coli infections susceptible to such treatment.

Alpharma Inc.'s ANADA 200–259 is approved as a generic copy of Hoechst-Roussel's ANADA 200–091. Alpharma Inc.'s ANADA 200–260 is approved as a generic copy of Roche Vitamins, Inc.'s NADA 140–867. Alpharma Inc.'s ANADA's 200–259 and 200–260 are approved as of September 21, 1998, and 21 CFR 558.550(a)(3) is added and paragraph (d)(1)(xv) is amended to reflect the approvals. The basis for approval is discussed in the freedom of information summaries.

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.

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.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the 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.

2. Section 558.550 is amended by revising paragraph (a) and the last sentence in paragraph (d)(1)(xv)(*c*) to read as follows:

§ 558.550 Salinomycin.

(a) *Approvals.* Type A medicated articles containing 30 or 60 grams of salinomycin activity per pound (as salinomycin sodium biomass) as follows:

(1) To 063238 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(2) To 012799 for use as in paragraphs (d)(1)(i), (d)(1)(iii) through (d)(1)(xvi), and (d)(3)(i) through (d)(3)(iii) of this section.

(3) To 046573 for use as in paragraph (d)(1)(xv) of this section.

* * * * *

(d) * * *

(1) * * *

(xv) * * *

(*c*) * * * Chlortetracycline as provided by Nos. 046573 and 063238 and roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.

* * * * *

Dated: November 12, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–31575 Filed 11–25–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Chlortetracycline

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 Roche Vitamins, Inc. The supplemental NADA provides for a zero-day withdrawal period for use of 500 grams per ton (g/t) chlortetracycline (CTC) Type C medicated chicken feeds.

EFFECTIVE DATE: November 27, 1998.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0212.

SUPPLEMENTARY INFORMATION: Roche Vitamins, Inc., 45 Waterview Blvd., Parsippany, NJ 07054–1298, filed supplemental NADA 48–761 that provides for use of Aureomycin® (CTC) Type A medicated articles to make 500 g/t CTC Type C chicken feeds. The 500 g/t CTC Type C chicken feeds are used for 5 days for reduction of mortality due to CTC susceptible *Escherichia coli* infections. The supplement provides for reducing the 24-hour withdrawal period to a zero-day slaughter withdrawal period. The supplemental NADA is approved as of October 26, 1998, and the regulations in 21 CFR 558.128(d)(1)(viii) are amended 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 supplemental 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)(3) 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.

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.

§ 558.128 [Amended]

2. Section 558.128 *Chlortetracycline* is amended in the table in paragraph (d)(1) in the entry for ''(viii) 500 g/ton'' under the column ''Limitations'' by removing the phrase ''; withdraw 24 h prior to slaughter''.

Dated: November 16, 1998.

Andrew J. Beaulieu,

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

[FR Doc. 98–31572 Filed 11–25–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 807

[Docket No. 98N–0520]

Medical Devices; Establishment Registration and Device Listing for Manufacturers and Distributors of Devices; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a direct final rule that appeared in the

Federal Register of September 29, 1998 (63 FR 51825). The document amended certain regulations governing establishment registration and device listing by domestic distributors. The document was published with an error. This document corrects that error.

EFFECTIVE DATE: February 11, 1999.

FOR FURTHER INFORMATION CONTACT: Walter W. Morgenstern, Center for Devices and Radiological Health (HFZ–305), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4699.

SUPPLEMENTARY INFORMATION: In FR Docs. 98–25796 appearing on page 51825 in the **Federal Register** of September 29, 1998, the following correction is made:

On page 51826, in the third column, amendatory paragraph four is corrected to read:

4. Section 807.20 is amended by revising paragraph (a)(4), by removing paragraph (c), by redesignating paragraph (d) as paragraph (c), and by adding paragraph (c)(3) to read as follows:

* * * * *

Dated: November 19, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–31569 Filed 11–25–98; 8:45 am]

BILLING CODE 4160–01–F

LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 251

[Docket No. RM 98–4 CARP]

Digital Performance Right in Sound Recordings and Ephemeral Recordings

AGENCY: Copyright Office, Library of Congress.

ACTION: Final rule and initiation of voluntary negotiation period.

SUMMARY: The Copyright Office is initiating the six-month voluntary negotiation periods, as required by the Digital Millennium Copyright Act of 1998, for negotiating terms and rates for two compulsory licenses, which in one case, allows public performances of sound recordings by means of eligible nonsubscription transmissions and by new subscription services, and in the second instance, allows the making of an ephemeral phonorecord of a sound recording in furtherance of making a permitted public performance of the sound recording. In addition, the Office is adopting procedural regulations to implement the Digital Millennium Copyright Act of 1998.

EFFECTIVE DATES: The effective date of the regulation is December 28, 1998. The effective date of the initiation of the six-month voluntary negotiation periods is November 27, 1998.

ADDRESSES: Copies of voluntary license agreements and petitions, if sent by mail, should be addressed to: Copyright Arbitration Royalty Panel (CARP), P.O. Box 70977, Southwest Station, Washington, DC 20024. If hand delivered, they should be brought to: Office of the General Counsel, James Madison Memorial Building, Room LM–403, First and Independence Avenue, SE, Washington, DC 20559–6000.

FOR FURTHER INFORMATION: David O. Carson, General Counsel, or Tanya M. Sandros, Attorney Advisor, Copyright Arbitration Royalty Panel, P.O. Box 70977, Southwest Station, Washington, D.C. 20024. Telephone (202) 707–8380 or Telefax (202) 707–8366.

SUPPLEMENTARY INFORMATION: On October 28, 1998, the President signed into law the ''Digital Millennium Copyright Act of 1998'' (''DMCA'' or ''Act''). Public Law 105–304. Among other things, the DMCA amends sections 112 and 114 of the Copyright Act, title 17 of the United States Code, to create a new license, governing the making of an ephemeral recording of a sound recording, and to expand another to facilitate the public performance of sound recordings by means of certain audio transmissions. *See* 17 U.S.C. 112(e)(1) and 114(d)(2). In amending these sections, Congress sought to ''first, further a stated objective of Congress when it passed the Digital Performance Right in Sound Recordings Act of 1995 (DPRA) to ensure that recording artists and record companies will be protected as new technologies affect the ways in which their creative works are used; and second, to create fair and efficient licensing mechanisms that address the complex issues facing copyright owners and copyright users as a result of the rapid growth of digital audio services.'' H.R. Conf. Rep. No. 105–796, at 79–80 (1998).

In enacting the Digital Performance Right in Sound Recordings Act of 1995 (DPRA), Pub. L. 104–39, Congress created an exclusive right for copyright owners of sound recordings, subject to certain limitations, to perform publicly the sound recordings by means of certain digital audio transmissions. Among the limitations on the performance was the creation of a new compulsory license for nonexempt, noninteractive, digital subscription transmissions. The DMCA expands this license to allow a nonexempt eligible nonsubscription transmission and a nonexempt transmission by a preexisting satellite digital audio radio service to perform publicly a sound recording in accordance with the terms and rates of the statutory license. 17 U.S.C. 114(a).

An ''eligible nonsubscription transmission'' is a noninteractive, digital audio transmission which, as the name implies, does not require a subscription for receiving the transmission. The transmission must also be made as part of a service that provides audio programming consisting in whole or in part of performances of sound recordings which purpose is to provide audio or entertainment programming, but not to sell, advertise, or promote particular goods or services. A ''preexisting satellite digital audio radio service'' is a subscription digital audio radio service that received a satellite digital audio radio service license issued by the Federal Communications Commission on or before July 31, 1998. *See* 17 U.S.C. 114(j)(6) and (10). Only two known entities, CD Radio and American Mobile Radio Corporation, qualify under the statutory definition as preexisting satellite digital audio radio services.

In addition to expanding the current 114 license, the DMCA creates a new statutory license for the making of an ''ephemeral recording'' of a sound recording by certain transmitting organizations. The new statutory license allows entities that transmit performances of sound recordings to business establishments, pursuant to the limitations set forth in section 114(d)(1)(C)(iv), to make an ephemeral recording of a sound recording for purposes of a later transmission. The new license also provides a means by which a transmitting entity with a statutory license under section 114(f) can make more than the one phonorecord specified in section 112(a). 17 U.S.C. 112(e).

Determination of Reasonable Terms and Rates

The statutory scheme for establishing reasonable terms and rates is the same for both licenses. The terms and rates for the two new statutory licenses may be determined by voluntary agreement among the affected parties, or if necessary, through compulsory arbitration conducted pursuant to Chapter 8 of the Copyright Act. Because the DMCA does not establish reasonable rates and terms for either the new section 112 or the expanded section 114 license, the statute requires the Librarian of Congress to initiate a