(g)(3)(i) and (g)(3)(ii) of this section, and the documentation described in paragraphs (g)(3)(iii) and (g)(3)(iv) of this section.

(viii) *Documentation required where the claimant is the legal assignee of an eligible manufacturer's wool duty refund claim rights.* To file a wool duty refund claim where the claimant is the legal assignee of the existing wool duty refund claim rights of an eligible manufacturer described in paragraphs (f)(1), (f)(2) or (f)(3) of this section, the facts of such legal assignation, and the identity of all affected parties, must be submitted to Customs in a written attachment to the claim, and additional substantiating documentation must be available to Custom upon request. Only those assignees that substantiate, to Customs satisfaction, the terms and legality of the assignation will be eligible to claim a wool duty refund.

(h) *Wool duty refund claim processing procedures.* Upon receipt of a timely and complete wool duty refund claim filed pursuant to the terms of this section, Customs will determine the liquidation status of the entry summaries used to substantiate the claim. No duty refund will be issued to a claimant until all the entry summaries identified for purposes of substantiating the claim have been finally liquidated and the applicable amendment period, as set forth in paragraph (g)(1) of this section has expired or the claimant has submitted to Customs a signed waiver of amendment.

(i) *Denial of a wool duty refund claim.* Customs may deny a wool duty refund claim if the claim was not timely filed, if the claimant is not eligible pursuant to the terms of this section, or if the claimant has not complied with the requirements of this section. Customs will provide the claimant with written notice of the denial of the claim, including the reason for the denial.

(j) *Multiple refund claims and pending judicial review*—(1) *Allowance or denial of subsequent claims.* If an entry has been used to provide the basis for a duty refund claim pursuant to this section, and the entire amount of duties paid on that entry was refunded to the claimant, a claim for drawback, or any other refund claim authorized by law, that is based on that entry, will be denied by Customs. If an entry has been used to substantiate a claim for a duty refund under this section, and an amount in duties paid on that entry has not been refunded, the remaining amount may be eligible for subsequent duty refund claims under this section, drawback, or any other refund claim authorized by law. An entry that has already had 99% or more of the duties paid on that entry refunded by way of a drawback claim, protest, or any other claim authorized by law, may not be used to provide the basis for a wool duty refund claim.

(2) *Substitution of entry summary numbers.* If a duty refund claim under this section has not yet been processed by Customs, an importer may substitute an entry summary that has already been identified to Customs for purposes of substantiating the claim with another comparable entry summary, so long as the amount of duty paid in connection with the replacement entry is not less than the duty paid on the entry that was identified to Customs originally.

(3) *Pending judicial review.* If a summons involving the tariff classification or the dutiability of an imported wool product has been filed in the Court of International Trade, Customs will deem any entry summary at issue in that judicial proceeding ineligible to substantiate a duty refund claim.

(k) *Penalties and liquidated damages.* A wool duty refund claimant's failure to comply with any of the procedural requirements set forth in this document, or failure to adhere to all applicable laws and regulations, may subject the claimant to penalties, liquidated damages or other administrative sanctions.

Charles W. Winwood,

Acting Commissioner of Customs.

Approved: April 9, 2001.

Timothy E. Skud,

Acting Deputy Assistant Secretary of the Treasury.

[FR Doc. 01–10004 Filed 4–20–01; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

[Docket No. 00N–1634]

Public Hearing Before a Public Advisory Committee; Examination of Administrative Record and Other Advisory Committee Records; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) published in the **Federal Register** of January 8, 2001, a proposed rule (66 FR 1276) and a direct final rule (66 FR 1257) to amend FDA regulations governing the public disclosure of written information for consideration by an advisory committee at an advisory committee meeting. The comment period closed March 26, 2001. FDA is withdrawing the direct final rule because the agency received significant adverse comment.

DATES: The direct final rule published in the **Federal Register** of January 8, 2001 (66 FR 1257), is withdrawn as of April 23, 2001.

FOR FURTHER INFORMATION CONTACT: Andrea C. Masciale, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under the authority delegated to the Commissioner of Food and Drugs, the direct final rule published in the **Federal Register** of January 8, 2001 (66 FR 1257), is withdrawn.

Dated: April 17, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–9950 Filed 4–20–01; 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 Feeds; Amprolium, Bacitracin Methylene Disalicylate, and Roxarsone

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, single-ingredient amprolium, bacitracin methylene disalicylate, and roxarsone Type A medicated articles to make three-way combination drug Type C medicated feeds for replacement chickens.

DATES: This rule is effective April 23, 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 141–142 that provides for use of Amprol® (25 percent amprolium), BMD® (10, 25, 30, 40, 50, 60, or 75 grams per pound (g/lb) bacitracin methylene disalicylate), and 3-Nitro® (45.4, 90, 227, or 360 g/lb roxarsone) Type A medicated articles to make combination Type C medicated feeds containing 36.3 to 113.5 g/ton amprolium, 50 g/ton bacitracin methylene disalicylate, and 22.7 to 45.4 g/ton roxarsone for use in replacement chickens. The Type C medicated feeds are used for the development of active immunity to coccidiosis; as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin; and for increased rate of weight gain, improved feed efficiency, and improved pigmentation. The NADA is approved as of February 16, 2001, and 21 CFR 558.55 is 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 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)(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:

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

2. Section 558.55 is amended in the table in paragraph (d)(2) by alphabetically adding an item under entry (i) to read as follows:

§ 558.55 Amprolium.

* * * * *

(d) * * *

(2) * * *

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 36.3 to 113.5 (0.004% to 0.0125%).				
*	*	*	*	*
	Bacitracin methylene disalicylate 50 plus roxarsone 22.7 to 45.4.	Replacement chickens; development of active immunity to coccidiosis; as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin; increased rate of weight gain, improved feed efficiency, and improved pigmentation.	Feed according to subtable in entry (i); bacitracin methylene disalicylate and roxarsone as provided by 046573 in § 510.600(c) of this chapter.	046573
*	*	*	*	*

* * * * *

Dated: April 9, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01–9872 Filed 4–20–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 660

[Docket No. 00N–1586]

Revision to Requirements for Licensed Anti-Human Globulin and Blood Grouping Reagents; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of June 11, 2001, for the direct final rule that appeared in the **Federal Register** of December 12, 2000 (65 FR 77497). The direct final rule rule amends the biologics regulations applicable to microbiological controls for licensed Anti-Human Globulin and Blood Grouping Reagents by removing the requirement that these products be sterile. This document confirms the effective date of the direct final rule.

DATES: Effective date confirmed: June 11, 2001.

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 12, 2000 (65 FR 77497), FDA solicited comments concerning the direct final rule for a 75-