

applicable to title XVI by section 1631(d)(1) of the Social Security Act;

(2) A tax refund to which a person is entitled to after notice to the Secretary of the Treasury under 31 U.S.C. § 3720A;

(3) By authorities provided under the Debt Collection Act of 1982, as amended, 31 U.S.C. 3711, to the extent applicable to debts arising under the Social Security Act; or

(4) Any combination of the foregoing.

(e) Matters that were raised or that could have been raised in a hearing before an administrative law judge or in an appeal to the United States Court of Appeals under sections 1129 or 1140 of the Social Security Act may not be raised as a defense in a civil action by the United States to collect a penalty and assessment, as applicable, under this part.

14. Section 498.129 is added to read as follows:

**§ 498.129 Notice to other agencies.**

As provided in section 1129 of the Social Security Act, when a determination to impose a penalty and assessment, as applicable, with respect to a physician or medical provider becomes final, the Office of the Inspector General will notify the Secretary of the final determination and the reasons therefore.

15. Section 498.132 is revised to read as follows:

**§ 498.132 Limitations.**

The Office of the Inspector General may initiate a proceeding in accordance with § 498.109(a) to determine whether to impose a penalty and assessment, as applicable—

(a) In cases brought under section 1129 of the Social Security Act, after receiving authorization from the Attorney General pursuant to procedures agreed upon by the Inspector General and the Attorney General; and

(b) Within 6 years from the date on which the violation was committed.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 558**

**New Animal Drugs; Change of Sponsor**

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the change of sponsor for 33 approved new animal drug applications (NADA's) from American Cyanamid Co. to Hoffmann-La Roche, Inc. In addition, the agency is amending its regulations to correct some errors. This action is being taken to clarify and improve the accuracy of the animal drug regulations.

**EFFECTIVE DATE:** April 24, 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:** American Cyanamid Co., Berdan Ave., Wayne, NJ 07470, has informed FDA that it has transferred ownership of, and all rights and interests in, the following approved NADA's to Hoffmann-La Roche, Inc., Nutley, NJ 07110-1199.

NADA no.	Ingredients
33-950 .....	Sulfamerazine.
35-688 .....	Chlortetracycline Calcium Complex, Penicillin G Procaine, Sulfamethazine
35-805 .....	Chlortetracycline Hydrochloride, Sulfamethazine.
36-361 .....	Chlortetracycline Calcium Complex, Ampromilium, Ethopabate, Sodium Sulfate.
41-647 .....	Sulfamethazine, Chlortetracycline Calcium Complex.
41-648 .....	Sulfamethazine, Chlortetracycline Calcium Complex.
41-649 .....	Sulfamethazine, Chlortetracycline Calcium Complex.
41-650 .....	Sulfamethazine, Chlortetracycline Calcium Complex.
41-651 .....	Sulfamethazine, Chlortetracycline Calcium Complex.
41-652 .....	Sulfamethazine, Chlortetracycline Calcium Complex.
41-653 .....	Sulfamethazine, Chlortetracycline Calcium Complex.
41-654 .....	Sulfamethazine, Chlortetracycline Calcium Complex.
46-920 .....	Bacitracin zinc.
48-486 .....	Robenidine Hydrochloride.
48-761 .....	Chlortetracycline Calcium Complex.
48-762 .....	Chlortetracycline Calcium Complex.
48-763 .....	Chlortetracycline Calcium Complex.
55-040 .....	Chlortetracycline Hydrochloride.

NADA no.	Ingredients
92-507 .....	Chlortetracycline Calcium Complex, Robenidine Hydrochloride.
93-372 .....	Chlortetracycline Hydrochloride.
95-546 .....	Robenidine Hydrochloride, Roxarsone.
96-933 .....	Bacitracin zinc, Robenidine Hydrochloride.
97-085 .....	Robenidine Hydrochloride, Bacitracin MD.
105-758 .....	Bacitracin zinc, Ampromilium, Ethopabate, Roxarsone.
114-794 .....	Bacitracin zinc, Ampromilium, Ethopabate.
121-553 .....	Monensin Sodium, Chlortetracycline Hydrochloride.
123-154 .....	Monensin Sodium, Bacitracin ZN, Roxarsone.
136-484 .....	Bacitracin zinc, Carbasone.
139-075 .....	Maduramicin ammonium.
139-190 .....	Bacitracin zinc, Salinomycin, Sodium Roxarsone.
139-235 .....	Bacitracin zinc, Salinomycin, Sodium Roxarsone.
140-859 .....	Chlortetracycline Calcium Complex, Salinomycin Sodium.
140-867 .....	Chlortetracycline Calcium Complex, Roxarsone, Salinomycin Sodium.

Accordingly, the agency is amending the regulations in part 558 (21 CFR part 558) to reflect the change of sponsor. FDA is also correcting some errors that have been incorporated into the agency's codified regulations. The errors in the regulations are as follows:

In § 558.95(b)(1)(xiii)(b) the reference to the limitations cited in (e)(1)(vii)(b) is incorrect; the correct cite is "paragraph (b)(1)(vii)(b) of this section". In § 558.355(b)(9) the cited reference "paragraphs (f)(1)(xv), (xvi), and (xvii)" incorrectly listed the sponsor, "(xvii)" should refer to sponsor 012799. The agency is correcting this error by removing "(xvii)" from § 558.355(b)(9) and adding sponsor 012799 to § 558.355(b)(10).

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

#### § 558.58 [Amended]

2. Section 558.58 *Amprolium and ethopabate* is amended in the table in paragraph (d)(1), in the entry for (iii), under the "Limitations" and the "Sponsor" columns by removing "010042" wherever it appears and adding in its place "000004".

#### § 558.78 [Amended]

3. Section 558.78 *Bacitracin zinc* is amended in paragraph (a)(2), and in the table in paragraph (d)(1) in the entries for (i), (ii), (v), and (vi) under the "Sponsor" column, and in paragraph (d)(2)(ii) by removing "010042" and adding in its place "000004".

#### § 558.95 [Amended]

4. Section 558.95 *Bambermycins* is amended in paragraph (b)(1)(xiii)(b) by removing "(e)(1)(vii)(b)" and adding in its place "(b)(1)(vii)(b)".

#### § 558.120 [Amended]

5. Section 558.120 *Carbarson* (not U.S.P.) is amended in paragraph (c)(1)(iii)(b) by removing "010042" and adding in its place "000004".

#### § 558.128 [Amended]

6. Section 558.128 *Chlortetracycline* is amended in paragraph (a) by removing "010042" and adding in its place "000004".

#### § 558.145 [Amended]

7. Section 558.145 *Chlortetracycline, procaine penicillin, and sulfamethazine* is amended in paragraphs (a)(1) and (a)(2) by removing "010042" and adding in its place "000004".

#### § 558.340 [Amended]

8. Section 558.340 *Maduramicin ammonium* is amended in paragraph (a) by removing "010042" and adding in its place "000004".

#### § 558.355 [Amended]

9. Section 558.355 is amended in paragraphs (b)(8), (b)(9), (f)(1)(iv)(b), (f)(1)(v)(b), (f)(1)(xiv)(b), (f)(1)(xv)(b), and (f)(1)(xvi)(b) by removing "010042" and adding in its place "000004", in paragraph (b)(9) by removing " (xvi), and (xvii)" and adding in its place "and (xvi)", and by adding paragraph (b)(10) to read as follows:

#### § 558.355 Monensin.

\* \* \* \* \*

(b) \* \* \*

(10) To 012799: 45 and 60 grams per pound, as monensin sodium, paragraph (f)(1)(xvii) of this section.

\* \* \* \* \*

#### § 558.515 [Amended]

10. Section 558.515 *Robenidine hydrochloride* is amended in paragraphs (a), (d)(1)(iii)(b), (d)(1)(iv)(b), and (d)(1)(v)(b) by removing "010042" and adding in its place "000004" and in paragraph (d)(1)(vi)(b) by removing "No. 011716" and adding in its place "Nos. 000004 and 011716".

#### § 558.550 [Amended]

11. Section 558.550 *Salinomycin* is amended in paragraphs (b)(1)(vii)(c), (b)(1)(ix)(c), (b)(1)(xv)(c), and (b)(1)(xvi)(c) by removing "010042" and adding in its place "000004".

#### § 558.582 [Amended]

12. Section 558.582 *Sulfamerazine* is amended in paragraph (a) by removing "010042" and adding in its place "000004".

Dated: April 4, 1996.

Robert C. Livingston,  
Director, Office of New Animal Drug  
Evaluation, Center for Veterinary Medicine.  
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## DEPARTMENT OF THE INTERIOR

### Bureau of Indian Affairs

#### 25 CFR Part 151

[1076-AD65]

#### Land Acquisitions

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Final Rule.

**SUMMARY:** This rule establishes a 30-day waiting period after final administrative decisions to acquire land into trust under the Indian Reorganization Act and other federal statutes. The Department is establishing this waiting period so that parties seeking review of final decisions by the Interior Board of Indian Appeals or of decisions of the Assistant Secretary-Indian Affairs, will have notice of administrative decisions to take land into trust before title is actually transferred. This notice allows interested parties to seek judicial or other review under the Administrative Procedure Act and applicable regulations.

**EFFECTIVE DATE:** April 24, 1996.

**FOR FURTHER INFORMATION CONTACT:** Mary Jane Sheppard, Staff Attorney, Office of the Solicitor, Division of Indian Affairs, Room 6456, Main Interior Building, 1849 C Street, NW, Washington, DC 20240; Telephone (202) 208-6260.

**SUPPLEMENTARY INFORMATION:** On July 15, 1991, the proposed rule for off-reservation land acquisitions for Indian tribes was published in the Federal Register (56 FR 32278-32280). On June 23, 1995, the final rule was published at 60 FR 32878. That rulemaking supplemented the existing regulations in part 151. This procedural rule adds a subsection to existing 25 CFR 151.12, Action on requests.

#### Background

In response to a recent court decision, *State of South Dakota v. U.S. Department of the Interior*, 69 F.3d 878 (8th Cir. 1995), the Department of the Interior is establishing a procedure to ensure the opportunity for judicial review of administrative decisions to acquire title to lands in trust for Indian tribes and individual Indians under section 5 of the Indian Reorganization Act (IRA) (Pub. L. 73-383, 48 Stat. 984-988, 25 U.S.C. 465). Following consideration of the factors in the current regulations and completion of the title examination, the Department, through Federal Register notice, or other notice to affected members of the public, will announce any final administrative determination to take land in trust. The Secretary will not acquire title to the land in trust until at least 30 days after publication of the announcement. This procedure permits judicial review before transfer of title to the United States. The Quiet Title Act (QTA), 28 U.S.C. 2409a, precludes judicial review after the United States acquires title. See, e.g., *United States v. Mottaz*, 476 U.S. 834 (1986); *North Dakota v. Block*, 461 U.S. 273 (1983); *Florida v. Department of Interior*, 768 F.2d 1248 (11th Cir. 1985).

Section 5 of the IRA authorizes the Secretary to acquire land in trust for Indians and Indian tribes: (1) Within or adjacent to an Indian reservation; or (2) for purposes of facilitating tribal self-determination, economic development, or Indian housing. *State of South Dakota*, a case involving an off-reservation trust land acquisition, held Section 5 of the IRA unconstitutional on the ground that it violates the nondelegation doctrine. The court's decision was based in substantial part on the understanding that judicial review is not available to challenge the Secretary's action. The court noted that "judicial review is a factor weighing in favor of upholding a statute against a nondelegation challenge." This rule ensures that such review is available before formal conveyance of title to land to the United States, when the QTA's bar to judicial review becomes operative. Judicial review is available