

service bulletin previously described. Repair or replacement, if necessary, must be accomplished in a manner approved by the FAA.

This is considered to be interim action. The manufacturer is developing a modification that will preclude the need for repetitive inspections. Once this is developed, the FAA may consider further rulemaking to revise this AD to require additional necessary action.

Since a situation exists that requires immediate adoption of this regulation, it is found that notice and public procedure hereon are impracticable, and good cause exists for making this amendment effective in less than 30 days.

The regulations adopted herein will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation and that it is not considered to be major under Executive Order 12291. It is impracticable for the agency to follow procedures of Executive Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It had been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the regulatory docket (otherwise, an evaluation is not required). A copy of it, if filed, may be obtained from the Rules Docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

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

PART 39—[AMENDED]

1. The 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:

Short Brothers: Applies to Model SD3-60 series airplanes, Serial Numbers SH3601 through SH3642, inclusive, certificated in any category. Compliance is required as indicated, unless previously accomplished.

To prevent reduced structural integrity of the wings, accomplish the following:

A. Upon the accumulation of 9,600 hours time-in-service or within 30 days after the effective date of this AD, whichever occurs later, and thereafter at intervals not to exceed 600 hours time-in-service, perform the following inspections:

1. For airplanes with Serial Numbers SH3601 through SH3635, inclusive: Perform a visual inspection of the left and right outwing/strut attachment fittings in accordance with Short Brothers Service Bulletin SD360-57-12, dated June 8, 1990.

2. For airplanes with Serial Numbers SH3601 through SH3642, inclusive: Perform a visual inspection of the left and right stub wing/strut attachment fittings in accordance with Short Brothers Service Bulletin SD360-57-12, dated June 8, 1990.

B. If cracks are found, prior to further flight, repair or replace with serviceable part in a manner approved by the Manager, Standardization Branch, ANM-113, FAA, Transport Airplane Directorate.

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, Standardization Branch, ANM-113, FAA, Transport Airplane Directorate.

Note: The request should be submitted directly to the Manager, Standardization Branch, ANM-113, and a copy sent to the cognizant FAA Principal Inspector (PI). The PI will then forward comments or concurrence to the Manager, Standardization Branch, ANM-113.

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 information from the manufacturer may obtain copies upon request to Short Brothers, PLC, Service Representative, 2011 Crystal Drive, Suite 713, Arlington, Virginia 22202-3702. This information may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or the Standardization Branch, 9010 East Marginal Way South, Seattle, Washington.

This amendment becomes effective July 23, 1990.

Issued in Seattle, Washington, on June 27, 1990.

Steven B. Wallace,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.
[FR Doc. 90-15651 Filed 7-5-90; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 341

[Docket No. 88P-0142]

RIN 0905-AA06

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule that amends the final monograph for over-the-counter (OTC) antitussive drug products by adding a new section that exempts antitussive drug products containing menthol in a lozenge dosage form from that part of the accidental overdose warning required by § 330.1(g) (21 CFR 330.1(g)) that states, "In case of accidental overdose, seek professional assistance or contact a poison control center immediately." The exemption is being provided because OTC antitussive drug products containing menthol in a lozenge dosage form have been determined to have a low potential for acute toxicity resulting from accidental ingestion. This amendment of the final monograph is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: July 6, 1990.

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, 1987 (52 FR 30042), FDA issued a final monograph for OTC antitussive drug products (21 CFR part 341) that established conditions under which these products are generally recognized as safe and effective and not misbranded. The monograph provides for menthol to be used in a lozenge

dosage form at a dose of 5 to 10 milligrams (mg).

Under 21 CFR 330.1(g), the following general warning statements are required on all orally administered OTC drug products: "Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center immediately." Section 330.1(g) also states that FDA will grant an exemption from these general warnings where appropriate upon petition.

Since the publication of the final monograph for OTC antitussive drug products, two companies submitted citizen petitions (Refs. 1 and 2) requesting an exemption for menthol-containing antitussive cough drops from the required general warning statements in § 330.1(g). After reviewing the citizen petitions, the agency proposed to provide for this exemption in a proposed amendment of the final monograph for OTC antitussive drug products published in the *Federal Register* of July 6, 1989 (54 FR 28442). The agency concluded that accidental ingestion of menthol lozenges marketed in the monograph dosage (5 to 10 mg) is highly unlikely to present any degree of acute oral toxicity. Because of this low potential for acute toxicity, the agency proposed to amend the monograph for OTC antitussive drug products by adding a new section providing an exemption for antitussive drug products containing menthol in a lozenge dosage form from the second part of the accidental overdose warning required by § 330.1(g), which states, "In case of accidental overdose, seek professional assistance or contact a poison control center immediately."

However, the agency concluded that products containing menthol should continue to bear the first part of the general warning, which states, "Keep this and all drugs out of the reach of children." The agency considers this part of the warning necessary to reinforce and ensure that all drugs, regardless of potential toxicity, are treated by consumers as drugs and kept out of the reach of all children.

Interested persons were invited to file written comments regarding the proposal by September 5, 1989. Comments on the agency's economic impact determination could have been submitted until November 3, 1989. Final agency action occurs with the publication of this amendment to the final monograph for OTC antitussive drug products.

One comment from a manufacturer was received in response to the copies of the comment are on

public display in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. The comment requested that OTC antitussive drug products containing menthol in a lozenge dosage form also be exempted from the first part of the general warning which states "Keep this and all drugs out of the reach of children." The comment stated that this warning gives the impression that an antitussive drug product containing menthol in a lozenge dosage form is potentially harmful. The agency stated its position on this part of the warning in the proposal (54 FR 28442). (See also the discussion above.) The agency has not changed its position that this part of the warning is necessary to reinforce and ensure that all drugs, regardless of potential toxicity, are treated by consumers as drugs and kept out of the reach of all children.

Based on the above, the agency is finalizing this exemption as proposed and is adding new § 341.74(f) to the final monograph for OTC antitussive drug products to provide an exemption for products containing 5 to 10 mg menthol in a lozenge dosage form from the requirement in § 330.1(g) that the labeling bear the general warning statement. "In case of accidental overdose, seek professional assistance or contact a poison control center immediately." However, the labeling must continue to bear the first part of the general warning in § 330.1(g) of this chapter, which states, "Keep this and all drugs out of the reach of children."

In the *Federal Register* of October 2, 1989 (54 FR 40412), FDA proposed to amend the final monograph for OTC antitussive drug products to adopt the new United States Pharmacopeial (U.S.P.) definition of the term "lozenge." Comments submitted to that proposed rulemaking are being reviewed, and the agency will publish a final rule in a future issue of the *Federal Register*. However, the finalization of the rulemaking for the new U.S.P. definition of the term "lozenge" is not necessary before final action is taken on the proposed exemption from the accidental overdose warning for antitussive drug products containing menthol in a lozenge dosage form.

References

- (1) Comment No. CP1, Docket No. 88P-0142, Dockets Management Branch.
- (2) Comment No. CP2, Docket No. 88P-0142, Dockets Management Branch.

No comments were received in response to the agency's request for specific comment on the economic impact of this rulemaking (54 FR 28442).

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 not one of these rules, including this final rule for OTC antitussive 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 antitussive drug products is not expected to pose such an impact on small businesses. 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 environment assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 341

Antitussive drug products, Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act, subchapter D of chapter I of title 21 of the Code of Federal Regulations is amended in part 341 as follows:

PART 341—COLD, COUGH, ALLERGY, BRONCHODILATOR, AND ANTI-ASTHMATIC 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 341.74 is amended by adding new paragraph (f) to read as follows:

§ 341.74 Labeling of antitussive drug products.

(f) *Exemption from the general accidental overdose warning.* The labeling for antitussive drug products containing the active ingredient identified in § 341.14(b)(2) marketed in accordance with § 341.74(d)(2)(iii) is exempt from the requirement in § 330.1(g) of this chapter that the labeling bear the general warning statement "In case of accidental overdose, seek professional assistance or contact a poison control center immediately." The labeling must continue to bear the first part of the general warning in § 330.1(g) of this chapter, which states, "Keep this and all drugs out of the reach of children."

Dated: June 9, 1990.

James S. Benson,

Acting Commissioner of Food and Drugs.

[FR Doc. 90-15686 Filed 7-5-90; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF JUSTICE

Office of the Attorney General

28 CFR Part 0

[Order No. 1417-90]

Revision of Delegations Respecting the Settlement Authority of Claims Against the Federal Bureau of Investigation

AGENCY: Department of Justice.

ACTION: Final rule.

SUMMARY: The current regulation respecting the authority of the Director of the Federal Bureau of Investigation (FBI) to settle certain claims against the Bureau for damage arising from certain Department of Justice (DOJ) law enforcement activities is being revised to reflect a recent amendment to the United States Code which expanded that authority to allow settlement of claims up to \$50,000.

EFFECTIVE DATE: May 15, 1990.

FOR FURTHER INFORMATION CONTACT: Joseph R. Davis, Assistant Director—Legal Counsel, Federal Bureau of Investigation, Washington, DC 20535 (202) 324-5018.

SUPPLEMENTARY INFORMATION: A recent amendment to 31 U.S.C. 3724 increased the authority vested in the Attorney General to settle claims for damage caused by certain DOJ law enforcement

activities from \$500 to \$50,000. In order to facilitate the settlement of such claims, the settlement authority delegated to the Director of the FBI by the Attorney General is being increased from \$500 to \$50,000. Public comment will not be necessary on this rule because its subject is limited to a matter of internal Department procedure.

This rule is not a major rule for the purposes of Executive Order 12291 of February 17, 1981. As required by the Regulatory Flexibility Act, it is hereby certified that this rule will not have a significant impact on small business entities.

List of Subjects in 28 CFR Part 0

Authority delegation (Government agencies), Government employees, Organization and functions (Government agencies), Whistleblowing.

For the reasons set forth in the preamble, subpart P of 28 CFR part 0 is amended as follows:

PART 0—ORGANIZATION OF THE DEPARTMENT OF JUSTICE

1. The authority citation for part 0 is revised to read as follows:

Authority: 5 U.S.C. 301, 2303, 3103; 8 U.S.C. 1103, 1324A, 1427(g); 15 U.S.C. 644(k); 18 U.S.C. 2254, 3621, 3622, 4001, 4041, 4042, 4044, 4082, 4201 *et seq.*, 6003(b); 21 U.S.C. 871, 878(a), 881(d), 904; 22 U.S.C. 263a, 1621-1645o, 1622 note; 28 U.S.C. 509, 510, 515, 516, 519, 524, 543, 552, 552a, 569; 31 U.S.C. 1108, 3801 *et seq.*; 50 U.S.C. App. 1989b, 2001-2017p; Pub. L. No. 91-513, sec. 501; EO 11919; EO 11267, EO 11300; Pub. L. No. 110-203.

2. Section 0.89a is amended by revising paragraph (b) to read as follows:

§ 0.89a Delegations respecting claims against the FBI.

(b) The Director of the Federal Bureau of Investigation is further authorized to exercise the power and authority vested in the Attorney General under the Act of December 7, 1989, Public Law 101-203, 103 Stat. 1805 (31 U.S.C. 3724) with regard to claims thereunder not exceeding \$50,000 in any one case.

Dated: May 15, 1990.

Dick Thornburgh,

Attorney General.

[FR Doc. 90-15673 Filed 7-5-90; 8:45 am]

BILLING CODE 4410-01-M

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 2610

Payment of Premiums

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation's regulation on Payment of Premiums, 29 CFR part 2610, to add an exemption and a special rule. The exemption, which implements a retroactive statutory change and is thus applicable beginning with the 1988 premium payment year, provides that plans that were at the full funding limit for the preceding plan year are not subject to the variable rate portion of the premium for the current plan year. The special rule, which is applicable beginning with the 1990 premium payment year, provides that plans with fewer than 500 participants that are paying the maximum variable rate premium are not required to calculate the amount of their unfunded vested benefits.

EFFECTIVE DATE: July 6, 1990.

FOR FURTHER INFORMATION CONTACT: Harold J. Ashner, Assistant General Counsel, Office of the General Counsel (Code 22500), Pension Benefit Guaranty Corporation, 2020 K Street NW., Washington, DC 20006; telephone 202-778-8824 (202-778-8059 for TTY and TDD). These are not toll-free numbers.

SUPPLEMENTARY INFORMATION:

Background

The Omnibus Budget Reconciliation Act of 1987, Public Law 100-203 ("OBRA '87"), included the Pension Protection Act, which amended section 4006 of the Employee Retirement Income Security Act of 1974, as amended ("ERISA") to establish a two-part premium structure for single-employer plans. This new structure, effective for plan years beginning on or after January 1, 1988, provides for a flat rate assessment of \$16 per participant and a variable rate assessment of up to \$34 per participant, resulting in a maximum per participant premium of \$50. (The \$34 statutory ceiling for the variable rate portion is subject to reduction based on the contribution history of the plan.) The variable rate assessment is determined in accordance with a formula that is based on the amount of the plan's "unfunded vested benefits" as of the last day of the preceding plan year.

To implement these changes, the Pension Benefit Guaranty Corporation