The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—[AMENDED]

1. Authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Boeing of Canada, Ltd., De Havilland Division: Applies to all de Havilland Model DHC-7 series airplanes, certificated in any category. Compliance is required as indicated unless previously accomplished.

To prevent possible malfunction of the right main landing gear (MLG), accomplish the following:

A. Within 100 landings after the effective date of this AD, and thereafter at intervals not to exceed 500 landings, conduct a visual inspection of the right MLG frame and attachment bolts, in accordance with paragraph A. of the Accomplishment Instructions in de Havilland Service Bulletin No. 7-24-66, Revision B, dated June 23, 1989.

1. If no damage is found, reassemble parts and return the airplane to service.

2. If damage is found, replace with serviceable parts prior to further flight, in accordance with the service bulletin.

B. Within 180 days after the effective date of this AD, relocate the external power grounding studs by incorporating Modification No. 7/2577, in accordance with paragraph B. of the Accomplishment Instructions in de Havilland Service Bulletin No. 7-24-66, Revision B, dated June 23, 1989. Accomplishment of this modification constitutes terminating action for the repetitive inspections required by paragraph A., above.

C. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, New York Aircraft Certification Office, ANE-170, FAA, New England Region.

Note: The request should be forwarded through an FAA Principal Maintenance Inspector (PMI), who will either concur or comment and then send it to the Manager, New York Aircraft Certification Office, ANE-170.

D. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

All persons affected by this directive who have not already received the appropriate service documents from the manufacturer may obtain copies upon request to Boeing of Canada, Ltd., de Havilland Division, Garratt Boulevard, Downsview, Ontario M3K 1Y5, Canada. These documents may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or at the FAA, New England Region, New York Aircraft Certification Office, 181 South Franklin Avenue, Valley Stream, New York.

Issued in Seattle, Washington, on November 15, 1989.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 341

[Docket No. 76N-052G]

RIN 0905-AA06

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Reopening of Record for Receipt of Comments Regarding the Marketing Status of Combination Drug Products Containing Promethazine Hydrochloride

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of administrative record.

SUMMARY: The Food and Drug Administration (FDA) is reopening the administrative record for over-the-counter (OTC) cold, cough, allergy, bronchodilator, and antiasthmatic combination drug products to accept additional comments and data concerning combination drug products containing promethazine hydrochloride.

DATES: Comments and data by January 29, 1990.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 12, 1988 (53 FR 30522), FDA published a notice of proposed rulemaking in the form of a tentative final monograph that would establish conditions under which OTC cough-cold combination drugs are generally recognized as safe and effective and not misbranded. In that document, FDA proposed OTC marketing of cough-cold combination drug products containing promethazine hydrochloride. Before the proposal, such drug products had been marketed as prescription drugs only.

At the time FDA proposed OTC marketing of promethazine hydrochloride-containing cough-cold combination drug products, the agency believed that these products could be generally recognized as safe and effective for short-term (7-day) use for treating the symptoms of the common cold. In accordance with the enforcement policy set out in 21 CFR 330.13, the agency stated that it would allow the OTC marketing of promethazine-containing combination cough-cold drug products to begin.

On December 15, 1988, the agency received a citizen petition (Ref. 1) from the Public Citizen Health Research Group (HRG) and the University of Maryland SIDS Institute objecting to OTC status for promethazine-containing cough-cold drug products. The agency also received letters from a number of physicians (Refs. 2 through 8) voicing the same objection. The major concern that the petition and the letters raised was that the possibility that the use of drug products containing promethazine hydrochloride in children under 2 years of age may be associated with the occurrence of sudden infant death syndrome (SIDS), and that OTC availability of these drug products could "dramatically increase overuse" of these drug products in children this age. The petition also raised concerns about possible adverse neurological reactions to drug products containing promethazine hydrochloride, and about the use on a prescription basis of promethazine-containing drug products in children under age 2, in pregnant or nursing women, and in the elderly.

In response to these concerns, FDA held a meeting of its Pulmonary-Allergy Drugs Advisory Committee on July 31, 1989, to discuss OTC marketing of promethazine hydrochloride combination drug products. Presentations were made by FDA staff, by representatives of HRG, and by representatives of the major manufacturer of promethazine-containing drug products. The presentations addressed adverse neurological reactions associated with the use of promethazine and other

phenothiazine drugs, and the possible relationship between promethazine use in children under 2 years of age and the occurrence of SIDS. By a vote of seven to one, the advisory committee recommended to FDA that these drug products not be marketed OTC at this time. In the **Federal Register** of September 5, 1989 (54 FR 36762), the agency announced that promethazine-containing combination drug products for use in treating the symptoms of the common cold may not be marketed OTC at this time.

The administrative record for the proposed rule on OTC cough-cold combination drug products had several closing dates: December 12, 1988, for the submission of comments, August 14, 1989, for the submission of new data, and October 12, 1989, for the submission of comments on the new data submitted. As provided in § 330.10(a)(10)(iii) of the procedural regulations for OTC drugs (21 CFR 330.10(a)(10)(iii)), new data and comments received after August 14, 1989, and October 12, 1989, respectively, can not be included in the administrative record unless the agency reopens the record. Because the Pulmonary-Allergy Drugs Advisory Committee's recommendations of July 31, 1989, were part of the basis for the agency's decision to rescind the OTC marketing status of promethazine hydrochloride at this time, FDA is reopening the administrative record to provide an opportunity for further public comment on the advisory committee's recommendations concerning promethazine hydrochloride combination drug products. The agency has placed the transcripts of the advisory committee's July 31, 1989, meeting in the docket for this rulemaking (Ref. 9). The minutes of this meeting will be placed in the docket for this rulemaking as soon as they are completed. The agency is also reopening the administrative record for OTC cough-cold combination drug products to accept any additional available data relating to the issue of OTC marketing of combination cough-cold drug products containing promethazine hydrochloride. Accordingly, the record is reopened for the receipt of comments and data on this subject only until January 29, 1990.

This notice also serves to inform interested persons of the existence of comments, data, and information on promethazine-containing drug products; their availability for review at the Dockets Management Branch between 9 a.m. and 4 p.m. Monday through Friday, and to provide for the filing of written comments and data by January 29, 1990, on the OTC marketing of promethzine-containing cough-cold combination drug products. 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.

References

(1) Comment No. CP, Docket No. 76N-052G, Dockets Management Branch.
(2) Comment No. C00205, Docket No. 76N-052G, Dockets Management Branch.
(3) Comment No. C00206, Docket No. 76N-052G, Dockets Management Branch.
(4) Comment No. C00207, Docket No. 76N-052G, Dockets Management Branch.
(5) Comment No. C00208, Docket No. 76N-052G, Dockets Management Branch.
(6) Comment No. C00209, Docket No. 76N-052G, Dockets Management Branch.
(7) Comment No. C00212, Docket No. 76N-052G, Dockets Management Branch.
(8) Comment No. C00214, Docket No. 76N-052G, Dockets Management Branch.
(9) Transcripts of the July 31, 1989 Meeting of the FDA Pulmonary-Allergy Drugs Advisory Committee, Docket No. 76N-052G, Dockets Management Branch.

Dated: November 20, 1989.

Ronald S. Chesemore,

Acting Associate Commissioner for Regulatory Affairs.

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21 CFR Part 444

[Docket No. 89N-0448]

Certain Neomycin Sulfate-Polymyxin B Sulfate Containing Ophthalmic Dosage Forms; Revision of Upper Potency Specification

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the antibiotic drug regulations by revising the upper potency specification for certain neomycin sulfate-polymyxin B sulfate ophthalmic dosage forms. This action is being taken at the request of a manufacturer and to make the upper potency specification for these products consistent with other neomycin sulfate ophthalmic dosage forms.

DATES: Written comments by January 29, 1990; requests for an informal conference by December 28, 1989.

ADDRESSES: Written comments and requests for an informal conference to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Peter A. Dionne, Center for Drug Evaluation and Research (HFD-520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8046.

SUPPLEMENTARY INFORMATION: At the request of a manufacturer, FDA is proposing to amend the antibiotic drug regulations by revising the upper potency specification for certain neomycin sulfate-polymyxin B sulfate ophthalmic dosage forms.

The individual monographs (regulations) for these products currently specify an upper potency limit for neomycin sulfate and polymyxin B sulfate of 125 percent of label claim. To bring its products in line with the upper potency specifications of other neomycin sulfate ophthalmic products, the manufacturer requests that the upper potency limit for neomycin sulfate and polymyxin B sulfate be increased to 130 percent of label claim.

FDA has reviewed the manufacturer's request and has tentatively concluded that the requested change is acceptable. Therefore, FDA is proposing that the subject monographs for neomycin sulfate-polymyxin B sulfate ophthalmic dosage forms be amended to revise the upper potency specification for neomycin sulfate and polymyxin B sulfate from 125 percent to 130 percent of label claim. The agency proposes to revise 21 CFR 444.342h(a)(1), 444.342i(a)(1)(ii), 444.342j(a)(1), and 444.342k(a)(1).

Environmental Impact

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

Economic Impact

The agency has considered the economic impact of this proposed rule and has determined that it does not require a regulatory flexibility analysis, as defined in the Regulatory Flexibility Act (Pub. L. 96-354). Specifically, the proposal would impose an insubstantial amendment to an existing technical requirement without imposing a more stringent requirement. Accordingly, the agency certifies that this regulation, if promulgated, will not have a significant economic impact on a substantial number of small entities.

Submitting Comments or Requests for Conference

Interested persons may on or before January 29, 1990, submit to the Dockets