(ii) A responsible person from your firm must sign and date the notification letter.

(iii) You must submit the notification letter to the Center for Veterinary Medicine, Division of Animal Feeds (HFV–220), 7500 Standish Pl., Rockville, MD 20855, prior to beginning your first distribution.

(iv) You must notify the Center for Veterinary Medicine at the above address within 30 days of any change in name or business address.

(2) If you are a distributor who ships an animal feed containing a VFD drug to another consignee-distributor in the absence of a valid VFD, you must obtain an ''acknowledgment letter,'' as defined in § 558.3(b)(11), from the consignee-distributor. The letter must include a statement affirming that the consignee-distributor has complied with ''distributor notification'' requirements of paragraph (d)(1) of this section.

(e) What are the additional recordkeeping requirements if I am a distributor?

(1) You must keep records of receipt and distribution of all medicated animal feed containing a VFD drug.

(2) You must keep these records for 2 years from date of receipt and distribution.

(3) You must make records available for inspection and copying by FDA.

(f) What cautionary statements are required for VFD drugs and animal feeds containing VFD drugs? All labeling and advertising must prominently and conspicuously display the following cautionary statement: ''Caution: Federal law limits this drug to use under the professional supervision of a licensed veterinarian. Animal feed bearing or containing this veterinary feed directive drug shall be fed to animals only by or upon a lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian's professional practice.''

§ 558.618 [Amended]

8. Section 558.618 *Tilmicosin* is amended by removing paragraph (d)(4).

Dated: November 30, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–31151 Filed 12–7–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 556

Tolerances for Residues of New Animal Drugs in Food; Moxidectin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is updating the animal drug regulations to correctly reflect the tolerance for moxidectin in cow's milk. This document amends the regulations to state the correct tolerance is 40 parts per billion (ppb). This action is being taken to improve the accuracy of the agency's regulations. Changes to a current format are also being made.

DATES: This rule is effective December 8, 2000.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578.

SUPPLEMENTARY INFORMATION:

Moxidectin solution is approved for topical use in cattle for the treatment and control of infections and infestations of certain internal and external parasites. When the November 2, 1999, approval of the use of moxidectin in lactating dairy cows was published in the **Federal Register** of June 9, 2000 (65 FR 36616), the tolerance for parent moxidectin in the milk of cattle was incorrectly listed. At this time, the regulations are being amended in 21 CFR 556.426 to state the correct tolerance is 40 ppb and, editorially, to reflect current format.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 556

Animal drugs, Foods.

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 556 is amended as follows:

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

1. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

2. Section 556.426 is amended by revising paragraph (b) to read as follows:

§ 556.426 Moxidectin.

* * * * *

(b) *Tolerances*—(1) *Cattle*—(i) *Liver (the target tissue*). The tolerance for parent moxidectin (the marker residue) is 200 parts per billion (ppb).

(ii) *Muscle*. The tolerance for parent moxidectin (the marker residue) is 50 ppb.

(iii) *Milk*. The tolerance for parent moxidectin (the marker residue in cattle milk) is 40 ppb.

(2) [Reserved]

Dated: November 29, 2000.

David R. Newkirk,

Acting Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 00–31248 Filed 12–7–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. 00P–1343]

Medical Device; Exemption From Premarket Notification; Class II Devices; Barium Enema Retention Catheters and Tips With or Without a Bag

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing an order granting a petition requesting exemption from the premarket notification requirements for barium enema retention catheters and tips with or without a bag with certain limitations. This rule will exempt from premarket notification barium enema retention catheters and tips with or without a bag. FDA is publishing this order in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: This rule is effective December 8, 2000.