

Interpretative Statement nor the statutory bases for adverse registration action set forth in Section 8a of the Act, 7 U.S.C. § 12a, establish a specific basis for denying or otherwise affecting registration in this situation. The Commission is publishing its amendment of the 8a(3)(M) Interpretative Statement to inform the public that failure to comply with an exchange or other SRO settlement agreement to withdraw from registration and/or not to apply for registration constitutes "other good cause" to deny or otherwise affect registration under Section 8a(3)(M).

#### List of Subjects in 17 CFR Part 3

Registration, Statutory disqualifications.

### PART 3—[AMENDED]

For the reasons set forth above, part 3 of title 17 of the Code of Federal Regulations is amended as follows:

1. The authority citation for Part 3 continues to read as follows:

Authority: 7 U.S.C. 1a, 2, 4, 4a, 6, 6b, 6c, 6d, 6e, 6f, 6g, 6h, 6i, 6k, 6m, 6n, 6o, 6p, 8, 9, 9a, 12, 12a, 13b, 13c, 16a, 18, 19, 21, 23; 5 U.S.C. 552, 552b.

#### Appendix A to Part 3 [Amended]

2. Appendix A to part 3 is amended by adding a new paragraph after the paragraph which bears the heading "Section 8a(3)(M)," to read as follows:

\* \* \* \* \*

Similarly, the Commission interprets paragraph (M) to authorize the Commission to refuse to register, register conditionally or otherwise affect the registration of any person if such person has consented, in connection with an agreement of settlement with a contract market, a registered futures association, or any other self-regulatory organization, to comply with an undertaking to withdraw all forms of existing or pending registration and/or not to apply for registration with the National Futures Association or the Commission in any capacity. Such person's effort to violate his or her prior undertaking to withdraw from and/or not to apply for registration shall be considered to constitute "other good cause" under paragraph (M). The Commission believes that allowing such a person to be registered would be inappropriate and inconsistent with the intention of parties to the prior settlement agreement. The failure to withdraw or the attempt to register in the face of such an undertaking would indicate the lack of fair and honest dealing which the Commission believes constitutes "other good cause" for

denying, revoking or conditioning registration under the Act. The Commission also believes that allowing registration in such a situation would be inconsistent with both Section 8a(2)(A), which authorizes the Commission to refuse to register, to register conditionally, or to revoke, suspend or place restrictions upon the registration of any person if such person's prior registration has been suspended (and the period of such suspension has not expired) or has been revoked, and Section 8a(3)(J), which authorizes the Commission to refuse to register or to register conditionally any person if he or she is subject to an outstanding order denying, suspending, or expelling such person from membership in a contract market, a registered futures association, or any other self-regulatory organization.

Issued in Washington, D.C., on October 31, 1996.

Jean A. Webb,

Secretary to the Commission, Commodity Futures Trading Commission.

[FR Doc. 96-28842 Filed 11-15-96; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 176

[Docket No. 94F-0257]

#### Indirect Food Additives: Paper and Paperboard Components

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of the copolymer of the sodium salt of acrylic acid with polyethyleneglycol allyl ether in paper mill boilers. This action is in response to a petition filed by Betz Laboratories, Inc.

**DATES:** Effective November 18, 1996; written objections and requests for a hearing by December 18, 1996.

**ADDRESSES:** Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** John R. Bryce, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3023.

**SUPPLEMENTARY INFORMATION:** In a notice published in the Federal Register of August 19, 1994 (59 FR 42837), FDA announced that a food additive petition (FAP 4B4426) had been filed by Betz Laboratories, Inc., 4636 Somerton Rd., Trevose, PA 19053-6783. The petition proposed to amend the food additive regulations in § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) to provide for the safe use of the copolymer of the sodium salt of acrylic acid with polyethyleneglycol allyl ether in paper mill boilers.

FDA has evaluated the data and information in the petition and other relevant material. The agency concludes that the proposed use of the additive as an anticorrosion agent in paper mill boilers is safe, that it will achieve its intended technical effect, and that the regulations in § 176.170 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. In the August 19, 1994, notice of filing, the agency announced that it was placing the petitioner's environmental assessment on public display and provided 30 days for comments on that assessment. FDA received no comments on the assessment. Based upon the information available, FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before December 18, 1996, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made

and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in

response to the regulation 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 176

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 176 is amended as follows:

#### **PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS**

1. The authority citation for 21 CFR part 176 continues to read as follows:

Authority: Secs. 201, 402, 406, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 346, 348, 379e).

2. Section 176.170 is amended in the table in paragraph (a)(5) by alphabetically adding a new entry under the headings "List of Substances" and "Limitations" to read as follows:

#### **§ 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.**

\* \* \* \* \*

(a) \* \* \*

(5) \* \* \*

List of Substances	Limitations
* * *	* * *
Acrylic acid, sodium salt copolymer with polyethyleneglycol allyl ether (CAS Reg. No. 86830-15-1).	For use only in paper mill boilers.
* * *	* * *

\* \* \* \* \*

Dated: October 25, 1996.

Fred R. Shank,

*Director, Center for Food Safety and Applied Nutrition.*

[FR Doc. 96-29393 Filed 11-15-96; 8:45 am]

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#### **21 CFR Part 328**

[Docket No. 95N-0341]

#### **Over-the-Counter Drug Products Intended for Oral Ingestion that Contain Alcohol; Amendment of Final Rule**

**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) drug products intended for oral ingestion that contain alcohol as an inactive ingredient by exempting ipecac syrup from the maximum concentration limits of 0.5 percent alcohol or less when used by children under 6 years of age. This final rule is part of the ongoing review of OTC drug products conducted by FDA. **EFFECTIVE DATE:** December 18, 1996.

#### **FOR FURTHER INFORMATION CONTACT:**

William E. Gilbertson, Center for Drug Evaluation and Research (HFD-105), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2304.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In the Federal Register of March 13, 1995 (60 FR 13590), the agency issued a final rule establishing in § 328.10 (21 CFR 328.10) maximum concentration limits for alcohol (ethyl alcohol) as an inactive ingredient in OTC drug products intended for oral ingestion. The maximum concentration limit was set at 0.5 percent for any OTC drug product labeled for use by children under 6 years of age, and 5 percent for any OTC drug product labeled for use by children 6 to under 12 years of age. The final rule did not discuss ipecac syrup, an OTC drug product used to cause vomiting when poisoning occurs.

The United States Pharmacopeia (USP) 23d Revision states that alcohol is contained in ipecac syrup in concentrations between 1.0 and 2.5 percent (Ref. 1). Alcohol is used in the preparation of the syrup to ensure the complete extraction of alkaloids as their amine salts from ipecac powder and to reject extraneous material when ipecac

syrup is prepared by percolation (Ref. 2).

Under § 201.308(c) (21 CFR 201.308(c)), OTC marketing of ipecac syrup is limited to a 1-fluid-ounce (30 milliliters (mL)) package. The product's labeling must contain a statement conspicuously boxed and in red letters that states: "For emergency use to cause vomiting in poisoning. Before using, call physician, the Poison Control Center, or hospital emergency room immediately for advice." The labeling also must state: "Usual dosage: 1 tablespoon (15 milliliters) in persons over 1 year of age."

As part of the rulemaking for OTC poison treatment drug products (50 FR 2244, January 15, 1985), the agency proposed a dose of 1 tablespoonful (15 mL or 1/2 bottle) of ipecac syrup for children 1 to under 12 years of age. The agency also proposed a dose of 1 teaspoonful (5 mL) for children 6 months to under 1 year of age, and that ipecac syrup not be given to children under 6 months of age unless directed by a health professional. The agency will finalize these directions for use in a future issue of the Federal Register.

In the Federal Register of May 10, 1996 (61 FR 21392), the agency published a proposed amendment of § 328.10 to exempt ipecac syrup from the requirements of § 328.10(d), which