DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 341

[Docket No. 76N-052E]

RIN 0905-AA06

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Final Monograph for Expectorant Drug Products; Updating and Technical Changes

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule amending the regulations for over-the-counter (OTC) expectorant drug products that will update these regulations by making noncontroversial technical changes that clarify use of the terms "mucus" and "sputum" in the labeling of OTC antitussive and expectorant drug products. The final rule also establishes a warning statement for OTC expectorant drug products intended solely for use in children under 12 years of age, should manufacturers decide to market such products. This warning is consistent with similar warnings in the labeling of OTC antitussive and other cold, cough, allergy, bronchodilator, and antiasthmatic drug products. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Effective July 30, 1992; written comments by August 31, 1992; written comments on the agency's economic impact determination by August 31, 1992.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 28, 1989 (54 FR 8494), FDA issued a final rule for OTC expectorant drug products (21 CFR part 341) that specifies the following indication and warning statements for these drug products under § 341.78(b) and (c)(1), respectively. "Helps loosen phlegm (sputum) and thin bronchial secretions to" (select one or more of the following: "rid the bronchial passageways of bothersome mucus," "drain bronchial tubes," and "make coughs more productive,") and "Do not take this product for persistent or chronic cough such as occurs with smoking, asthma, or where cough is accompanied by excessive phlegm (sputum) unless directed by a doctor."

In the **Federal Register** of August 12, 1987 (52 FR 30042), FDA issued a final rule for OTC antitussive drug products (21 CFR part 341) that specifies the following warning statements for these drug products under § 341.74(c)(2) and (c)(3), respectively: "*For oral and topical antitussives labeled for adults or for adults and children under 12 years of age.* 'Do not take this product for persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor.'" and "*For oral and topical antitussives labeled only for children under 12 years of age.* 'Do not give this product for persistent or chronic cough such as occurs with asthma or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor.'"

The indication and warning statements for expectorant drug products include the parenthetical term "(sputum)," while the parenthetical term "(mucus)" is used for antitussive drug products. This final rule provides consistency in the labeling of these drug classes by revising the expectorant labeling to include the parenthetical term "(mucus)" in place of the parenthetical term "(sputum)." This change will facilitate the labeling of combination drug products containing an expectorant and an antitussive ingredient and provide more consistent labeling for OTC cold, cough, allergy, bronchodilator, and antiasthmatic drug products.

In addition, this final rule amends the expectorant final monograph to include a new warning identical to the warning described above for drug products labeled only for use by children under 12 years of age that is included in the antitussive portion of the cold, cough, allergy, bronchodilator, and antiasthmatic monograph. Although the expectorant final monograph includes warnings for products used by adults only or by adults and children, it does not include a specific warning for drug products labeled only for use by children under 12 years of age. Because expectorant drug products could be marketed with labeling for use only by children under 12 years of age, the agency believes that the expectorant final monograph should include a children's warning that is identical to the warning for OTC antitussive drug products.

This final rule provides consistency between the expectorant and antitussive final monographs by revising the terminology used in the indications and warning statements for expectorant drug products to make them consistent with the terminology used in the warnings for antitussive drug products and by adding a children's warning to the expectorant final monograph. This warning appears in § 341.78(c)(3) as follows: "*For expectorant drug products labeled only for children under 12 years of age.* 'Do not give this product for persistent or chronic cough such as occurs with asthma or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor.'" In addition, the agency is redesignating § 341.78(c)(1) as § 341.78(c)(2) and is adding the following heading to § 341.78(c)(2) to differentiate the warning in this paragraph from the new warning added in § 341.78(c)(3): "*For expectorant drug products labeled for adults or for adults and children under 12 years of age.*" Finally, the agency is redesignating § 341.78(c)(2) as § 341.78(c)(1).

These labeling revisions represent minor clarifying changes that do not change the substance of the labeling requirements contained in the final regulations. Therefore, the agency has determined that these labeling revisions do not need to be implemented on the effective date of this final rule. Manufacturers may implement the revisions at the next printing of labels for affected products.

The agency has examined the economic consequences of this final rule in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this final rule amending the final monograph for OTC cold, cough, allergy, bronchodilator, and antiasthmatic drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as

defined in the Regulatory Flexibility Act (Pub. L. 96–354). That assessment included a discretionary regulatory flexibility analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC expectorant drug products is not expected to pose such an impact on small business. The only requirement is minor labeling revisions, and the agency is allowing these to be made at the manufacturer's next printing of labels for affected products. Therefore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

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.

As noted previously, this final rule institutes changes that are of a nonsubstantive nature. Because the revisions are not controversial and because, when effective, they provide clarification of a final OTC drug monograph, FDA finds that the usual notice and comment procedures are unnecessary. The final rule, therefore, shall become effective July 30, 1992. However, interested persons may, on or before August 31, 1992, submit written comments on this final rule, including the agency's economic impact determination, to the Dockets Management Branch (address above). Three copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 341

Expectorant drug products, 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, 21 CFR part 341 is 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: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

2. Section 341.78 is amended by revising the first sentence in paragraph (b), by redesignating existing paragraph (c)(1) as paragraph (c)(2) and revising it, by redesignating existing paragraph (c)(2) as paragraph (c)(1), and by adding new paragraph (c)(3) to read as follows:

§ 341.78 Labeling of expectorant drug products.

* * * * *

(b) *Indications.* The labeling of the product states, under the heading "Indications," the following: "Helps loosen phlegm (mucus) and thin bronchial secretions to" (select one or more of the following: "rid the bronchial passageways of bothersome mucus," "drain bronchial tubes," and "make coughs more productive"). * * *

(c) * * *

(2) *For expectorant drug products labeled for adults or for adults and children under 12 years of age.* "Do not take this product for persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema, or where cough is accompanied by excessive phlegm (mucus) unless directed by a doctor."

(3) *For expectorant drug products labeled only for children under 12 years of age.* "Do not give this product for persistent or chronic cough such as occurs with asthma or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor."

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Dated: June 17, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

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