

from this AD, and include the policy and procedures for implementing this alternate method in the air carrier's maintenance manual required by § 121.369(c) of the Federal Aviation Regulations [14 CFR 121.369(c)]; however, the alternate system must be accepted by the appropriate PMI and require the maintenance records be maintained either indefinitely or until the work is repeated. Records of the piece-part inspections are not required under § 121.380(a)(2)(vi) of the Federal Aviation Regulations [14 CFR 121.380(a)(2)(vi)]. All other Operators must maintain the records of mandatory inspections required by the applicable regulations governing their operations.

Note 3: The requirements of this AD have been met when the engine manual changes are made and air carriers have modified their continuous airworthiness maintenance plans to reflect the requirements in the Engine Manuals.

Issued in Burlington, Massachusetts, on August 9, 1999.

David A. Downey,

Assistant Manager, Engine and Propeller Directorate, Aircraft Certification Service.

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RAILROAD RETIREMENT BOARD

20 CFR Part 375

RIN 3220-AB36

Plan of Operation During a National Emergency

AGENCY: Railroad Retirement Board.

ACTION: Proposed rule.

SUMMARY: The Railroad Retirement Board (Board) hereby proposes to amend its regulations to update its emergency procedures in light of recent internal reorganizations. This would allow the Board to more effectively continue service and handle payments to civilian employees and their dependents in the event of a national emergency.

DATES: Comments must be received on or before October 18, 1999.

ADDRESSES: Comments may be submitted to the Secretary to the Board, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611.

FOR FURTHER INFORMATION CONTACT: Thomas W. Sadler, Senior Attorney, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611, (312) 751-4513, TDD (312) 751-4701.

SUPPLEMENTARY INFORMATION: Part 375 of the regulations of the Board provides for operations of the Board during emergencies. This rulemaking would amend part 375 to refer to procedures of the Office of Personnel Management

regarding advances, evacuation payments, and allowances for civilian employees in time of national emergency. Also, the rulemaking would update references to offices in the Board to reflect recent reorganizations.

The Board, with the concurrence of the Office of Management and Budget, has determined that this is not a significant regulatory action for purposes of Executive Order 12866. Therefore, no regulatory analysis is required. There are no information collections associated with this rule.

List of Subjects in 20 CFR Part 375

Civil defense, Railroad retirement, Railroad unemployment insurance.

For the reasons set out in the preamble, title 20, chapter II of the Code of Federal Regulations is proposed to be amended as follows:

PART 375—PLAN OF OPERATION DURING A NATIONAL EMERGENCY

1. The authority citation for part 375 is revised to read as follows:

Authority: 45 U.S.C. 231f(b)(5), 362(l).

2. In § 375.1, paragraph (a) is revised and a new paragraph (c) is added to read as follows:

§ 375.1 Purpose.

(a) The Railroad Retirement Board has adopted a plan to provide basic organization and methods of operation which may be needed to continue uninterrupted service during a period of national emergency as defined in § 375.2.

* * * * *

(c) For purposes of Government-wide uniformity, the procedures of the Board regarding payments during evacuation to employees and their dependents shall conform to those contained in subpart D of part 550 of the regulations of the Office of Personnel Management pertaining to "Payments During Evacuation" (5 CFR Part 550, Subpart D).

§ 375.2 [Amended]

3. Section 375.2 is amended by removing "chairman" and adding in its place "Chair" and by adding "or her" after "his" in two places.

4. In § 375.5, revise paragraphs (a), (b) introductory text, (b)(1) and (b)(2) to read as follows:

§ 375.5 Organization and functions of the Board, delegations of authority, and lines of succession.

(a) During a national emergency, as defined in § 375.2, the respective functions and responsibilities of the Board shall be, to the extent possible, as

set forth in the U.S. Government Manual, which is published annually by the Office of the Federal Register, and is available on the Internet at <http://www.nara.gov/fedreg/>, under *Other Publications*.

(b) The following delegation of authority is made to provide continuity in the event of a national emergency:

(1) The Chair of the Board shall act with full administrative authority for the Board.

(2) In the absence or incapacity of the Chair, the authority of the Chair to act shall pass to the available successor highest on the following list:

Labor Member of the Board
Management Member of the Board
Director of Administration
Director of Programs
General Counsel
Chief Information Officer
Director of Supply and Service
Regional Directors in order of length of Board service

* * * * *

§ 375.5 [Amended]

5. Paragraph (b)(3) of § 375.5 is amended by removing "Chairman" and by adding in its place "Chair", by removing "bureau" and adding in its place "office" in three places, and by adding "or her" after "his" in three places.

6. Paragraphs (a), (b)(1), (b)(2) introductory text and (c)(1) of § 375.6 are revised to read as follows:

§ 375.6 Personnel, fiscal, and service functions.

(a) *Personnel.* In a national emergency as defined in § 375.2, when it is no longer possible for a regional director to communicate with the Chair or his or her successor as set forth in § 375.5, complete responsibility and authority for administration of the personnel function are delegated to such regional director for his or her respective geographic area.

(b) *Fiscal.* (1) In a national emergency, as defined in § 375.2, the Chair of the Board or his or her successor, as set forth in § 375.5, shall designate an individual to assume the responsibilities of the Chief Financial Officer in the event that he or she is unable to assume those responsibilities.

(2) In a national emergency, incumbents of the following positions are hereby authorized to appoint emergency certifying officers:

Director of Administration
Director of Programs
Chief Financial Officer
Regional Directors

* * * * *

(c) *Supply and service.* (1) In a national emergency, as defined in

§ 375.2, complete responsibility and authority for the procurement of needed supplies, equipment, space, communications, transportation, and repair services, are delegated to each regional director for his or her geographic area.

* * * * *

§ 375.7 [Amended]

7. Section 375.7 is amended as follows:

a. In paragraph (a)(2), by removing "Director of Retirement Claims" and adding in its place "Director of Programs".

b. In paragraph (b)(1)(ii), by removing "such as claim file folders or magnetic tape master records".

c. In paragraph (b)(1)(vi), by removing "and in the regions" and "or if those offices become inoperative".

d. In paragraph (b)(2), by removing "Director of Unemployment and Sickness Insurance" and adding in its place "Director of Programs".

e. Paragraph (c) is removed.

8. Section 375.8 is revised to read as follows:

§ 375.8 Regulations for employers.

(a) In a national emergency, as described in § 375.2, employers shall continue to follow, to the greatest extent possible, the requirements pertaining to employers in subchapters A, B, and C of this chapter.

(b) Where a national emergency, as described in § 375.2, prevents an employer from following any requirement imposed by paragraph (a) of this section, the employer shall comply with such requirement as soon as possible after the cessation of the national emergency.

(c) In a national emergency, as defined in § 375.2, all communications by employers shall be directed as set forth in § 375.4.

Dated: August 5, 1999.

By Authority of the Board.

Beatrice Ezerski,

Secretary to the Board.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310 and 344

[Docket No. 77N-334S]

RIN 0910-AA01

Topical Otic Drug Products for Over-the-Counter Human Use; Products for Drying Water-Clogged Ears; Proposed Amendment of Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

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) topical otic drug products (the regulation that establishes conditions under which these drug products are generally recognized as safe and effective and not misbranded). The amendment would add conditions for marketing topical otic drug products for drying water-clogged ears. Concurrently, the agency is proposing to remove water-clogged ears from one part of the regulation that lists conditions that are not generally recognized as safe and effective and that are misbranded. This proposal contains labeling in the new OTC drug format and is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Submit written comments on the proposed regulation by November 15, 1999. Please see section VIII for the effective date of any final rule that may publish based on this proposal.

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 July 9, 1982 (47 FR 30012), the agency published a tentative final monograph for OTC topical otic drug products used as earwax removal aids. Subsequently, in the **Federal Register** of July 30, 1986 (51 FR 27366), the agency proposed to amend this tentative final monograph to consider OTC topical otic drug products for the prevention of swimmer's ear and

for the drying of water-clogged ears. At that time, no topical otic drug products for these conditions were proposed as generally recognized as safe and effective and not misbranded. The agency, however, did propose Category I (monograph) labeling for such products in case data were submitted that resulted in upgrading any ingredient(s) to monograph status in the final rule.

In the **Federal Register** of August 8, 1986 (51 FR 28656), the agency issued a final rule establishing part 344 (21 CFR part 344) for topical otic drug products for OTC human use. The monograph included one active ingredient for use as an earwax removal aid.

In the **Federal Register** of November 7, 1990 (55 FR 46914), the agency published a final rule establishing that certain active ingredients that had been under consideration in a number of OTC drug rulemaking proceedings were not generally recognized as safe and effective (hereinafter referred to as the 1990 final rule). The 1990 final rule was effective on May 7, 1991, and included in § 310.545(a)(15) (21 CFR 310.545(a)(15)) the active ingredient acetic acid, which had been under consideration as part of this rulemaking for OTC topical otic drug products for the prevention of swimmer's ear and for the drying of water-clogged ears. After the 1990 final rule published, only two ingredients remained to be evaluated in this rulemaking: Isopropyl alcohol and anhydrous glycerin.

In the **Federal Register** of February 15, 1995 (60 FR 8916), the agency issued a final rule establishing that OTC topical otic drug products for prevention of swimmer's ear or for drying water-clogged ears were not generally recognized as safe and effective for OTC use and were new drugs under section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(p)). The agency listed the ingredients considered in the rulemaking (i.e., glycerin, anhydrous glycerin, and isopropyl alcohol) in § 310.545(a)(15)(ii), with an effective date of August 15, 1995, after which products containing these ingredients for these uses could no longer be initially introduced or initially delivered for introduction into interstate commerce. Acetic acid, which had been listed solely in § 310.545, was now listed in § 310.545(a)(15)(i), with the same effective date of May 7, 1991. This final rule did not affect the conclusion reached in the 1990 final rule that acetic acid was not generally recognized as safe and effective for the prevention of swimmer's ear. The phrase "approved