represented or suggested to be camphorated oil is misbranded under section 502(f) of the act. The introduction or delivery for introduction into interstate commerce of a misbranded drug is a prohibited act under section 301(a) of the act (21 U.S.C. 331(a)).

In addition, under section 201(p) of the act, a drug whose composition is "not generally recognized among [qualified] experts * * * as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling" is a "new drug." The regulations detailing the standards for determining whether OTC drugs are generally recognized as safe and effective are set forth in 21 CFR 330.10(a)(4). The safety criteria include a low incidence of ill effects under adequate directions and warnings against unsafe use, as well as "low potential for harm which may result from abuse under conditions of widespread availability" (21 CFR 330.10(a)(4)(i)). The results of human experience during marketing are to be included in making the safety determination.

The "conditions" of use of camphorated oil products have included a long history of nonprescription use accompanied by confusion resulting in accidental ingestions and toxicities. As has been pointed out previously, statistics compiled by the National Clearinghouse for Poison Control Centers show 836 accidental ingestions in the period 1974 to 1979 alone. The marketing experience thus has shown camphorated oil products to have a significant potential for harm under their customary conditions of use.

Under the applicable regulations, the benefit-to-risk ratio of a drug is to be considered in determining its safety and effectiveness (21 CFR 330.10(a)(4)(iii)). As discussed more fully in comment 2 above, the agency believes that the risk of poisonings from camphorated oil products greatly outweighs any marginal benefits these products might have. The agency concludes that camphorated oil products are not generally recognized as safe and, therefore, are new drugs within the meaning of section 201(p) of the act. The continued marketing of these products without approved new drug applications would be in violation of section 505(a) of the act (21 U.S.C. 355(a)).

The agency concludes that it does have authority under the act to declare camphorated oil products to be misbranded and "new drugs" in this final regulation. Therefore, there is no need to request CPSC to take separate regulatory action. The agency also believes that the administrative record in this rulemaking proceeding supports the agency's determinations as reasonable and correct.

II. Summary of Significant Changes From the Proposed Rule

The agency proposed that any drug product labeled as "camphorated oil," camphor liniment,"or any similar name, and drug products containing camphor in excess of 11 percent be declared misbranded and not generally recognized as safe and effective. As discussed in comment 4 above, the final rule is limited to drug products containing camphor in oil and camphor-containing drug products that are represented, suggested, or purported to be camphorated oil. The agency's conclusions on camphor-containing OTC drug products other than camphorated oil drug products, including those that contain camphor in excess of 11 percent, will be made as part of other appropriate individual rulemakings (e.g., antimicrobial, anorectal, cough/cold, and external analgesic).

III. The Agency's Final Conclusions on Camphorated Oil Drug Products

Historically, camphorated oil (also known as camphor liniment), a solution of 20 percent camphor in cottonseed oil, has been marketed as an OTC drug product for various uses, primarily as a topical counterirritant or liniment. A large number of accidental ingestions of camphorated oil and resultant toxicities have been reported, often because camphorated oil is mistaken for castor oil, cod liver oil, mineral oil, olive oil, cough medicine, or other drug products intended for oral ingestion. Even with labeling explicitly stating that these drug products are intended for extenal use only and not for ingestion, ingestions and toxicities have continued to occur. The agency does not believe that the

suggested alternatives to removing camphorated oil products from the market would effectively reduce the risk of accidental ingestions. The agency concludes that adequate directions and warnings cannot be written to protect against dangerous use by children or to protect the user from an unsafe method of administration. The agency also concludes that any benefit to be obtained from the continued availability of camphorated oil and similar products is insignificant when compared to the risk. Based upon this adverse benefit-to-risk ratio, camphorated oil and similar drug products (i.e., any drug product containing camphor in oil or any camphor-containing drug product that is represented, suggested, or purported to be camphorated oil) cannot be generally recognized as safe. Therefore, the continued marketing of these drug products is not warranted.

Based on the available evidence, the agency is making a final determination that "camphorated oil" or any drug product which is represented, suggested, or purported to be camphorated oil, e.g., "camphor liniment," "camphor oil," "camphorated liniment," is misbranded under section 502(f) of the act and is a new drug under section 201(p) of the act for which an approved new drug application under section 505 of the act and Part 314 of the regulations (21 CFR Part 314) is required for marketing. Any such drug product may not be initially introduced or initially delivered for introduction into interstate commerce on or after the effective date of this final rule. Any such drug product in interstate commerce after the effective date of this final rule that is not in compliance with the regulation is subject to regulatory action. The agency is unaware of any camphorated oil drug product that is the subject of an approved new drug application.

In addition, because of the risk associated with the continued availability of camphorated oil drug products, the agency is requesting firms to recall to the retail level all camphorated oil and similar drug products.

The agency has examined the economic consequences of this rulemaking and has determined that it does not require a Regulatory Impact Analysis as specified in Executive Order 12291. The final rule will prohibit the continued marketing of camphorated oil as an OTC drug product and establish it as a new drug under 21 CFR Part 310. The final rule will further require the recall (market withdrawal) of all stocks of camphorated oil currently marketed as an OTC drug product to eliminate the risk of poisonings resulting from the accidental ingestion of the product. The agency believes that the benefits of camphorated oil are insignificant when compared to this risk and that this final rule will benefit society because it will result in the withdrawal of an unsafe drug product. Given the small volume of sales of camphorated oil products in 1981 and the small number of firms listed as marketing these products, the agency believes that the negative economic effects of this rule will be minimal. Therefore, the agency concludes that the final rule is not a "major" rule as defined in section 1(b) of Executive Order 12291. A copy of the threshold assessment supporting this determination is on file with the Dockets Management Branch (address above). The requirement for a regulatory flexibility analysis under the Regulatory Flexibility Act does not apply to this final rule because the proposed rule was issued prior to January 1, 1981, and is therefore exempt.

List of Subjects in 21 CFR Part 310

New drugs.

PART 310—NEW DRUGS

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 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 21 CFR 5.11 as revised (see 47 FR 16010; April 14, 1982), Part 310 is amended by adding new § 310.526 to Subpart E, to read as follows:

§ 310.526 Camphorated oil drug products.

(a) Historically, camphorated 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 topical counterirritant or liniment. A large number of accidental ingestions of camphorated oil, often mistaken for castor oil, cod liver oil, mineral oil, olive oil, cough medicine, or other drug 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 product containing camphor in oil or from using any camphor-containing drug product that is 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, camphorated oil, any drug product containing camphor in oil, or any other drug product containing camphor that is represented, suggested, or purported to be camphorated oil, such as a product labeled "camphor liniment," "camphor oil," "camphorated liniment," or any similar name, cannot be considered generally recognized as safe.

(b) Any camphorated oil drug product, any drug product containing camphor in oil, or any other drug product containing camphor that is represented, suggested or purported to be camphorated oil, e.g., "camphor liniment," "camphor oil," "camphorated liniment," 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 camphorated oil drug product is safe for the purpose intended.

(d) Any such drug product in interstate commerce after September 21, 1982 that is not in compliance with this section is subject to regulatory action.

Effective date. This rule is effective on September 21, 1982.

(Secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); secs. 4, 5, 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704))

Mark Novitch,

Acting Commissioner of Food and Drugs.

Dated: August 18, 1982.

Richard S. Schweiker,

Secretary of Health and Human Services.

[FR Doc. 82–25993 Filed 9–20–82; 8:45 am]

BILLING CODE 4160–01–M

Proposal No. 2

§ 1207.320 [Amended]

Add a new paragraph (e) to § 1207.320 to read:

* * * * *

(e) In the event that producer Board members fail to select a public representative nominee the Secretary may appoint such a member.

Proposal No. 3

§ 1207.322 [Amended]

Where "members" or "nominees" appears in paragraphs (a), (b), and (c) of § 1207.322 insert "producer" before each. Also, add a new paragraph (d) to § 1207.322 to read:

* * * * *

(d) The public member shall be nominated by the producer members of the Board. The Board shall prescribe such additional qualifications, administrative rules and procedure for selection and voting for each candidate as it deems necessary and the Secretary approves.

Proposal No. 4

§ 1207.328 [Amended]

Amend paragraph (a) of § 1207.328 by adding "to nominate the public member;" after "of Board members;".

Proposal No. 5

§ 1207.341 [Amended]

Revise paragraph (b) of § 1207.341 to read:

* * * * *

(b) The Board is authorized to incur such expenses for research, development, advertising, or promotion of potatoes and potato products, such other expenses for the administration, maintenance, and functioning of the Board, and any referendum and administrative costs incurred by the Department of Agriculture as are approved pursuant to § 1207.361.

* * * * *

Proposal No. 6

§ 1207.342 [Amended]

Revise paragraph (a) of § 1207.342 to read:

(a) The funds to cover the Board's expenses shall be acquired by the levying of assessments upon handlers as designated in regulations issued by the Board. Such assessments shall be levied at a rate fixed by the Secretary which shall not exceed one-half of one per centum of the immediate past ten calendar year average United States average price received for potatoes by growers as reported by the Department of Agriculture and not more than one such assessment may be collected on any potatoes.

* * * * *

Proposal No. 7

Make such changes as may be necessary to make the entire Plan conform with any amendments thereto that may result from this hearing.

Copies of this notice of hearing and the Plan may be obtained from Kurt J. Kimmel, Fruit and Vegetable Division, AMS, Room 2545–S, U.S. Department of Agriculture, Washington, D.C. 20250, or from Robert B. Case, Fruit and Vegetable Division, AMS, U.S. Department of Agriculture, 721 19th Street, Room 365, Denver, Colorado 80202.

From the time this hearing notice is issued and until the issuance of a final decision in a proceeding, Department employees involved in the decisional process are prohibited from discussing the merits of the hearing issues on an ex parte basis with any person having an interest in the proceeding. For this particular proceeding, the prohibition applies to employees in the following organizational units:

Office of the Secretary of Agriculture;
Office of the Administrator, Agricultural Marketing Service;
Office of the General Counsel;
Fruit and Vegetable Division, Agricultural Marketing Service.

Procedural matters are not subject to the above prohibition and may be discussed at any time.

(Title III of Pub. L. 91–670; 84 Stat; 7 U.S.C. 2611–2627)

Signed at Washington, D.C., on September 17, 1982.

William T. Manley,

Deputy Administrator, Marketing Program Operations.

[FR Doc. 82–26099 Filed 9–20–82; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 145

[Docket No. 82N–0160]

Canned Fruits; Proposal To Remove Standards of Identity for Canned Fruits With Rum

AGENCY: Food and Drug Administration.

ACTION: Proposal.

SUMMARY: The Food and Drug Administration (FDA) is proposing to remove the standards of identity for canned apricots with rum, canned cherries with rum, canned peaches with rum, and canned pears with rum and is inviting comments regarding the need for such standards. This action is taken in conjunction with FDA's plan for the retrospective review of existing standards to minimize regulatory burdens as required by the Regulatory Flexibility Act and Executive Order 12291.

DATE: Comments by November 22, 1982.

ADDRESS: Written comments, data, or information to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: F. Leo Kauffman, Bureau of Foods (HFF–214), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–245–1164.

SUPPLEMENTARY INFORMATION: FDA is required by the Regulatory Flexibility Act, Executive Order 12291, and the Paperwork Reduction Act of 1980 to review its existing regulations. FDA published a notice in the **Federal Register** of July 14, 1981 (46 FR 36333) announcing the undertaking of a systematic review of its regulations to minimize regulatory burden while maintaining an acceptable level of consumer protection. Among the regulations scheduled for review by FDA during the retrospective review process are the four standards of identity for canned fruits with rum. This action is also in accordance with the Administration's desire for fewer regulations.

In the **Federal Register** of October 23, 1947 (12 FR 6907), FDA published standards of identity for canned apricots with rum (21 CFR 27.13), canned cherries with rum (21 CFR 27.33), canned peaches with rum (21 CFR 27.3), and canned pears with rum (21 CFR 27.23). In the **Federal Register** of March 15, 1977 (42 FR 14302), these regulations were recodified as 21 CFR 145.118, 145.128, 145.173, and 145.178, respectively. Canned apricots with rum, canned cherries with rum, canned peaches with rum, and canned pears with rum conform to the definitions and standards of identity prescribed for canned apricots (21 CFR 145.115), canned cherries (21 CFR 145.125), canned peaches (21 CFR 145.170), and canned pears (21 CFR 145.175), respectively, except that they contain added rum in an amount such that the alcohol content is more than 3 percent but less than 5 percent by weight.

FDA is unaware of any manufacturer producing these foods. Therefore, the agency believes that the standards of