Proposed Rule

Accordingly, as set forth in the preamble, the Federal Crop Insurance Corporation, proposes to amend 7 CFR part 457 as follows:

PART 457—COMMON CROP INSURANCE REGULATIONS; REGULATIONS FOR THE 1998 AND SUBSEQUENT CONTRACT YEARS

1. The authority citation for 7 CFR part 457 continues to read as follows:

Authority: 7 U.S.C. 1506(l), 1506(p).

2. In § 457.128 revise section 10(b)(7) to read as follows:

§ 457.128 Guaranteed Production Plan of Fresh Market Tomato Crop Insurance Provisions.

10. Insurance Period.

* * * * *

(b) * * *

(7) October 15 of the crop year in Delaware, Maryland, New Jersey, North Carolina, and Virginia; October 31 of the crop year in California; November 10 of the crop year in Florida, Georgia, and South Carolina; and September 20 of the crop year in all other states.

Signed in Washington, DC, on July 13, 1998.

Kenneth D. Ackerman,

Manager, Federal Crop Insurance Corporation.

[FR Doc. 98–19245 Filed 7–17–98; 8:45 am]

BILLING CODE 3410–08–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 341

[Docket No. 76N–052T]

RIN 0910–AA01

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph for OTC Antitussive Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking that would amend the final monograph for over-the-counter (OTC) antitussive drug products (drug products that relieve cough) to revise the labeling warnings and directions for topical/inhalant products containing the active ingredients camphor and/or menthol. New information indicates that use of these drug products near an open flame, in hot water, or in a microwave oven can cause the products to catch on fire and cause serious burns to the user. Therefore, the agency is proposing warnings and directions for safer use of these drug products by informing consumers not to expose the products to flame, hot water, or a microwave oven. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Submit written comments by October 19, 1998; written comments on the agency's economic impact determination by October 19, 1998. FDA is proposing that any final rule that may issue based on this proposal become effective 12 months after its date of publication in the **Federal Register**.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Ryland, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 9, 1976 (41 FR 38312 at 38343), the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products (the Panel) recommended that the single ingredients camphor and menthol for topical/inhalant antitussive use be classified in Category III (available data are insufficient to classify as safe and effective, and further testing is required). The Panel based its recommendations on a lack of effectiveness data, but determined that these products are safe (41 FR 38312 at 38344 and 38349 to 38352). The Panel was not aware of and did not discuss any information concerning possible safety hazards occurring when these products are placed near a flame, into containers of hot water, or in a microwave oven. The Panel recommended the following directions for topical/inhalant use for camphor and menthol:

* * * 1 tablespoonful of solution per quart of water is added directly to the water in a hot steam vaporizer, bowl, or washbasin; or 2 teaspoonfuls of solution per pint of water are added to an open container of boiling water. Breathe in vapors during the period of medicated steam generation. May be repeated 3 times daily.

In the final monograph for OTC antitussive drug products (52 FR 30042 at 30045 to 30046, August 12, 1987), the agency provided the following directions in § 341.74(d)(2)(i) and (d)(2)(ii) (21 CFR 341.74(d)(2)(i) and (d)(2)(ii)) for products containing the single ingredient camphor or menthol for ointment vehicle use based on additional clinical studies that supported effectiveness:

* * * Adults and children 2 to under 12 years of age: Rub on the throat and chest as a thick layer. The area of application may be covered with a warm, dry cloth if desired. However, clothing should be left loose about the throat and chest to help the vapors rise to reach the nose and mouth. Applications may be repeated up to three times daily or as directed by a doctor. Children under 2 years of age: consult a doctor.

For products containing the single ingredient camphor or menthol for steam inhalation use, the agency provided the following directions in § 341.74(d)(2)(iv) and (d)(2)(v), based on additional clinical studies that supported effectiveness:

* * * Adults and children 2 to under 12 years of age: Add 1 tablespoonful of solution, for each quart of water, directly to the water in a hot steam vaporizer, bowl, or wash basin; or add 1½ teaspoonsful of solution, for each pint of water, to an open container of boiling water. Breathe in the medicated vapors. May be repeated up to three times daily or as directed by a doctor. Children under 2 years of age: consult a doctor.

When the final monograph was published, the agency was not aware of safety problems occurring when products containing camphor and/or menthol are added to hot water. Since that time, the agency has received new information (Refs. 1, 2, and 3) that indicates that the current warnings and directions may not be adequate and that safety concerns (e.g., burns caused by flashing) could arise if these products are heated near an open flame, in a container of hot water, or in a microwave oven. From 1983 to mid-1997, 34 fire-related events from usage of antitussive drug products containing camphor and menthol were reported (Refs. 2 and 3). Twenty-one fire-related events concerned a combination of camphor and menthol in an ointment vehicle. This product when added to hot water in a container on the stove, or when added to water and heated in a microwave oven, caused flashing and severe burns. One of the 21 events involved adding the product to hot water in a vaporizer. An additional 11 events concerned heating products that were combinations of camphor and menthol in an alcohol-based solution. These products, like the products in the ointment vehicles, also caused flashing and burns when placed in hot water or

heated in a microwave oven. For example, a product flashed from the top of its container when it was opened close to the gas stove where water had been heated, but the gas flame had been extinguished. In still another fire-related event (the 33d event), the alcohol-based solution product was poured over lava rocks in a sauna. The product ignited, caught the consumer's bathrobe on fire, and caused burns over 65 percent of her body. The last reported fire-related event involved the ointment product and the alcohol-based product added to water and heated together resulting in flashing and burns. No fire-related events were reported when these products were added to cold water in a hot steam vaporizer and then heated.

In all 34 reported events, flashing occurred; in 5 events, the flashing caused first and second degree burns to the face, eyes, chest, shoulders, arms, and/or hands. In some instances, these burns may have caused permanent scarring or reduced vision. Some consumers treated themselves at home and others went to a physician's office, a clinic, a medical center, or an emergency room for treatment. One case required hospitalization.

References

(1) Food and Drug Administration Drug Product Reporting System, dated May 31, 1995, in OTC Vol. 04TFMA, Docket No. 76N–052T, Dockets Management Branch.

(2) MEDWATCH: Adverse Event Reports dated 1983 to 1995 in OTC Vol. 04TFMA, Docket No. 76N–052T, Dockets Management Branch.

(3) MEDWATCH: Adverse Event Reports dated 1995 to 1997 in OTC Vol. 04TFMA, Docket No. 76N–052T, Dockets Management Branch.

II. The Agency's Tentative Conclusions and Proposal

The agency tentatively concludes that the case reports raise safety concerns that could be alleviated by providing consumers with additional warnings and directions for topical/inhalant OTC antitussive drug products that contain camphor and/or menthol. The agency also notes that the labeling on one manufacturer's currently marketed products (containing camphor and menthol) (Ref. 3) is similar to the labeling proposed in this document. The agency believes that consumers need to be informed not to expose these products to flame or a microwave oven, not to place the products in any container in which water is being heated, and to add to cool water when using a hot steam vaporizer. Accordingly, the agency is proposing to amend the final monograph for OTC antitussive drug products to expand the warnings against possible flammability or combustibility and a precaution to keep them away from fire or flame. Labeling may also tell consumers to close caps tightly and store containers at room temperature away from heat.

The following information shall appear on any labeling that contains warnings and shall appear after the subheader ''Do Not Use:'' ''near an open flame'', ''by adding to hot water'', ''in a microwave oven'', or ''in a container in which water is being heated, except when adding to cold water in only a hot steam vaporizer''.

Additionally, the agency is proposing to amend the final monograph for OTC antitussive drug products to shorten and simplify the directions in § 341.74(d)(2)(i), (d)(2)(ii), (d)(2)(iv), and (d)(2)(v) for products containing camphor or menthol for topical/inhalation use. Further, the agency is proposing to add the following statements at the end of the directions: ''See important warnings about not using near a flame, in hot water, or in a microwave oven. Improper use may cause the mixture to splatter and cause burns.'' (Last two sentences to be highlighted in boldface type or contrasting color.)

The agency is also proposing to add an additional revision to the directions in § 341.74(d)(2)(iv) and (d)(2)(v) for products containing camphor or menthol for steam inhalation. The proposed revised directions inform users to add the solution directly to cold water in only a hot steam vaporizer. All suggestions to use the product in any other container have been deleted. This part of the proposed revised directions reads as follows:

Adults and children 2 to under 12 years of age: Add 1 tablespoonful of solution, for each quart of water, or add 1½ teaspoonsful of solution, for each pint of water, directly to cold water in only a hot steam vaporizer. Breathe in the medicated vapors. Use up to three times daily or as directed by a doctor. Children under 2 years of age: Consult a doctor.

The agency is inviting comment on the specific wording of these warnings and directions, and the best way to convey this information to persons using these drug products.

III. Effective Date

The agency is proposing that these new warnings and directions become effective 12 months after the date of publication of a final rule in the **Federal Register**. The agency believes that the 12-month effective date is needed because this period of implementation would allow many manufacturers to coordinate this change with routinely scheduled label printing and/or revisions as well as the new OTC drug product labeling format proposed in the **Federal Register** of February 27, 1997 (62 FR 9024). The agency encourages manufacturers of OTC antitussive drug products to voluntarily implement this labeling as of the date of publication of this proposal because of the potential for safety problems. Manufacturers, however, should be aware of the possibility that FDA may change the wording of the warnings and/or directions as a result of comments filed in response to this proposal. Because FDA is encouraging that the proposed warnings and directions be used on a voluntary basis at this time, the agency advises that manufacturers will be given ample time after publication of a final rule to use up any labeling implemented in conformance with this proposal.

IV. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Under the Regulatory Flexibility Act, if a rule has a significant economic impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant economic impact of a rule on small entities.

Title II of the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq*.) requires that agencies prepare a written statement and economic analysis before proposing any rule that may result in the expenditure in any 1 year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation).

The agency believes that this proposed rule is consistent with the principles set out in the Executive Order and in these two statutes. The purpose of this proposed rule is to revise and improve the labeling (add additional warning and direction statements) for topical/inhalant products that contain camphor, menthol, or both ingredients. This revised labeling addresses the flammability of these products when used near an open flame, in hot water, or in a microwave oven, and is intended to provide consumers additional information to help ensure safer use of these products. Potential benefits include reduction in the number of flash

fires and serious burns when consumers use these products.

This proposed rule would amend the final monograph for OTC antitussive drug products and would require some relabeling for topical/inhalant products that contain camphor, menthol, or both ingredients. The agency's Drug Listing System identifies approximately 30 manufacturers and 79 marketers of over 100 stock keeping units (SKU) (individual products, packages, and sizes) of topical/inhalant antitussive drug products containing camphor, menthol, or both ingredients. There may be a few additional marketers and products that are not identified in the sources FDA reviewed.

The agency estimates that relabeling costs of the type that would be required by this proposal generally average about $2,000 to $3,000 per SKU. Assuming that there are about 110 affected OTC SKU's in the marketplace, total one-time costs of relabeling would be $220,000 to $330,000. The agency believes that actual costs would be lower for several reasons. First, most of the label changes will be made by private label manufacturers that tend to use relatively simple and less expensive labeling. Second, the agency is proposing a 12-month implementation period that would allow many manufacturers to coordinate this change with routinely scheduled label printing and/or revisions. Similarly, labeling changes for these products would not be required until the monograph amendment is issued and becomes effective. Thus, manufacturers would have time to use up existing labeling stocks and the relabeling costs would be mitigated. Third, manufacturers may be able to implement the new labeling required by this proposal at the same time that they implement the new labeling format proposed for OTC drug products (62 FR 9024). Thus, the relabeling costs resulting from two different but related final rules may be individually reduced by implementing both required changes at the same time.

The agency considered but rejected a shorter implementation period. While the agency would like to have this new labeling in place as soon as possible, it considers a period less than 12 months difficult for some manufacturers to implement all of the labeling that would be required by this proposal.

The proposed rule would not require any new reporting and recordkeeping activities. Therefore, no additional professional skills are needed. There are no other Federal rules that duplicate, overlap, or conflict with the proposed rule. The agency does not believe that there are any significant alternatives to the proposed rule that would reduce the economic impact of the rule on small entities and would still adequately provide for the safe and effective OTC use of antitussive topical/inhalant drug products that contain camphor, menthol, or both ingredients. For example, the agency considered a longer implementation period but concluded that the marginal reduction in costs associated with an implementation period greater than 12 months could not be justified in light of the additional injuries that would likely occur. The agency also considered but rejected more permissive warning language but concluded that such language would not adequately reduce the number of adverse events and accidents.

Based on current information, the agency does not believe that this proposed rule will have a significant economic impact on a substantial number of small entities, using the U.S. Small Business Administration designations for this industry (750 employees). As discussed above, FDA is aware of only 30 manufacturers affected by this rule, most of which are assumed to be small for the purposes of this analysis. In addition, the agency believes that any other unidentified manufacturer of these products is also likely to be a small entity. From information available to the agency, it appears that only one small entity manufactures more than three SKU's of these products. Based on the limited number of SKU's each manufacturer has to relabel, the cost for each manufacturer except one should be minimal.

The analysis shows that this proposed rule is not economically significant under Executive Order 12866 and that the agency has made an effort to reduce the burden to small entities. In addition, this economic analysis, together with other relevant sections of this document, serves as the agency's initial regulatory flexibility analysis, as required under the Regulatory Flexibility Act. Finally, this analysis shows that the Unfunded Mandates Act does not apply to the proposed amendment because it would not result in an expenditure in any 1 year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on manufacturers of OTC antitussive topical/inhalant drug products that contain camphor, menthol, or both ingredients. Comments regarding the impact of this rulemaking on such manufacturers should be accompanied by appropriate documentation. The agency is providing a period of 90 days from the date of publication of this proposed rulemaking in the **Federal Register** for comments to be developed and submitted. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

In the **Federal Register** of February 27, 1997 (62 FR 9024), FDA proposed to establish a standardized format for the labeling of OTC drug products. When the agency finalizes the February 27, 1997, labeling rule, the agency will also amend the final version of this proposed rule, as needed, to conform to the final labeling rule.

V. Paperwork Reduction Act of 1995

FDA tentatively concludes that the labeling requirements proposed in this document are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*). Rather, the proposed labeling requirements are a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

VI. Environmental Impact

The agency has determined under 21 CFR 25.24(c)(6) that this action 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.

VII. Request for Comment

Interested persons may, on or before October 19, 1998, submit written comments to the Dockets Management Branch (address above). Written comments on the agency's economic impact determination may be submitted on or before October 19, 1998. Three copies of all 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 and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 341

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 341 be amended as follows:

PART 341—COLD, COUGH, ALLERGY, BRONCHODILATOR, AND ANTIASTHMATIC DRUG PRODUCTS FOR OVER–THE–COUNTER HUMAN USE

1. The authority citation for 21 CFR part 341 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

2. Section 341.74 is amended by adding paragraphs (c)(5)(iii), (c)(5)(iv), and (c)(5)(v), and revising paragraphs (d)(2)(i), (d)(2)(ii), (d)(2)(iv), and (d)(2)(v) to read as follows:

§ 341.74 Labeling of antitussive drug products.

* * * * *

(c) * * *

(5) * * *

(iii) *For any product containing camphor or menthol in a suitable ointment vehicle or for steam inhalation use.*—(A) The labeling should contain an appropriate flammability signal word, e.g., ''extremely flammable,'' ''flammable,'' ''combustible,'' consistent with 16 CFR 1500.3(b)(10).

(B) ''Keep away from fire or flame.''

(iv) *For any product formulated in a volatile vehicle.* ''Cap container tightly and store at room temperature away from heat.''

(v) *For any product with labeling that contains warnings, the following information shall appear after the subheader ''Do Not Use''.*—(A) ''Near an open flame.''

(B) ''By adding to hot water.''

(C) ''In a microwave oven.''

(D) ''In a container in which water is being heated, except when adding to cold water in only a hot steam vaporizer.''

(d) * * *

(2) * * *

(i) *For products containing camphor identified in § 341.14(b)(1) in a suitable ointment vehicle.* The product contains 4.7 to 5.3 percent camphor. Adults and children 2 to under 12 years of age: Rub on the throat and chest in a thick layer. Cover with a warm, dry cloth if desired. However, clothing should be loose about throat and chest to help vapors reach the nose and mouth. Use up to three times daily or as directed by a doctor. Children under 2 years of age: Consult a doctor. ''See important warnings about not using near a flame, in hot water, or in a microwave oven. Improper use may cause the mixture to splatter and cause burns.'' (Last two sentences to be highlighted in bold type or contrasting color.)

(ii) *For products containing menthol identified in § 341.14(b)(2) in a suitable ointment vehicle.* The product contains 2.6 to 2.8 percent menthol. Adults and children 2 to under 12 years of age: Rub on the throat and chest in a thick layer. Cover with a warm, dry cloth if desired. However, clothing should be loose about throat and chest to help vapors reach the nose and mouth. Use up to three times daily or as directed by a doctor. Children under 2 years of age: Consult a doctor. ''See important warnings about not using near a flame, in hot water, or in a microwave oven. Improper use may cause the mixture to splatter and cause burns.'' (Last two sentences to be highlighted in bold type or contrasting color.)

* * * * *

(iv) *For products containing camphor identified in § 341.14(b)(1) for steam inhalation use.* The product contains 6.2 percent camphor. Adults and children 2 to under 12 years of age: Add 1 tablespoonful of solution, for each quart of water, or add 1½ teaspoonsful of solution, for each pint of water, directly to cold water in only a hot steam vaporizer. Breathe in the medicated vapors. Use up to three times daily or as directed by a doctor. Children under 2 years of age: Consult a doctor. ''See important warnings about not using near a flame, in hot water, or in a microwave oven. Improper use may cause the mixture to splatter and cause burns.'' (Last two sentences to be highlighted in bold type or contrasting color.)

(v) *For products containing menthol identified in § 341.14(b)(2) for steam inhalation use.* The product contains 3.2 percent menthol. Adults and children 2 to under 12 years of age: Add 1 tablespoonful of solution, for each quart of water, or add 1½ teaspoonsful of solution, for each pint of water, directly to cold water in only a hot steam vaporizer. Breathe in the medicated vapors. Use up to three times daily or as directed by a doctor. Children under 2 years of age: Consult a doctor. ''See important warnings about not using near a flame, in hot water, or in a microwave oven. Improper use may cause the mixture to splatter and cause burns.'' (Last two sentences to be highlighted in bold type or contrasting color.)

Dated: July 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–19239 Filed 7–17–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

28 CFR Part 23

[OJP (BJA)–1177]

RIN 1121–ZB14

Criminal Intelligence Sharing Systems; Policy Clarification

AGENCY: Bureau of Justice Assistance (BJA), Office of Justice Programs (OJP), Justice.

ACTION: Proposed clarification of policy.

SUMMARY: The current policy governing the entry of identifying information into criminal intelligence sharing systems requires clarification. This policy clarification is to make clear that the entry of individuals, entities and organizations, and locations that do not otherwise meet the requirements of reasonable suspicion is appropriate when it is done solely for the purposes of criminal identification or is germane to the criminal subject's criminal activity. Further, the definition of ''criminal intelligence system'' is clarified. While this clarification is not a rulemaking for the purposes of the Administrative Procedure Act, 5 U.S.C. 553, BJA is of the opinion that this clarification is significant enough to warrant public comment.

DATES: Public comment is due by September 18, 1998. Comments may be faxed to (202) 307–1419, e-mailed to ''fisheral@ojp.usdoj.gov,'' or mailed to the Office of the General Counsel, 810 7th Street NW, Washington, DC, 20531.

FOR FURTHER INFORMATION CONTACT: Paul Kendall, General Counsel, Office of Justice Programs, 810 7th Street NW, Washington, DC 20531, (202) 307–6235.

SUPPLEMENTARY INFORMATION: The operation of criminal intelligence information systems is governed by 28 CFR Part 23. This regulation was written to both protect the privacy rights of individuals and to encourage and expedite the exchange of criminal intelligence information between and among law enforcement agencies of different jurisdictions. Frequent interpretations of the regulation, in the form of policy guidance and correspondence, have been the primary method of ensuring that advances in technology did not hamper its effectiveness.