20 and 514.11(e)(2)(iii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 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 Subject in 21 CFR Part 520

Animal drugs.

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM
NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:


§520.1660d [Amended]

2. Section 520.1660d Oxytetracycline hydrochloride soluble powder is amended in paragraph (d)(1)(iii)(C) by removing “Nos. 000069 and 059130” and by adding in its place “No. 059130 and zero days those products sponsored by No. 000069”.


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

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 Feeds; Lasalocid and Bacitracin Zinc

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 new animal drug application (NADA) filed by Alpharma, Inc. The NADA provides for use of approved lasalocid and bacitracin zinc Type A medicated articles to make two-way combination drug Type C medicated feeds used for prevention of coccidiosis, increased rate of weight gain, and improved feed efficiency in broiler chickens.

DATES: This rule is effective May 29, 2001.

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–1600.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141–083 that provides for use of Avatec® (90.7 grams per pound (g/lb) lasalocid as lasalocid sodium) and Baciferm® (50 g/lb bacitracin zinc) Type A medicated articles to make two-way combination drug Type C medicated chicken feeds. The combination Type C medicated feeds are used for prevention of coccidiosis caused by Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati, and E. maxima, and for increased rate of weight gain and improved feed efficiency in broiler chickens. The NADA is approved as of April 18, 2001, and the regulations are amended in 21 CFR 558.311 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FDA has determined under 21 CFR 25.33(a)(2) 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:


2. Section 558.311 is amended in paragraph (e)(1) in the table by redesignating paragraphs (e)(1)(xii) through (e)(1)(xvi) as paragraphs (e)(1)(xii) through (e)(1)(xvii), respectively, and by adding new paragraph (e)(1)(xiii) to read as follows:

§558.311 Lasalocid.

* * * *

(e) * * *

(1) * * *

(Lasalocid) 046573

Feed continuously as sole ration. Bacitracin zinc and lasalocid sodium as provided by No. 046573 in §510.600(c) of this chapter.

(x) 68 (0.0075 pct) to 113 (0.0125 pct) Bacitracin zinc 4 to 50.

Broiler chickens. For prevention of coccidiosis caused by Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati, and E. maxima, and for increased rate of weight gain and improved feed efficiency.

* * * *

(xii) 100 (0.0125)

Feed continuously as sole ration. For prevention of coccidiosis caused by Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati, and E. maxima.
DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 70

[T.D. ATF–450 ]

RIN 1512–AC19

Delegation of Authority

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Treasury.

ACTION: Treasury decision, final rule.

SUMMARY: This final rule places most ATF authorities contained in its Procedure and Administration regulations with the “appropriate ATF officer” and requires that persons file documents related to these regulations with the “appropriate ATF officer” or, in accordance with the instructions on the ATF form, file with the ATF officer with whom they must be filed. In this final rule, ATF also believes these multiple delegation instruments complicate and hinder the task of determining which ATF officer is authorized to perform a particular function. ATF also believes that the instrument reflecting such delegation documents must be reviewed and amended as necessary.

This final rule amends certain of these authorities to appropriate subordinate officers by way of various means, including by regulation, ATF delegation orders, regional directives, or similar delegation documents. As a result, to ascertain what particular officer is authorized to perform a particular function under such provisions, each of these various delegation instruments must be consulted. Similarly, each time a delegation of authority is revoked or redelegated, each of the delegation documents must be reviewed and amended as necessary.

Accordingly, this final rule rescinds delegations. Also, this final rule eliminates the references to an ATF region, which was previously delegated and made available as specified in this rule. Through this order, the Director has delegated most of the authorities to the appropriate ATF officers and specified the ATF officers with whom applications, notices and other reports, which are not ATF forms, are filed. In addition, this final rule corrects some typographical errors and updates the disclosure provisions.

EFFECTIVE DATE: This rule is effective May 29, 2001.

FOR FURTHER INFORMATION CONTACT: Robert Ruhf, Regulations Division, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue NW., Washington, DC 20226 (telephone 202–267–8210 or e-mail to acltob@atfhq.atf.treas.gov).

SUPPLEMENTAL INFORMATION:

Delegations of Authority

Pursuant to Treasury Order 120–01 (formerly 221), dated June 6, 1972, and 120–03, dated November 5, 1990, the Secretary of the Treasury delegated to the Director of the Bureau of Alcohol, Tobacco and Firearms (ATF), the authority to enforce, among other laws, the provisions of section 4181 of chapter 32 and chapters 51, 52 and 53 of the Internal Revenue Code of 1986 (IRC) and the Federal Alcohol Administration (FAA) Act. The Director has subsequently redelegated certain of these authorities to appropriate subordinate officers by way of various means, including by regulation, ATF delegation orders, regional directives, or similar delegation documents. As a result, to ascertain what particular officer is authorized to perform a particular function under such provisions, each of these various delegation instruments must be consulted. Similarly, each time a delegation of authority is revoked or redelegated, each of the delegation documents must be reviewed and amended as necessary.

ATF has determined that this multiplicity of delegation instruments complicates and hinders the task of determining which ATF officer is authorized to perform a particular function. ATF also believes that the instrument reflecting such delegation documents must be reviewed and amended as necessary.

Accordingly, this final rule rescinds all authorities of the Director in part 70 that were previously delegated and places those authorities with the “appropriate ATF officer.” Most of the authorities of the Director that were not previously delegated are also placed with the “appropriate ATF officer.” Along with this final rule, ATF is publishing ATF Order 1130.19, Delegation Order—Delegation of the Director’s Authorities in 27 CFR Part 70, Procedure and administration, which delegates certain of these authorities to the appropriate organizational level. The effect of these changes is to consolidate all delegations of authority in part 70 into one delegation instrument. This action both simplifies the process for determining what ATF officer is authorized to perform a particular function and facilitates the updating of delegations in the future. As a result, delegations of authority will be reflected in a more timely and user-friendly manner.

In addition, this final rule also eliminates all references in the regulations that identify the ATF officer with whom an ATF form is filed. This is because ATF forms will indicate the officer with whom they must be filed. Similarly, this final rule also amends part 70 to provide that the submission of documents other than ATF forms (such as letterhead applications, notices filed with the “appropriate ATF officer” identified in ATF Order 1130.19. These changes will facilitate the identification of the officer with whom forms and other required submissions are filed.

This final rule eliminates all references to an obsolete ATF publication, corrects references to other sections of regulations in §70.253(b)(1) and (2) and in §70.438, corrects §70.224 that refers to the general statute of limitations on collecting an assessment in accordance with 26 U.S.C. 6502, and corrects §70.482(e) by raising the amount for which a Chief Counsel’s opinion need not be filed for offers-in-compromise in accordance with 26 U.S.C. 7122(b).

Disclosure Changes

In §70.802 we have eliminated the card index record of permits, which is no longer maintained, and made appropriate changes to the information available or provided by ATF because of the disclosure restrictions of 26 U.S.C. 6103.