

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."

and by adding in its place "Granary Chambers, 37-39 Burton St., Melton Mowbray, Leicestershire LE13 1AF, England".

Dated: October 29, 1996.

Andrew J. Beaulieu,  
Deputy Director, Office of New Animal Drug  
Evaluation, Center for Veterinary Medicine.  
[FR Doc. 96-29388 Filed 11-15-96; 8:45 am]  
BILLING CODE 4160-01-F

## 21 CFR Parts 510 and 558

### Animal Drugs, Feeds, and Related Products; Tylosin

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to remove that portion reflecting approval of a new animal drug application (NADA) held by Countrymark Cooperative, Inc. (formerly Indiana Farm Bureau Cooperative Association, Inc.). The NADA provides for use of a tylosin Type A medicated article for making a tylosin Type C medicated swine feed. In a notice published elsewhere in this issue of the Federal Register, FDA is withdrawing approval of the NADA.

**EFFECTIVE DATE:** November 29, 1996.

**FOR FURTHER INFORMATION CONTACT:** Mohammad I. Sharar, Center for Veterinary Medicine (HFV-216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1722.

**SUPPLEMENTARY INFORMATION:** In a notice published elsewhere in this issue of the Federal Register, FDA is withdrawing approval of NADA 125-226 held by Countrymark Cooperative, Inc., 950 North Meridian St., Indianapolis, IN 46204-3909 (formerly Indiana Farm Bureau Cooperative Association, Inc., 120 East Market St., Indianapolis, IN 46204). The NADA provides for use of tylosin Type A medicated articles to make tylosin Type C medicated swine feeds. Countrymark Cooperative, Inc., voluntarily requested withdrawal of approval of the NADA because it no longer makes Type A medicated articles for use in medicated feeds. This document removes the entry in 21 CFR 558.625(b) to reflect the withdrawal of approval of this NADA.

This NADA was originally held by Indiana Farm Bureau Cooperative Association, Inc. The regulations had not been amended in § 510.600(c) (21 CFR 510.600(c)) to reflect the sponsor change to Countrymark Cooperative. At

this time, Indiana Farm Bureau Cooperative Association is no longer the sponsor of any approved NADA's. Therefore, § 510.600(c) is amended to remove the entries for the firm.

#### List of Subjects

#### 21 CFR Part 510

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

#### 21 CFR Part 558

Animal drugs, Animal feeds.

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 parts 510 and 558 are 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 paragraph (c)(1) by removing the entry for "Indiana Farm Bureau Cooperative Association, Inc.," and in paragraph (c)(2) by removing the entry for "021502."

### PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

#### § 558.625 [Amended]

4. Section 558.625 *Tylosin* is amended by removing and reserving paragraph (b)(76).

Dated: October 18, 1996.

Stephen F. Sundlof,  
Director, Center for Veterinary Medicine.  
[FR Doc. 96-29389 Filed 11-15-96; 8:45 am]  
BILLING CODE 4160-01-F

## Health Care Financing Administration

### 42 CFR Part 413

[BPD-805-CN]

RIN 0938-AG68

### Medicare and Medicaid Programs; New Payment Methodology for Routine Extended Care Services Provided in a Swing-Bed Hospital; Correction

**AGENCY:** Health Care Financing Administration (HCFA), HHS.

**ACTION:** Correction notice.

**SUMMARY:** This document corrects the final rule published October 3, 1996 (61 FR 51611) that revised the methodology for payment of routine extended care services furnished in a swing-bed hospital. The final rule also revised the regulations concerning the method used to allocate hospital general routine inpatient service costs for purposes of determining payments to swing-bed hospitals.

**EFFECTIVE DATE:** These corrections are effective as of November 4, 1996.

**FOR FURTHER INFORMATION CONTACT:** John Davis, (410) 786-0008.

**SUPPLEMENTARY INFORMATION:** We are making the following corrections to the October 3, 1996 final rule (61 FR 51611):

1. On page 51612, in the first column, fourth line from the bottom, the duplicate word "harmless" is deleted.

2. On page 51612, in the third column, lines 16 and 17, the phrase "ending on or after June 30, 1989 and through May 31, 1990" is corrected to read "ending on or after June 30, 1989 through May 31, 1990".

3. On page 51615, in the third column, lines 30 and 31, the phrase "we are changing to the out method" is corrected to read "we are changing to the carve-out method".

4. On page 51616, in the first column, under Subpart D, item number 2, the amendatory language is corrected by adding the phrase "the introductory text of paragraph (a)(1)(ii);" after the phrase "Section 413.53 is amended by revising".

(Catalog of Federal Domestic Assistance Program No. 93.773 Medicare—Hospital Insurance Program; No. 93.778, Medical Assistance Program)

Dated: November 7, 1996.

Neil J. Stillman,  
Deputy Assistant Secretary for Information  
Resources Management.  
[FR Doc. 96-29398 Filed 11-15-96; 8:45 am]

BILLING CODE 4120-01-P