

Issued in Kansas City, MO, on November 4, 1997.

**Herman J. Lyons, Jr.,**

*Manager, Air Traffic Division, Central Region.*

[FR Doc. 97-29833 Filed 11-12-97; 8:45 am]

BILLING CODE 4910-13-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 510 and 558

#### New Animal Drugs for Use in Animal Feeds; Salinomycin 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 two abbreviated new animal drug applications (ANADA's) filed by Alpharma Inc. The ANADA's provide for using approved salinomycin and bacitracin zinc Type A medicated articles to make Type C medicated broiler chicken feeds used for the prevention of coccidiosis and for increased rate of weight gain. This document is also amending the animal drug regulations to reflect the correct sponsor name for Alpharma Inc.

**EFFECTIVE DATE:** November 13, 1997.

**FOR FURTHER INFORMATION CONTACT:**

Jeffrey M. Gilbert, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1602.

**SUPPLEMENTARY INFORMATION:** Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, is sponsor of ANADA's 200-204 and 200-210 that provide for combining approved salinomycin and bacitracin zinc Type A medicated articles to make Type C medicated broiler feeds containing salinomycin 40 to 60 grams per ton (g/t) and bacitracin zinc 10 to 50 g/t. The Type C medicated feed is used for the 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.

ANADA 200-204, filed by Alpharma Inc., provides for using approved BIO-COX® (Hoffmann-LaRoche Inc.'s salinomycin NADA 128-686) and ALBAC® (Alpharma Inc.'s bacitracin zinc ANADA 200-223) Type A medicated articles to make the combination drug Type C medicated feeds. ANADA 200-210, also filed by

Alpharma Inc., provides for using approved SACOX® (Hoechst-Roussel Vet's salinomycin ANADA 200-075) and ALBAC® (Alpharma Inc.'s bacitracin zinc ANADA 200-223) Type A medicated articles to make the combination drug Type C medicated feeds.

Alpharma Inc.'s ANADA 200-204 is approved as a generic copy of Hoffmann-LaRoche, Inc.'s NADA 139-235. Alpharma Inc.'s ANADA 200-210 is approved as a generic copy of Hoechst-Roussel Vet's ANADA 200-089. The ANADA's are approved as of September 19, 1997, and the regulations are amended in 21 CFR

558.550(b)(1)(vii)(c) to reflect the approvals. The basis for approval is discussed in the freedom of information summaries.

FDA is also amending the animal drug regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the correct firm name for Alpharma Inc.

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 these applications may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

FDA has determined under 21 CFR 25.33(a)(1) that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### List of Subjects

##### 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

##### 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 parts 510 and 558 are amended as follows:

#### PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

#### § 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) in the entry for "ALPHARMA INC." and in paragraph (c)(2) in the entry for "046573" by removing the name "ALPHARMA INC." and adding in its place "Alpharma Inc."

#### 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.

#### § 558.550 [Amended]

4. Section 558.550 *Salinomycin* is amended in paragraph (b)(1)(vii)(c) by removing "No. 000004" and adding in its place "Nos. 000004 and 046573".

Dated: October 30, 1997.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 97-29905 Filed 11-12-97; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF THE TREASURY

### Departmental Offices

#### 31 CFR Part 1

#### Privacy Act of 1974; Implementation

**AGENCY:** Departmental Offices, Treasury.

**ACTION:** Final Rule.

**SUMMARY:** In accordance with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a, the Department of the Treasury gives notice of an amendment to exempt the system of records entitled, "Integrated Data Retrieval System (IDRS) Security Files—Treasury/IRS 34.018," from certain provisions of the Privacy Act.

**EFFECTIVE DATE:** November 13, 1997.

**FOR FURTHER INFORMATION CONTACT:**

Michael Sincavage, Director, 6103/ Privacy Operations, Governmental Liaison & Disclosure, Internal Revenue Service at (202) 622-6240.

**SUPPLEMENTARY INFORMATION:** The Department of the Treasury published a notice of a proposed rule exempting a system of records from certain provisions of the Privacy Act of 1974, as Amended, at 60 FR 40797, dated August 10, 1995. The Internal Revenue Service published an alteration to the system notice on July 31, 1995, at 60 FR 30972.

Under 5 U.S.C. 552a(k)(2), the head of an agency may promulgate rules to exempt any system of records within the agency from certain provisions of the

Privacy Act of 1974 if the system is investigatory material compiled for law enforcement purposes. The Internal Revenue Service has as its principal function enforcement of the tax law of the United States. System of records Treasury/IRS 34.018—Integrated Data Retrieval System Security Files, contains records that enable the Service to investigate and monitor the activities of its employees to ensure the protection and confidentiality of tax return information. The information in this system is used in investigations relating to unauthorized use of the Integrated Data Retrieval Files.

The proposed rule requested that public comments be sent to the Director, Office of Disclosure, Internal Revenue Service no later than September 11, 1995. No comments pertaining to the proposed rule were received by the Office of Disclosure. Accordingly, the Department of the Treasury is hereby giving notice that the system of records entitled, "Integrated Data Retrieval System (IDRS) Security Files—Treasury/IRS 34.018," is exempt from certain provisions of the Privacy Act. The following are the reasons why certain systems of records maintained by the Internal Revenue Service are exempt pursuant to 5 U.S.C. 552a(k)(2) of the Privacy Act of 1974.

(1) 5 U.S.C. 552a(c)(3). This provision of the Privacy Act provides for the release of the disclosure accounting required by 5 U.S.C. 552a(c)(1) and (2) to the individual named in the record at his request. The reasons for exempting systems of records from the foregoing provision are as follows:

- (i) The release of disclosure accounting would put the subject of an investigation on notice of the existence of an investigation and that such person is the subject of that investigation;
- (ii) Such release would provide the subject of an investigation with an accurate accounting of the date, nature, and purpose of each disclosure and the name and address of the person or agency to whom the disclosure is made. The release of such information to the subject of an investigation would provide the subject with significant information concerning the nature of the investigation and could result in the altering or destruction of documentary evidence, the improper influencing of witnesses, and other activities that could impede or compromise the investigation. In the case of a delinquent account, such release might enable the subject of the investigation to dissipate assets before levy;
- (iii) Release to the individual of the disclosure accounting would alert the individual as to which agencies were

investigating this person and the scope of the investigation, and could aid the individual in impeding or compromising investigations by those agencies.

(2) 5 U.S.C. 552a(d)(1),(2),(3), and (4), (e)(4)(G) and (H) and (f). These provisions of the Privacy Act relate to an individual's right to notification of the existence of records pertaining to such individual; requirements for identifying an individual who requests access to records; the agency procedures relating to access to records and the contest of the information contained in such records; and the civil remedies available to the individual in the event of adverse determinations by an agency concerning access to or amendment of information contained in such record systems. The reasons for exempting systems of records from the foregoing provisions are as follows: To notify an individual at the individual's request of the existence of records in an investigative file pertaining to such individual or to grant access to an investigative file could interfere with investigative and enforcement proceedings; deprive co-defendants of a right to a fair trial or an impartial adjudication; constitute an unwarranted invasion of the personal privacy of others, disclose the identity of confidential sources and reveal confidential information supplied by such sources; and disclose investigative techniques and procedures.

(3) 5 U.S.C. 552a(e)(4)(I). This provision of the Privacy Act requires the publication of the categories of sources of records in each system of records. In cases where an exemption from this provision has been claimed, the reasons are as follows:

- (i) Revealing categories of sources of information could disclose investigative techniques and procedures;
  - (ii) Revealing categories of sources of information could cause sources who supply information to investigators to refrain from giving such information because of fear of reprisal, or fear of breach of promises of anonymity and confidentiality.
- (4) 5 U.S.C. 552a(e)(1). This provision of the Privacy Act requires each agency to maintain in its records only such information about an individual as is relevant and necessary to accomplish a purpose of the agency required to be accomplished by statute or executive order. The reasons for exempting systems of records from the foregoing provisions are as follows:
- (i) The Internal Revenue Service will limit its inquiries to information which is necessary for the enforcement and administration of tax laws. However, an

exemption from the foregoing provision is needed because, particularly in the early stages of a tax audit or other investigation, it is not possible to determine the relevance or necessity of specific information.

(ii) Relevance and necessity are questions of judgement and timing. What appears relevant and necessary when collected may subsequently be determined to be irrelevant or unnecessary. It is only after the information is evaluated that the relevance and necessity of such information can be established with certainty.

(iii) When information is received by the Internal Revenue Service relating to violations of law within the jurisdiction of other agencies, the Service processes this information through Service systems in order to forward the material to the appropriate agencies.

As required by Executive Order 12866, it has been determined that this final rule is not a significant regulatory action and, therefore, does not require a regulatory impact analysis.

Pursuant to the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601–612, it is hereby certified that this rule will not have significant economic impact on a substantial number of small entities. The final rule imposes no duties or obligations on small entities.

In accordance with the provisions of the Paperwork Reduction Act of 1995, the Department of the Treasury has determined that this rule will not impose new record keeping, application, reporting, or other types of information collection requirements.

**List of Subjects in 31 CFR Part 1**

Privacy.  
Part 1 of Title 31 of the Code of Federal Regulations is amended as follows:  
1. The authority citation for Part 1 continues to read as follows:  
**Authority:** 5 U.S.C. 301 and 31 U.S.C. 321. Subpart A also issued under 5 U.S.C. 552 as amended. Subpart C also issued under 5 U.S.C. 552a.

**§ 1.36 [Amended]**

2. Section 1.36 of Subpart C is amended by adding the following text in numerical order under the heading THE INTERNAL REVENUE SERVICE:

* * * * *				
(b)	*	*	*	*
(1)	*	*	*	
Name of System				No.
* * * * *				*
Integrated Data Reporting System (IDRS) Security Files .....				34.018

Name of System	No.
* * *	*
* * *	*

Dated: October 3, 1997.

**Alex Rodriguez,**

*Deputy Assistant Secretary (Administration)*

[FR Doc. 97-29794 Filed 11-12-97; 8:45 am]

Billing Code: 4830-01-F

## DEPARTMENT OF VETERANS AFFAIRS

### 38 CFR Part 17

RIN 2900-A184

#### Grants to States for Construction or Acquisition of State Home Facilities

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Final rule.

**SUMMARY:** This document amends the "Medical" regulations regarding applications for grants to States for the construction or acquisition of State home facilities. VA awards grants based on a priority ranking system. Usually, the higher priority applications deplete the available funding to the extent that the lowest ranking application to be offered funding is offered only a partial grant. This final rule provides that if the lowest ranking grant application receives only a partial grant in a fiscal year and if such grant award is partial solely because VA has insufficient funds for a full grant, the application would be placed at the top of the list within its priority group for the next fiscal year. Often applicants are hesitant to accept a partial grant because of the uncertainty of receiving an additional grant the next fiscal year. This final rule will encourage States to accept a partial grant by creating the likelihood that the State would receive an additional grant in the subsequent fiscal year. Accordingly, this will help ensure that VA would be able to award grants to higher priority applicants that might otherwise reject partial funding.

Also, this final rule provides that the applicant receiving partial funding and receiving priority as proposed will not be required to submit a second application for additional funds in the subsequent fiscal year, but could be required to update information already submitted. The first application would

normally be adequate because the grant award in the second fiscal year would be for the same project which received the partial grant award.

Further, the final rule provides that the total amount awarded for the application may not exceed 65 percent of the total cost of the project as determined at the time of the second grant award for that grant application. This is consistent with the statutory requirement that limits grant awards to no more than 65 percent of the estimated cost construction or acquisition.

**DATES:** *Effective Date:* December 15, 1997.

**FOR FURTHER INFORMATION CONTACT:** Ms. Kathleen Greve, Geriatrics and Extended Care Strategic Healthcare Group, (202) 273-8534.

**SUPPLEMENTARY INFORMATION:** In a document published in the **Federal Register** on July 29, 1997 (62 FR 40492), VA proposed to amend the "Medical" regulations in 38 CFR part 17 as set forth in the SUMMARY portion of this document. The document provided a 60-day comment period, which ended on September 29, 1997. Three commentators submitted comments, all of whom expressed full approval for the provisions of the proposed rule.

Based on the rationale set forth in the proposed rule and this document, the provisions of the proposed rule are adopted as a final rule without change.

The Secretary hereby certifies that the adoption of this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601-612. The rule will affect grants to States and will not directly affect small entities.

Therefore, pursuant to 5 U.S.C. 605(b), this rule is exempt from the initial and final regulatory flexibility analyses requirements of secs. 603 and 604.

The Catalog of Federal Domestic Assistance program number for this document is 64.005.

#### List of Subjects in 38 CFR Part 17

Administrative practice and procedure. Alcohol abuse, Alcoholism, Claims, Drug abuse, Foreign relations, Government contracts, Grant programs-health, Grant programs-veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing homes,

Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Approved: November 3, 1997.

**Hershel W. Gober,**

*Acting Secretary of Veterans Affairs.*

For the reasons set forth above, 38 CFR part 17 is amended as set forth below:

#### PART 17—MEDICAL

1. The authority citation for part 17 continues to read as follow:

**Authority:** 38 U.S.C. 501, 1721, unless otherwise noted.

2. In § 17.212, paragraph (d) is added and the authority citation for the section is revised to read as follows:

#### § 17.212 Scope of grants program.

\* \* \* \* \*

(d)(1) Notwithstanding paragraph (c) of this section and the provisions for ranking projects within a priority group in § 17.213(c)(3)(i), the Secretary shall give an application first priority within the priority group to which it is assigned on the list of projects established under § 17.213(d) for the next fiscal year if:

(i) the State has accepted a grant for that application as of August 15 of the current fiscal year that is less than the amount that the Secretary would have awarded if VA had sufficient grant funds to award the grant in such amount in that fiscal year; and

(ii) the application is the lowest ranking application on the priority list for the current fiscal year for which grant funds are available as of August 15 of that year.

(2) The Secretary shall not require a State to submit a second grant application for a project which receives priority under paragraph (d)(1) of this section but may require the State to update information already submitted in the application for the project. The Secretary shall determine the amount of a second grant at the time of the award of that grant. In no case shall the total amount awarded for the application exceed 65 percent of the total cost of the project as determined at the time of the second grant award for that grant application.

(Authority: 38 U.S.C. 8135(b))

[FR Doc. 97-29788 Filed 11-12-97; 8:45 am]

BILLING CODE 8320-01-M