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.
* * *	* * * *

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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]

BILLING CODE 4160–01–F

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

limit alcohol content to 0.5 percent or less in OTC drug products intended for oral ingestion for use by children 6 years of age or less.

The agency noted that the maximum amount of ipecac syrup per packaged container does not exceed 30 mL, and the maximum quantity of alcohol at a 2.5 percent concentration contained in 30 mL of ipecac syrup is 0.75 mL. If a child under 6 years old swallowed the entire contents of a 30 mL container of ipecac syrup, the ingested amount of alcohol (0.75 mL) is insignificant. The labeled dose of ipecac syrup is a one-time treatment of 15 mL (0.375 mL alcohol) for children 1 to under 12 years of age. In addition, the alcohol and the ipecac syrup are generally vomited together with other stomach contents. Thus, the benefit of ipecac syrup as an emetic outweighs any risk of adverse effects from ingestion of 0.375 to 0.75 mL of alcohol.

Interested persons were invited to submit comments by June 10, 1996, and comments on the agency's economic impact determination by June 10, 1996. No comments were submitted in response to the proposed rule.

II. References

(1) United States Pharmacopeia 23/ National Formulary 18, United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 834–835, 1994.

(2) ''Solutions Using Mixed Solvent Systems: Spirits, Elixirs, and Extracted Products,'' in *Sprowls' American Pharmacy*, 7th ed., J. B. Lipincott Co., Philadelphia, pp. 100–101, 1974.

III. The Agency's Final Conclusions

The agency is adding new § 328.10(f) to state: ''Ipecac syrup is exempt from the provisions of paragraph (d) of this section.'' This means that ipecac syrup may contain more than 0.5 percent alcohol even though labeled for use by children under 6 years of age. Also, the agency is redesignating current § 328.10(f) as § 328.10(g).

IV. Analysis of Impacts

No comments regarding the economic impact of the proposed rulemaking were received.

FDA has examined the impacts of this final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

Under the Regulatory Flexibility Act, if a rule has a significant impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule has no effect on the OTC marketing of ipecac syrup drug products, it will not impose a significant economic burden on affected entities. Therefore, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commissioner of Food and Drugs certifies that the final rule will not have a significant economic impact on a substantial number of small entities. No further analysis is required.

V. Environmental Impact

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 environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 328

Drugs, Labeling, Alcohol.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 328 is amended as follows:

PART 328—OVER-THE-COUNTER DRUG PRODUCTS INTENDED FOR ORAL INGESTION THAT CONTAIN ALCOHOL

1. The authority citation for 21 CFR part 328 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 371).

2. Section 328.10 is amended by redesignating paragraph (f) as paragraph (g) and by adding new paragraph (f) to read as follows:

§ 328.10 Alcohol.

* * * * *

(f) Ipecac syrup is exempt from the provisions of paragraph (d) of this section.

* * * * *

Dated: November 5, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–29387 Filed 11–15–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 510

New Animal Drugs; Change of Sponsor Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor address for Alstoe, Ltd., Animal Health.

EFFECTIVE DATE: November 18, 1996.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: Alstoe, Ltd., Animal Health, 19 Foxhill, Whissendine, Oakham, Rutland, U.K. has informed FDA that it has changed its address to Granary Chambers, 37–39 Burton St., Melton Mowbray, Leicestershire LE13 1AF, England. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the new address.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) in the entry for ''Alstoe, Ltd., Animal Health'' and in the table in paragraph (c)(2) in the entry for ''062408'' by removing ''19 Foxhill, Whissendine, Oakham, Rutland, U.K.''