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:


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.

* * * * *
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, 7500 Standish Pl., Rockville, MD 20855, 301±594±

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 Association, Inc. The regulations had not been amended in § 510.600(c) (21 CFR 510.600(c)) to reflect 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:


§ 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:


§ 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.

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 third 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”.

Dated: November 7, 1996.

Neil J. Stillman,
Deputy Assistant Secretary for Information Resources Management.

BILLING CODE 4120±01±P