(b) *Special requirements for horses traveling through countries of transit.* In addition to meeting all of the applicable requirements of this subpart, horses shipped to the United States through a country or countries of transit must meet the following conditions:

(1) If a horse intended for importation into the United States will travel through a country or countries of transit but will not be offloaded in the country or countries of transit, then, prior to the horse's shipment from the country of origin, the owner of the horse, or the owner's representative, must certify that the horse will be shipped directly to the United States. The certification must read as follows: ''The horse will be sent directly from the premises of origin to the premises of destination without coming into contact with other equine animals not accompanied by an official health certificate, in vehicles cleaned and disinfected in advance with a disinfectant officially recognized in the country of origin.'' This certification must be signed by the owner of the horse or the owner's representative, and the signed certification must be presented to an inspector at the port of entry in the United States. If, after the certification is signed, an unscheduled offloading of a shipment of horses occurs in a country of transit, then the horses must meet all of the requirements of paragraphs (b)(2) and (b)(3) of this section.

(2) If a horse intended for importation into the United States will travel through a country or countries of transit and will be offloaded in the country or countries of transit, then the horse must be offloaded in a facility that is capable of being cleaned and disinfected and that is approved by the country of transit's Ministry of Agriculture for the offloading of in-transit horses. Within the facility, the horse must be kept separate from all other horses. All horses offloaded in a country or countries of transit must undergo a veterinary inspection and receive a health certificate from a salaried veterinary officer of the national government of each country of transit in which the horse is offloaded. The veterinary inspection must be performed no earlier than 24 hours before the horse is reloaded on a transport vehicle for shipment. If, after performing the inspection, the salaried veterinary officer of the national government of the country of transit finds the horse intended for importation into the United States to be free of evidence of communicable diseases and fit to travel, the veterinary officer must complete the form shown in paragraph (b)(3) of this section.

(3) A completed certificate of inspection, as shown below, must accompany any horse offloaded in a country of transit to the U.S. port of arrival and be produced for the inspector at the port of arrival upon the horse's arrival in the United States.

Certification of Inspection of Import Animals

1. Permit No. _____
2. Consignor's Name (Last name, first name, middle initial or business name) _____
3. Consignor's Street Address (Mailing address) _____
4. Consignor's City/Town _____
5. Consignor's Country _____
6. Consignee's Name (Last name, first name, middle initial or business name) _____
7. Consignee's City/Town _____
8. Consignor's State _____
9. Species of Animals Certified for Import __
10. Country of Origin _____
11. Breed of Animals Certified for Import __
12. Number of Animals Inspected _____
13. Country of Transit/City in Which Inspection Occurred _____
14. Date of Arrival in and Date of Departure from Country of Transit _____
15. Name of Veterinarian Performing Inspection in Country of Transit _____

The animals described on this form have been given a careful veterinary inspection and found to be free from evidence of communicable disease and, in my opinion, fit to travel.

16. Signature of Veterinarian Performing Inspection in Country of Transit _____
17. Date Issued _____
18. Seal _____
19. Remarks _____

(Approved by the Office of Management and Budget under control number 0579–0040)

Done in Washington, DC, this 3rd day of May 1996.

Terry L. Medley,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 96–11635 Filed 5–9–96; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter 1

[Docket No. 96N–0094]

Uniform Compliance Date for Food Labeling Regulations; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a proposed rule that appeared in the Federal Register of April 15, 1996 (61 FR 16422). The document proposed to establish January 1, 1998, as its new uniform compliance date for all food labeling regulations that are issued after the publication of a final rule based on the proposal and before January 1, 1997. The document was published with an editorial error. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Gerad L. McCowin, Center for Food Safety and Applied Nutrition (HFS–150), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4561.

In FR Doc. 96–9319, appearing on page 16422 in the Federal Register of Monday, April 15, 1996, the following correction is made:

1. On page 16422, in the first column, after the ''DATES'' caption, a new caption is added to read as follows: ''ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.''

Dated: May 6, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–11788 Filed 5–9–96; 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; Proposed Amendment of Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking that would amend 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 proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Submit written comments by June 10, 1996; written comments on the agency's economic impact determination by June 10, 1996. The agency is proposing that any final rule based on this proposal become effective on the date of its publication in the Federal Register.

ADDRESSES: Submit written comments to the Dockets Management Branch

(HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

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.

References

(1) United States Pharmacopeia 23d Revision 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.

II. The Agency's Proposed Amendment

The agency is proposing 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.

Ipecac syrup is indicated for use in potential life-threatening emergencies with directions for use calling for a one-time treatment dose of 15 mL for children 1 to under 12 years of age. Ipecac syrup is usually used under the advice of a health professional, and it is not indicated for repeated or routine use. Because the maximum amount of ipecac syrup per packaged container does not exceed 30 mL, 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. In addition, the alcohol and the ipecac syrup are generally vomited together with other stomach contents. The agency concludes that the benefit of ipecac syrup as an emetic outweighs any risk of adverse effects from ingestion of 0.75 mL of alcohol. Accordingly, the agency is proposing to add a new paragraph to § 328.10 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. The agency is designating this new paragraph as paragraph (f) and redesignating current paragraph (f) as paragraph (g).

III. Analysis of Impacts

The agency has examined the economic consequences of this proposed rulemaking 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. Executive Order 12291 has been superseded by Executive Order 12866. FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). 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 proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and, thus, is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. This proposal has no effect on the OTC marketing of ipecac syrup drug products. Therefore, the agency certifies that this proposal, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC drug products intended for oral ingestion that contain alcohol as an inactive ingredient. Comments regarding the impact of this rulemaking on OTC drug products intended for oral ingestion that contain alcohol as an inactive ingredient should be accompanied by appropriate documentation.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(c)(6) that this action is not 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.

V. Request for Comments

Interested persons may, on or before June 10, 1996, submit to the Dockets Management Branch (address above) written comments or objections on the proposed regulation. Written comments on the agency's economic impact determination may be submitted on or before June 10, 1996. Three copies of all comments or objections are to be submitted, except that individuals may submit one copy. Comments or

objections are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. The agency has determined that comments or objections should be submitted within 30 days because this proposal has no effect on currently marketed products.

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, it is proposed that 21 CFR part 328 be 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: May 1, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–11640 Filed 5–9–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 3500

[Docket No. FR–3780–N–07]

RIN 2502–AG40

Office of the Assistant Secretary for Housing—Federal Housing Commissioner; Mortgage Broker Fee Disclosure Rule: Notice of Meeting of Negotiated Rulemaking Advisory Committee

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice of committee meeting.

SUMMARY: The Department has established a Negotiated Rulemaking Advisory Committee to address certain issues concerning indirect payments to mortgage brokers and certain other mortgage originators (retail lenders) and volume-based compensation. The committee, which consists of representatives with a definable stake in the outcome of a proposed rule, has convened on 5 prior occasions in the past 5 months. This notice announces the time and place for the next meeting. This meeting is open to the public.

DATES: The sixth meeting of the committee will be held on May 20–21, 1996. On Monday, May 20, the meeting will start at 9:00 a.m. and will end at 5:00 p.m., and on Tuesday, May 21, the meeting will start at 9:00 a.m. and run until approximately 4:00 p.m.

ADDRESSES: The next meeting of the committee will be held in the Headquarters of the American Association of Retired Persons, 601 ''E'' Street, NW., Room 120, Floor 2–B, Washington, DC.

FOR FURTHER INFORMATION CONTACT: David R. Williamson, Director, Office of Consumer and Regulatory Affairs, Department of Housing and Urban Development, 451 7th Street, SW., Room 5241, Washington, DC 20410–8000); telephone number: (202) 708–4560 (this is not a toll-free number); e-mail through Internet at david—r.—williamson@hud.gov. For hearing- and speech-impaired persons, this number may be accessed via TDD by calling the Federal Information Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: On December 8, 1995 (60 FR 63008), HUD published a notice announcing the establishment and first meeting of the Negotiated Rulemaking Advisory Committee on Mortgage Broker Disclosures, to discuss and negotiate a proposed rule on the treatment under RESPA, including disclosure requirements, of payments to retail lenders and of volume-based compensation to mortgage brokers. The committee convened in Washington, DC, on December 13–14, 1995; January 18–19, 1996; February 22–23, 1996; March 18–19, 1996; and April 8–9, 1996. The committee expects that the upcoming meeting on May 20–21 will be the last meeting for this rulemaking effort.

This meeting is open to the public, with limited seating available on a first-come, first-served basis.

Authority: 42 U.S.C. 1437g, 3535(d).

Dated: May 3, 1996.

James E. Schoenberger,

Associate General Deputy Assistant Secretary for Housing Federal Housing Commissioner.

[FR Doc. 96–11648 Filed 5–9–96; 8:45 am]

BILLING CODE 4210–27–U

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Part 525

RIN 1076–AD67

Request for Comments on Establishing Departmental Procedures To Authorize Class III Gaming on Indian Lands When a State Raises an Eleventh Amendment Defense To Suit Under the Indian Gaming Regulatory Act

AGENCY: National Indian Gaming Commission, Interior.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Department of the Interior seeks comments on its authority under the Indian Gaming Regulatory Act (IGRA), 25 U.S.C. Section 2710, to promulgate ''procedures'' to authorize Class III gaming on Indian lands when a State raises an Eleventh Amendment defense to an action brought against it pursuant to Section ll of the Act, 25 U.S.C. Section 2710(d)(7), and on other related matters. This advance notice is the result of the Supreme Court decision in *Seminole Tribe of Florida* v. *State of Florida*, 116 S.Ct. 1114 (1996).

DATES: Written public comment is invited and will be considered in the development of a proposed rule. Comments on this advance notice of proposed rulemaking must be received no later than July 1, 1996, to be considered.

ADDRESSES: Any comments concerning this notice, including sections regarding conformance with statutory and regulatory authorities, may be sent to: George Skibine, Director, Indian Gaming Management Staff, 1849 C Street, N.W., MS–2070 MIB, Washington, D.C. 20240.

FOR FURTHER INFORMATION CONTACT: George Skibine, Director, Indian Gaming Management Staff, (202) 219–4066.

SUPPLEMENTARY INFORMATION:

Background

Congress enacted IGRA to provide a statutory basis for the operation and regulation of Indian gaming and to protect Indian gaming as a means of generating revenue for tribal governments. 25 U.S.C. Section 2702;