(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.

FOR FURTHER INFORMATION CONTACT: Linda L. Dart, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1220.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (the 1976 amendments (Public Law 94–295)), as amended by the Safe Medical Devices Act of 1990 (the SMDA (Public Law 101–629)), devices are to be classified into class I (general controls) if there is information showing that the general controls of the act are sufficient to assure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device or is for a use that is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976, (generally referred to as postamendments devices) are classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations (21 CFR part 807) require persons who intend to market a new device to submit a premarket notification report (510(k)) containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Public Law 105–115). Section 206 of FDAMA, in part, added a new section 510(m) to the act. Section 510(m)(1) of the act requires FDA, within 60 days after enactment of FDAMA, to publish in the **Federal Register** a list of each type of class II device that does not require a report under section 510(k) of the act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published that list in the **Federal Register** of January 21, 1998 (63 FR 3142).

Section 510(m)(2) of the act provides that 1 day after date of publication of the list under section 510(m)(1) of the act, FDA may exempt a device on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance that the agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff.'' That guidance can be obtained through the Internet on the CDRH home page at http://www.fda.gov/cdrh or by facsimile through CDRH Facts-on-Demand at 1–800–899–0381 or 301–827–0111. Specify ''159'' when prompted for the document shelf number.

III. Petition

On June 13, 2000, FDA received a petition requesting an exemption from premarket notification for the barium enema retention catheters and tips with or without a bag. Barium enema retention catheters and tips with or without a bag are currently classified under 21 CFR 876.5980 as a gastrointestinal tube and accessory. In the **Federal Register** of August 8, 2000 (65 FR 48527), FDA published a notice announcing that this petition had been received and providing opportunity for interested persons to submit comments on the petition by September 7, 2000. FDA received no comments. FDA has reviewed the petition and has determined that barium enema retention catheters and tips with or without a bag used as a gastrointestinal tube and accessory meet the criteria for exemption from the notification requirements. The exemption is limited to barium enema retention catheters and tips with or without a bag, as described, and is also subject to the general limitations on exemptions from premarket notification for therapeutic devices as described in 21 CFR 876.9. FDA also notes that all latex containing devices, including barium enema retention catheters and tips with or without a bag, and other devices that are exempt from the premarket notification requirements of the act, are subject to the labeling regulation found in 21 CFR 801.437 (User labeling for devices that contain natural rubber).

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). 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.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule will relieve a burden and simplify the marketing of these devices, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VI. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rules does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rules does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 876 is amended as follows:

PART 876—GASTROENTEROLOGY—UROLOGY DEVICES

1. The authority citation for 21 CFR part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Section 876.5980 is amended by revising paragraph (b)(1) to read as follows:

§ 876.5980 Gastrointestinal tube and accessories.

* * * * *

(b) *Classification.* (1) Class II (special controls). The barium enema retention catheter and tip with or without a bag that is a gastrointestinal tube and accessory is exempt from the premarket notification procedures in subpart E of this part subject to the limitations in § 876.9.

* * * * *

Dated: December 3, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–31292 Filed 12–7–00; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8889]

RIN 1545–AV10

Guidance Regarding Claims for Certain Income Tax Convention Benefits; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to final regulations.

SUMMARY: This document contains corrections to final regulations (TD 8889) which were published in the **Federal Register** on Monday, July 3, 2000 (65 FR 40993). The final regulations relate to claims for certain income tax convention benefits.

DATES: This correction is effective July 3, 2000.

FOR FURTHER INFORMATION CONTACT: Shawn R. Pringle (202) 622–3850 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are subject to these corrections are under section 894 of the Internal Revenue Code.

Need for Correction

As published, final regulations (TD 8889) contains errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of final regulations (TD 8889),which was the subject of FR Doc. 00–16761, is corrected as follows:

1. On page 40996, column 2, in the preamble under the paragraph heading ''D. Treatment of Complex Trusts'', paragraph 2, line 13 from the bottom of the paragraph, the language ''the hands of the interest holder are'' is corrected to read ''the hands of the interest holder are not''.

2. One page 40997, column 1, in the preamble under the paragraph heading ''Special Analyses'', paragraph 1, line 2, the language ''treasury decision not a significant'' is corrected to read ''Treasury decision is not a significant''.

§ 1.894–1 [Corrected]

3. On page 40997, column 1, correct the amendatory instruction for Par. 2. to read as follows:

Par. 2. Section 1.894–1 is amended as follows:

1. Paragraph (d) is redesignated as paragraph (e), and a new paragraph (d) is added.

2. In newly designated paragraph (e), add a sentence at the end of the paragraph.

The additions read as follows:

4. On page 40999, column 2, § 1.894–1(d)(5), paragraph (i) of *Example 7.,* line 10, the language ''legal personality of the arrangement, A is not'' is corrected to read ''legal personality in Country X of the arrangement, A is not''.

5. On page 40999, column 2, § 1.894–1(d)(5), paragraph (i) of *Example 7.,* lines 11 and 12, the language ''liable to tax at the entity level of Country X and is not a resident within the meaning of'' is corrected to read ''liable to tax as a person at the entity level in Country X and is thus not a resident within the meaning of''.

6. On page 40999, column 2, § 1.894–1(d)(5), paragraph (ii) of *Example 7.,* line 9, the language ''is not considered a resident of Country X'' is corrected to read ''is not considered a person in Country X and thus not a resident of Country X''.

7. On page 40999, column 2, § 1.894–1(d)(5), paragraph (ii) of *Example 7.,* line 12, the language ''derive the income for purposes of the U.S.-'' is corrected to read ''derive the income as a resident of Country X for purposes of the U.S.-''.

8. On page 41000, column 1, § 1.894–1(d)(5), paragraph (i) of *Example 11.,* the last line of the paragraph, the language ''subject to tax by Country X.'' is corrected to read ''taxed by Country X.''.

9. On page 41000, column 2, § 1.894–1, after paragraph (d)(6), add a sentence at the end of paragraph (e) to read as follows:

§ 1.894–1 Income affected by treaty.

* * * * *

(e) * * * See paragraph (d)(6) of this section for applicability dates for paragraph (d) of this section.

10. On page 41000, column 2, a new amendatory instruction Par. 3. is added to read as follows: