cooperation with banks or other financial institutions through agreements to participate on an immediate or deferred (guaranteed) basis to small business concerns receiving assistance under subsection 7(j)(10) and section 8(a) of the Act; i.e., firms which are presently participating in the section 8(a) program and are eligible for contractual assistance under section 8(a) of the Act; and not firms which may be eligible to apply for the program.

§ 122.59–2 Conditions.

(a) Any assistance provided under this section may be provided only if the Administration determines that—

(1) The type and amount of such assistance requested by such concern is not otherwise available on reasonable terms from other sources. Every applicant for a direct loan, immediate participation of guaranty loan must show that the loan is not available without SBA assistance. In addition, an applicant for a direct loan must show that neither an immediate participation nor a guaranty loan is available; an applicant for an immediate participation must show that a guaranty loan is not available;

(2) With such assistance such concern has a reasonable prospect for operating soundly and profitably within a reasonable period of time;

(3) The proceeds of such assistance will be used within a reasonable time for plant construction, conversion, or expansion, including the acquisition of equipment, facilities, machinery, supplies, or material or to supply such concern with working capital to be used in the manufacture of articles, equipment, supplies, or material for defense or civilian production or as may be necessary to insure a well-balanced national economy; and

(4) Such assistance is of such sound value as reasonably to assure that the terms under which it is provided will not be breached by the small business concern. No financial assistance shall be extended under this section unless there is reasonable assurance that the loan can be paid from the earnings of the business.

(b) No loan shall be made under this authority if the total amount outstanding and committed (by participation or otherwise) to the borrower would exceed $750,000.

(c) In no event shall debt refinancing or refunding be made by the Administration under this program.

§ 122.59–3 Conditions applicable to deferred participation assistance (guaranteed).

(a) Subject to the provisions of § 122.59–2(b), in agreements to participate in loans on a deferred (guaranteed) basis, participation by the Administration shall be no less than 90 per centum of the balance of the financing outstanding at the time of disbursement of loans of a principal amount does not exceed $155,000 and no less than 85 per centum of loans of a principal amount of more than $155,000.

(b) The rate of interest on financings made on a deferred (guaranteed) basis shall be legal and reasonable, and shall be calculated in accord with §§ 122.8–3 and 122.8–4 of this title.

§ 122.59–4 Conditions applicable to immediate participation and direct assistance.

(a) All immediate participation and direct financings made pursuant to this section shall be subject to the applicable provisions of this title and the following limitations:

(1) No immediate participation may be purchased unless it is shown that a deferred participation is not available.

(2) No direct financing may be made unless it is shown that a participation is unavailable.

(b) A direct loan or the Administration's share of an immediate participation loan made pursuant to this section shall be accomplished by the issuance of a secured debt instrument—

(1) That is subordinated by its terms to all other borrowings of the issuer from banks or other financial institutions which are in existence at the time that the SBA assistance is made. SBA will consider subordination of assistance it makes available under this subsection to subsequent borrowings on a case-by-case basis based upon reasonable credit criteria;

(2) The rate of interest on which shall be the same as that calculated pursuant to § 122.8–1 of this title, less one per centum;

(3) The term of which is not more than twenty-five years;

(4) The principal on which is amortized at such rate as may be deemed appropriate by the Administration, and the interest on which is payable not less often than annually.

(5) The maximum principal amount of which may be no more than $150,000; however, the Associate Administrator for Minority Small Business and Capital Ownership Development may authorize, in writing, the acceptance of an application that exceeds $150,000 but does not exceed $750,000.

Dated: August 23, 1989.

Susan Engeleiter,

Administrator.

[FR Doc. 89–20718 Filed 9–1–89; 8:45 am]

BILLING CODE 8025–01–M

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 Combination Drug Products Containing Promethazine Hydrochloride; Marketing Status; Policy Statement

AGENCY: Food and Drug Administration.

ACTION: Policy statement.

SUMMARY: The Food and Drug Administration (FDA) is announcing that cold, cough, allergy, bronchodilator, and antiasthmatic combination drug products containing promethazine hydrochloride may not be marketed over-the-counter (OTC) at this time. Such products may continue to be dispensed on prescription or administered by licensed practitioners, in accordance with approved new drug applications (NDA). This announcement is made in accordance with FDA's enforcement policy applicable to prescription drugs undergoing review in the OTC drug review (see 21 CFR 330.13(b)(2)). This policy statement is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: This policy statement is effective September 5, 1989.

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 September 9, 1976 (41 FR 38312), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC cold, cough, allergy, bronchodilator, and antiasthmatic drug products, together with the recommendations of the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products (Cough-Cold Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in these

drug classes. The Cough-Cold Panel recommended OTC marketing, in oral dosage forms with specific labeling (41 FR 38312 at 38390, 38391, 38418 to 38421, and 38423), of certain drug products containing promethazine hydrochloride that were previously marketed as prescription drug products. However, at that time, the agency did not agree with the Panel's recommendation to switch this drug to OTC marketing status (41 FR 38313) and products containing this ingredient could not then, under 21 CFR 330.13, be marketed OTC under the OTC drug review.

The enforcement policy set out in 21 CFR 330.13 permits OTC marketing, prior to the establishment of a final monograph, of drugs previously limited to prescription use only when certain conditions are met. In general, such drugs can only be marketed OTC either when FDA agrees with an advisory review panel or when FDA independently decides that such OTC marketing is appropriate and publishes a notice in the **Federal Register**. Even then, as stated in the enforcement policy, such drug products are marketed subject to the risk that the agency may later adopt a different position that would preclude OTC marketing.

The agency's proposed regulation, in the form of a tentative final monograph, for OTC cold, cough, allergy, bronchodilator, and antiasthmatic combination drug products was published in the **Federal Register** of August 12, 1988 (53 FR 30522). Publication of the tentative final monograph allowed OTC marketing of combination drug products containing promethazine, for certain indications and under specified conditions, under the terms of 21 CFR 330.13. To date, the agency is not aware of any OTC marketing of such products.

Interested persons were invited to file by December 12, 1988, written comments, objections, or requests for oral hearing before the Commissioner of Food and Drugs regarding the proposal. New data could be submitted until August 14, 1989, and comments on the new data can be submitted until October 12, 1989.

In response to the proposed rule on OTC cold, cough, allergy, bronchodilator, and antiasthmatic combination drug products, one manufacturer and seven health professionals submitted comments related to promethazine hydrochloride. Also, one consumer's group submitted a citizen petition. In addition, FDA's Pulmonary-Allergy Drugs Advisory Committee discussed the issue of OTC marketing of cough-cold combination drug products containing promethazine hydrochloride in a public meeting held on July 31, 1989. Copies of the comments, the citizen petition, and the transcripts of the advisory committee's meeting are on public display in the Dockets Management Branch, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday. Any additional information that has come to the agency's attention since publication of the proposed rule is also on public display in the Dockets Management Branch.

FDA is now announcing that cold, cough, allergy, bronchodilator, and antiasthmatic combination drug products containing promethazine hydrochloride may not be marketed OTC at this time in order to allow the agency to consider thoroughly all of the additional data and information that have been submitted on the safety of OTC marketing of these drug products. Therefore, under 21 CFR 330.13, OTC marketing of such products under the OTC drug review is no longer being permitted at this time.

I. Background

The Cough-Cold Panel classified promethazine hydrochloride in Category I as an OTC antihistamine (41 FR 38312 at 38390 and 38391). The agency dissented from the Panel's Category I classification of promethazine hydrochloride in the preamble to the Panel's report (41 FR 38312 and 38313). The agency's dissent was based in part on the degree of drowsiness produced by promethazine hydrochloride and the possible adverse effects that might occur, especially in children, such as extrapyramidal disturbances.

In the tentative final monograph (proposed rule) for OTC antihistamine drug products (50 FR 2200 at 2206 to 2208; January 15, 1985), the agency stated that the possibility of choreoathetosis (a condition marked by jerky, involuntary movements) occurring with OTC oral doses of promethazine is unlikely. This conclusion was supported by a review of FDA adverse reaction data for the period 1970–1981 and a review of the published literature. These sources revealed only a few cases of extrapyramidal effects possibly associated with dosages of promethazine that would be available OTC. Also, there was no evidence to indicate that these effects would be more likely to occur in children. Based upon the available data, the agency stated that concerns regarding the occurrence of extrapyramidal effects and choreoathetosis and the concern that children seem particularly liable to develop adverse central nervous system reactions to promethazine had been adequately addressed. Thus, in FDA's view, at that time these possible adverse effects were no longer considered issued that would preclude use of this ingredient at proposed OTC oral dosages.

However, the agency placed promethazine hydrochloride in single-ingredient drug products in Category III in the proposed rule for OTC antihistamine drug products because of concerns that the rare, but serious adverse reaction of the central nervous system known as tardive dyskinesia might occur if promethazine hydrochloride is used on a long-term basis (50 FR 2206 to 2208). (Placement in Category III at that time meant that there was insufficient evidence to determine whether the drug was generally recognized as safe and effective for OTC use.) The agency noted that promethazine hydrochloride has not been used extensively on a long-term basis as a single ingredient for antihistamine/allergic rhinitis/antiallergy use and that consumers who use OTC antihistamines to treat the symptoms of allergic rhinitis often use these products on a long-term basis because the symptoms of allergic rhinitis usually occur for extended periods of time. The agency also noted that promethazine hydrochloride as a prescription drug is used primarily in combination drug products for relief of acute cough-cold symptoms on a short-term basis.

Subsequently, in the tentative final monograph (proposed rule) for OTC cold, cough, allergy, bronchodilator, and antiasthmatic combination drug products (53 FR 30522 at 30558 to 30559 and 30563; August 12, 1988, and 53 FR 45774; November 14, 1988), the agency proposed that cough-cold combination drug products containing promethazine hydrochloride be Category I for short-term use (7 days) only for relief of symptoms of the common cold. By this action, OTC marketing for this limited use was permitted at that time under 21 CFR 330.13. Claims for use of these drug products in treating the symptoms of allergic rhinitis were specifically excluded from the labeling (53 FR 30559).

In response to this tentative final monograph, the agency received a citizen petition from Public Citizen Health Research Group and the University of Maryland Sudden Infant Death Syndrome (SIDS) Institute (Ref. 1), a letter from Public Citizen Health Research Group (Ref. 2), and comments from several physicians (Ref. 3) objecting to the agency's proposal

allowing limited OTC marketing of drug products containing promethazine hydrochloride.

The citizen petition requested an immediate ban on all OTC use of products containing promethazine hydrochloride; a contraindication of prescription promethazine hydrochloride use in children under the age of 2 years, or in pregnant or lactating females; strengthening of the physician labeling provisions to include a bold, prominent, boxed warning stating "This product contains promethazine hydrochloride, a drug which should not be used by children under the age of 2 years, or by pregnant or breast feeding women because safety is not established in these patients, and because promethazine is associated with SIDS and infant respiratory depression"; addition of a mandatory patient package insert stating that a modified dosage schedule should be used in elderly patients, and that the product should not be used in children under the age of 2 years, or by pregnant or breast feeding women; modification of the new drug application for promethazine hydrochloride-containing drug products to prohibit promethazine use as an antihistamine in prescription cold-cough analgesic-antipyretic compounds; and removal from prescription availability of promethazine-containing products marketed specifically for this antihistamine use.

The major concern that the petition and the letters from physicians raise is that there is a possibility that the use of drug products containing promethazine hydrochloride in children under 2 years of age may be associated with the occurrence of SIDS, and that OTC availability of these drug products could "dramatically increase" "overuse" of these drug products in children this age. In addition, the petition raised concerns about possible adverse neurological reactions to drug products containing promethazine hydrochloride. The petition also raised concerns regarding 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.

One manufacturer of combination drug products containing promethazine hydrochloride has submitted data and information to the agency (Ref. 4) in response to the concerns raised in the citizen petition and has objected to the requests in the petition. In addition, the agency has received other information concerning OTC use in Canada of drug products containing promethazine hydrochloride (Ref. 5).

In response to the citizen petition and the manufacturer's submission, FDA scheduled a meeting of its Pulmonary-Allergy Drugs Advisory Committee to further discuss the advisability of switching the marketing of cough-cold combination drug products containing promethazine hydrochloride from a prescription basis to an OTC basis. The advisory committee met on July 31, 1989. Presentations were made by FDA staff and consultants, by representatives of Public Citizen Health Research Group, and by representatives of Wyeth-Ayerst. Following these presentations, the advisory committee deliberated on several questions concerning OTC status for cough-cold combination drug products containing promethazine hydrochloride.

In response to one question concerning the relationship between the use of promethazine-containing drug products and SIDS and/or sleep apnea, one committee member voted that no relationship exists while the other seven members voted that there is a possible relationship. In response to a question concerning whether there is reason for concern about the use in the elderly of the proposed OTC adult oral dosage of promethazine hydrochloride (6.25 mg every 4 to 6 hours, not to exceed 37.5 mg in 24 hours) on a short-term (7-day) basis, four committee members voted yes and four members voted no. With respect to potential neurologic toxicities at the proposed OTC dosage, none of the committee members felt there was a definite concern, but all voted that there are possible concerns. In response to a question concerning whether (based on the data presented to the committee) a cough-cold combination drug product containing promethazine hydrochloride at proposed OTC doses with specific labeling requirements for short-term (7-day) use should be marketed OTC for relief of the symptoms of the common cold, the committee recommended to FDA by a vote of seven to one that these drug products not be marketed OTC at this time.

FDA has concluded that it should accept the advisory committee's advice and is limiting cough-cold combination drug products containing promethazine hydrochloride to prescription only status at this time. Before making a final decision concerning OTC status for these products and before responding to the various requests in the citizen petition (see discussion above), the agency intends to fully and thoroughly evaluate the data and information submitted to date, the data and information presented at the July 31, 1989 advisory committee meeting, and other data and information that may be pertinent.

FDA is aware that there is some controversy in the scientific and medical communities concerning whether a cause-and-effect relationship exists between use of promethazine hydrochloride containing drug products and the occurrence of SIDS and/or sleep apnea. There are also differences of opinion whether a modified dosage schedule should be used in elderly patients and on the extent of concern about possible neurologic toxicity resulting from the use of promethazine hydrochloride at proposed OTC dosages. The agency intends to reopen the administrative record for the rulemaking for OTC cold, cough, allergy, bronchodilator, and antiasthmatic combination drug products to allow additional information to be submitted on these and related subjects. A notice will appear in a future issue of the **Federal Register**. A final decision on the OTC marketing status of combination drug products containing promethazine hydrochloride will also appear in a future issue of the **Federal Register**.

References

(1) Comment No. CP, Docket No. 76N-052G, Dockets Management Branch.

(2) Comment No. C00210, Docket No. 76N-052G, Dockets Management Branch.

(3) Comments No. C000201, C000205, C000207, C000208, C000209, C000210, and C000212, Docket No. 76N-052G, Dockets Management Branch.

(4) Comments No. RC0001 and RC0002, Docket No. 76N-052G, Dockets Management Branch.

(5) Comments No. LET086 and LET089, Docket No. 76N-052G, Dockets Management Branch.

II. Compliance

Drug products containing promethazine hydrochloride were limited on or after May 11, 1972 (the date of the initiation of the OTC drug review), to prescription use for the indications and routes of administration considered by the OTC Cough-Cold Panel. As stated above, these products could only be marketed OTC after the date of publication in the **Federal Register** of the tentative final monograph (proposed rule) for OTC cold, cough, allergy, bronchodilator, and antiasthmatic combination drug products (53 FR 30522; August 12, 1988). Under 21 CFR 330.13(b)(2), OTC drug products containing promethazine hydrochloride that are marketed after the date of publication in the **Federal Register** of a tentative final monograph (proposed rule) but prior to the effective date of a final monograph, are

* * * subject to the risk that the Commissioner may not accept the Panel's recommendation and may instead adopt a different position that may require relabeling, recall, or other regulatory action. The Commissioner may state such position at any time by notice in the **Federal Register**, either separately or as part of another document; appropriate regulatory action will commence immediately and will not await publication of a final monograph. Marketing of such a product with a formulation or labeling not in accord with a proposed monograph or tentative final monograph also may result in regulatory action against the product, the marketer, or both.

Under this enforcement policy, the agency can stop OTC marketing of a drug while the agency reviews and evaluates relevant data and information. By this notice, all combination drug products containing promethazine hydrochloride are prescription drugs and may only be marketed in accordance with the terms and conditions specified in their approved NDA. Accordingly, the agency would consider as misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352) and a new drug under section 201(p) of the act (21 U.S.C. 321(p)), any combination drug product containing promethazine hydrochloride that is marketed OTC at this time.

The agency is not currently aware of any combination drug product containing promethazine hydrochloride having been marketed OTC to date. However, any combination drug product containing promethazine hydrochloride that has already been initially introduced or initially delivered for introduction into interstate commerce must be immediately removed from OTC sale. Manufacturers of any such products should contact the agency immediately to discuss how removal of their products will be accomplished (i.e., removed from retail shelves, placed under the control of pharmacists, and dispensed only on prescription). Affected manufacturers should contact the Division of Drug Labeling Compliance (HFD-310), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, phone 301-295-8063.

Dated: August 26, 1989.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 89-20732 Filed 9-1-89; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Secretary

24 CFR Parts 200 and 206

[Docket No. R-89-1415; FR-2481]

RIN 2501-AA67

Home Equity Conversion Mortgage Insurance; Corrections

AGENCY: Office of the Secretary, HUD.

ACTION: Final rule, corrections.

SUMMARY: The purpose of this document is to clarify a technical correction published in the **Federal Register** on August 4, 1989 (54 FR 32059), that corrected a final rule which authorized the Secretary to carry out a program for insuring mortgages on the homes of elderly homeowners, by enabling the homeowners to convert the equity in their homes into cash. It will also correct a typographical error published in that correction document.

FOR FURTHER INFORMATION CONTACT: Judith V. May, Office of Economic Affairs, Room 8218, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410. 202-755-5426. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On June 9, 1989 (54 FR 24822), the Department published a final rule that added a new part 206 to title 24, chapter II of the Code of Federal Regulations. Part 206 implemented section 417 of the Housing and Community Development Act of 1987 (Pub. L. 100-242), which added a new section 255 to the National Housing Act (Act). Section 255 authorized the Secretary to carry out a program for insuring mortgages on the homes of elderly homeowners, enabling the homeowners to convert the equity in their homes to cash.

On August 4, 1989 (54 FR 32059), the Department published technical corrections to that final rule. This document will clarify the correction for § 206.23(d) that was published on August 4, 1989.

Accordingly, the following corrections are made in FR Doc. 89-13639, to 24 CFR parts 200 and 206, published in the **Federal Register** issue dated June 9, 1989 (54 FR 24822), as corrected in FR Doc. 89-18252, published in the **Federal Register** issue dated August 4, 1989 (54 FR 32059):

§ 206.21 [Corrected]

1. In § 206.21(d), in the introductory text only, on page 24835, as corrected on page 32060, correct by removing the words "interest rate" and inserting in their place, "mortgage balance".

§ 206.23 [Corrected]

2. In § 206.23(d), on page 24835, as corrected on page 32060, correct the word "mortgage" the last time it appears, to read "mortgagee".

Dated: August 29, 1989.

Grady J. Norris,

Assistant General Counsel for Regulations.

[FR Doc. 89-20754 Filed 9-1-89; 8:45 am]

BILLING CODE 4210-32-M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

RIN 1218-AB26

Air Contaminants

AGENCY: Occupational Safety and Health Administration, Labor.

ACTION: Final rule; Grant of petitions for reconsideration of three exposure limits and partial stays of effective dates for four substances.

SUMMARY: OSHA reduced exposure limits for 375 air contaminants on January 19, 1989 at 54 FR 2332. OSHA is granting a petition for reconsideration of the Short Term Exposure Limit (STEL)) for acetone of 1000 ppm for the cellulose acetate fiber industry and it is not in effect for that industry. The STEL remains in effect for all other industries except the cellulose acetate fiber industry. The Time Weighted Average (TWA) of 750 ppm for acetone is stayed until September 1, 1990 for one operation in the cellulose acetate fiber industry.

OSHA is also granting a petition for reconsideration of the new limit of 5 mg/m^3 for calcium hydroxide and it is not in effect. The prior limit of 5 mg/m^3 respirable dust and 15 mg/m^3 total dust as a particulate not otherwise regulated remains in effect. OSHA will also reconsider the limit of 5 mg/m^3 for calcium oxide but the prior limit which was also 5 mg/m^3 will remain in effect.

A stay of the ceiling limit for carbon monoxide is granted for three operations in the steel industry. A stay of the new limits for nitroglycerin and ethylene glycol dinitrate is granted to the explosives industry until October 1, 1989. A stay until October 1, 1989 is granted to the drycleaning industry for the new limit for perchloroethylene.

DATE: These actions take effect on September 1, 1989.