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

■ 4. In paragraph (d) of § 558.4, in the ''Category II'' table, alphabetically add an entry for ''Zilpaterol'' to read as follows:

§ 558.4 Requirement of a medicated feed mill license.

* * * * *

(d) * * *

CATEGORY II

Drug	Assay limits percent[1] Type A	Type B maximum (100x)	Assay limits percent[1] Type B/C[2]
*	*	*	*
Zilpaterol	90–110	680 g/t (0.075%)	80–110/75–115

[1]Percent of labeled amount.

[2]Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limits, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make Type C medicated feed.

* * * * *

■ 5. Add § 558.665 to read as follows:

§ 558.665 Zilpaterol.

(a) *Specifications.* Type A medicated articles containing 21.77 grams (g) zilpaterol hydrochloride per pound.

(b) *Approvals.* See No. 057926 in § 510.600(c) of this chapter.

(c) *Tolerances.* See § 556.765 of this chapter.

(d)*Special considerations*—(1) Labeling of Type B and Type C cattle feeds shall bear the following:

(i) Do not allow horses or other equines access to feed containing zilpaterol.

(ii) Not for use in animals intended for breeding.

(iii) Do not use in veal calves.

(2) Type B Liquid Feeds can be manufactured containing 68 to 680 g zilpaterol hydrochloride/ton. The liquid Type B feeds must be maintained at a pH of 3.8 to 7.5. For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for not less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used. For liquid feeds stored in mechanical, air or other agitation-type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(3) Do not pellet medicated feeds containing zilpaterol.

(e) *Conditions of use in cattle*—(1) *Amount.* 6.8 g/ton of feed to provide 60 to 90 milligrams zilpaterol hydrochloride per head per day.

(2) *Indications for use.* For increased rate of weight gain, improved feed efficiency and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed.

(3) *Limitations.* Feed continuously as the sole ration during the last 20 to 40 days on feed. Withdrawal period: 3 days.

Dated: August 29, 2006.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. E6–14899 Filed 9–7–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use in Animal Feed; Oxytetracycline

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Phibro Animal Health. The supplemental NADA revises labeling of oxytetracycline Type A medicated article with the current genus for the causative bacteria for American foulbrood of honeybees.

DATES: This rule is effective September 8, 2006.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: *joan.gotthardt@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Phibro Animal Health, 65 Challenger Rd., 3d floor, Ridgefield Park, NJ 07660, filed a supplement to NADA 95–143 that provides for use of TERRAMYCIN 100MR (oxytetracycline dihydrate) Type A medicated article for treatment of various bacterial diseases of livestock. The supplemental NADA revises labeling with the current genus for the causative bacteria for American foulbrood of honeybees. The supplemental NADA is approved as of August 11, 2006, and the regulations in 21 CFR 558.450 are amended to reflect the approval.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

FDA has determined under § 25.33(a)(1) 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.

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 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 part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.450 [Amended]

■ 2. In § 558.450, in the table in paragraph (d)(1)(xiv) in the ''Indications for use'' column, remove ''*Bacillus*'' and add in its place ''*Paenibacillus*''.

Dated: August 30, 2006.

Steven D. Vaughn,

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

[FR Doc. E6–14898 Filed 9–7–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF STATE

22 CFR Part 181

RIN 1400–AC21

[Public Notice: 5527]

Publication, Coordination, and Reporting of International Agreements: Amendments

AGENCY: State Department.

ACTION: Final rule.

SUMMARY: The Department of State is updating the regulations implementing 1 U.S.C. 112a and 112b in order to reflect amendments to the statutes governing publication of U.S. international agreements and their transmittal to the Congress. It will not be publishing certain categories of international agreements in the compilation entitled ''United States Treaties and Other International Agreements'' or in the ''Treaties and Other International Acts Series.'' Further, the regulations are being amended to reflect adjustments to certain internal procedures within the State Department on the reporting of international agreements to Congress. Finally, the Department is adding a new requirement concerning procedures for consultation with the Secretary of State in the negotiation and conclusion of international agreements. Where an international agreement could reasonably require for its implementation the issuance of a significant domestic regulatory action, agencies proposing the agreement are to consult in a timely manner with the Office of Management and Budget (OMB), and the Department of State should confirm that timely consultations were undertaken.

DATES: *Effective Date:* This rule is effective October 10, 2006.

FOR FURTHER INFORMATION CONTACT: John Kim, Assistant Legal Adviser for Treaty Affairs, Office of the Legal Adviser, Department of State, Washington, DC 20520, 202–647–1660, or at *kimmjj@state.gov*.

SUPPLEMENTARY INFORMATION: Two statutes set forth the Secretary's unique role and important responsibilities in the area of publishing, coordinating, and reporting international agreements. Pursuant to 1 U.S.C. 112a, the Secretary of State is required to publish annually a compilation of all treaties and international agreements to which the United States is a party that were signed, proclaimed, or ''with reference to which any other final formality ha[d] been executed'' during the calendar year. The Secretary of State, however, may determine that certain categories of agreements should not be published if certain criteria are met. Any such determination must be published in the **Federal Register**.

Under the second statute, 1 U.S.C. 112b, the Secretary of State is required to transmit to the Congress the text of any international agreement other than a treaty to which the United States is a party as soon as practicable but no later than 60 days after it enters into force. Those agreements that the President determines should be classified are to be transmitted, not to Congress as a whole, but to the House Committee on International Relations (at that time called ''the House Committee on Foreign Affairs'') and to the Senate Foreign Relations Committee under an injunction of secrecy. The statute further recognizes the Secretary of State's special role in the negotiation and conclusion of all U.S. international agreements, providing that ''[n]otwithstanding any other provision of law, an international agreement may not be signed or otherwise concluded on behalf of the United States without prior consultation with the Secretary of State. Such consultation may encompass a class of agreements rather than a particular agreement.''

The Department of State has issued regulations to implement these statutory provisions. These regulations are codified in Part 181 of Chapter 22 of the Code of Federal Regulations (CFR). Congress has amended both 1 U.S.C. 112a and 1 U.S.C. 112b several times, most recently in section 7121 of the Intelligence Reform and Terrorism Prevention Act of 2004, Public Law 108–458 (Dec. 17, 2004). The State Department is amending sections of 22 CFR Part 181 in order to reflect (1) the changes made to 1 U.S.C. 112a and 112b in December 2004; (2) certain changes made to internal Departmental procedures; and (3) four additional categories of international agreements that meet the non-publication criteria of 1 U.S.C. 112a.

In addition, the Department is amending the procedures regarding the negotiation and conclusion of international agreements. These procedures are set forth in 22 CFR 181.4 and in the Circular 175 procedure referenced therein. In particular, if a proposed international agreement embodies a commitment that could reasonably be expected to require (for its implementation) the issuance of a ''significant regulatory action'' (as defined in section 3 of Executive Order 12866), the agency proposing the agreement shall consult in a timely manner with the OMB regarding such commitment. This amendment is aimed at ensuring that OMB is apprised of international commitments that may have a significant regulatory impact on domestic entities or persons prior to the negotiation or conclusion of the international agreement containing the commitment.

A proposed rule on these subjects was published in the **Federal Register** on May 18, 2006 (71 FR 28831), which contains a more detailed discussion. Only one comment was received on the proposed regulations. The comment supported the proposed amendment to the consultation procedures in 22 CFR 181.4(e) with respect to proposed international agreements that reasonably may result in a ''significant regulatory action.'' The commenter expressed the view that the amendment to the regulations would ensure a greater level of transparency in the negotiation and conclusion of international agreements that may lead to significant regulatory impacts on domestic U.S. entities.

Further, the comment made two recommendations relating to the implementation of the amendment once it was finalized. First, the commenter said that agencies should be required to consult with OMB at the earliest possible stage in the discussions of a possible international agreement. Second, the commenter requested that the State Department require agencies to publish a short notice in the **Federal Register** when consultation has been initiated with OMB, asking for public comment where appropriate. In the commenter's view, such a notice would ensure that the public and other interested agencies are made aware of consultations with OMB, thereby fostering the transparency of an agency's development of international agreements.

As there has been no objection to the proposed rule, the State Department will promulgate the final rule without change. The Department nevertheless has considered the commenter's suggestions. With respect to the first suggestion, the Department believes that the term ''timely'' is sufficient to indicate the need for agencies to consult with OMB at an appropriate stage in the discussions concerning proposed international agreements. The