

regulatory activities, or implementation of Federal-State agreements.

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3. Section 20.89 is amended by revising paragraph (d)(1); by removing paragraph (d)(3); and by adding paragraph (e) to read as follows:

§ 20.89 Communications with foreign government officials.

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(d)(1) The Senior Associate Commissioner for Policy, Planning, and Legislation, or the Deputy Commissioner for International and Constituent Relations, or any other officer or employee of the Food and Drug Administration whom the Senior Associate Commissioner for Policy, Planning, and Legislation or the Deputy Commissioner for International and Constituent Relations may designate to act on their behalf for the purpose, may authorize the disclosure to, or receipt from, an official of a foreign government agency of nonpublic, predecisional documents concerning the Food and Drug Administration's or the other government agency's regulations or other regulatory requirements, or other nonpublic information relevant to either agency's activities, as part of cooperative efforts to facilitate global harmonization of regulatory requirements, cooperative regulatory activities, or implementation of international agreements, provided that:

(i) The foreign government agency has the authority to protect such nonpublic documents from public disclosure and will not disclose any such documents provided without the written confirmation by the Food and Drug Administration that the documents no longer have nonpublic status; and

(ii) The Senior Associate Commissioner for Policy, Planning, and Legislation or the Deputy Commissioner for International and Constituent Relations or their designee makes the determination that the exchange is reasonably necessary to facilitate global harmonization of regulatory requirements, cooperative regulatory activities, or implementation of international agreements.

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(e) For purposes of this section, the term "official of a foreign government agency" includes, but is not limited to, employees (whether temporary or permanent) of and agents contracted by the foreign government, or by an international organization established by law, treaty, or other governmental action and having responsibility to facilitate global or regional harmonization of standards and

requirements in FDA's areas of responsibility or to promote and coordinate public health efforts. For such officials, the statement and commitment required by paragraph (c)(1)(i) of this section shall be provided on behalf of both the organization and the individual.

Dated: December 3, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00-5417 Filed 3-6-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Nicarbazine 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 Koffolk, Inc. The NADA provides for using approved nicarbazine and bacitracin zinc Type A medicated articles to make combination Type C medicated broiler chicken feeds used for prevention of coccidiosis and for increased rate of weight gain and improved feed efficiency.

DATES: This regulation is effective March 7, 2000.

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: Koffolk, Inc., P.O. Box 675935, 14735 Las Quintas, Rancho Santa Fe, CA 92067, filed NADA 141-146 that provides for combining approved Nicarb® (113.5 grams per pound (g/lb) nicarbazine) manufactured by Koffolk, Inc., and Baciferm® (50 g/lb bacitracin as bacitracin zinc) manufactured by Roche Vitamins, Inc., Type A medicated articles to make Type C medicated broiler chicken feeds. The Type C broiler feeds contain 113.5 g/ton (t) nicarbazine and 4 to 50 g/t bacitracin. The Type C broiler chicken feeds are used as an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina*, *E. maxima*, *E. necatrix*, and *E. brunetti*) coccidiosis, and for

increased rate of weight gain and improved feed efficiency.

The NADA is approved as of February 2, 2000, and the regulations are amended by adding 21 CFR 558.78(d)(3)(xxi) and by amending the table in 21 CFR 558.366(c) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

This approval is for use of Type A medicated articles to make combination drug Type C medicated feeds. Nicarbazine is a category II drug as defined in 21 CFR 558.3(b)(1)(ii). As provided in 21 CFR 558.4(b), an approved Form FDA 1900 is required to make a Type C medicated feed from a category II drug. Under 21 U.S.C. 360b(m), as amended by the Animal Drug Availability Act of 1996 (Public Law 104-250), medicated feed applications have been replaced by a requirement for feedmill licenses. Therefore, use of Type A medicated articles to make Type C medicated feeds as provided in NADA 141-146 is limited to manufacture in a licensed feedmill.

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 558.78 is amended by adding paragraph (d)(3)(xxi) to read as follows:

§ 558.78 Bacitracin zinc.

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(d) * * *

(3) * * *

(xxi) Nicarbazin as in § 558.366.

3. Section 558.366 is amended in the table in paragraph (c) under the entry for “113.5 (0.0125 pct)” by alphabetically adding an entry for

“Bacitracin zinc 4 to 50” to read as follows:

§ 558.366 Nicarbazin.

* * * * *

(c) * * *

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
113.5 (0.0125 pct)		* * *	* * *	* * *
*	*	*	*	*
	Bacitracin zinc 4 to 50.	Broiler chickens; aid in preventing outbreaks of cecal (<i>Eimeria tenella</i>) and intestinal (<i>E. acervulina</i> , <i>E. maxima</i> , <i>E. necatrix</i> , and <i>E. brunetti</i>) coccidiosis, and for increased rate of weight gain and improved feed efficiency.	For broiler chickens only. Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Discontinue medication 4 days before marketing the birds for human consumption to allow for elimination of the drug from edible tissue. Do not feed to laying hens in production. Nicarbazin as provided by 063271, bacitracin zinc by 063238.	063271
*	*	*	*	*

Dated: February 25, 2000.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 00-5415 Filed 3-6-00; 8:45 am]

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DEPARTMENT OF THE TREASURY**Bureau of Alcohol, Tobacco and Firearms****27 CFR Parts 4, 5, 7 and 16**

[T.D. ATF-425]

RIN 1512-AB98

Delegation of Authority (99R-247P)

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

ACTION: Treasury Decision, Final rule.

SUMMARY: Authority delegation. This final rule places most ATF authorities contained in parts 4, 5, and 7, title 27 Code of Federal Regulations (CFR), with the “appropriate ATF officer” and requires that persons file documents required by parts 4, 5, and 7, title 27 CFR, with the “appropriate ATF officer” or in accordance with the instructions on the ATF form. Also, this final rule removes the definitions of, and references to, specific officers subordinate to the Director. Concurrently with this Treasury Decision, ATF Order 1130.2A is being

published. Through this order, the Director has delegated most of the authorities in 27 CFR parts 4, 5 and 7 to the appropriate ATF officers and specified the ATF officers with whom applications, notices and other reports that are not ATF forms are filed. Finally, this final rule removes the definition of, and a reference to, the Director in part 16, title 27 CFR.

DATES: Effective March 7, 2000.

FOR FURTHER INFORMATION CONTACT:

Robert Ruhf, Regulations Division, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue NW, Washington, DC 20226 (202-927-8210).

SUPPLEMENTARY INFORMATION:**Background**

Pursuant to Treasury Order 120-01 (formerly 221), dated June 6, 1972, 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 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 the FAA Act,

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 these multiple delegation instruments exacerbate the administrative burden associated with maintaining up-to-date delegations, resulting in an undue delay in reflecting current authorities.

Accordingly, this final rule rescinds all authorities of the Director in parts 4, 5, and 7 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 1130.2A, Delegation Order—Delegation of the Director’s Authorities in 27 CFR parts 4, 5 and 7, Labeling and Advertising of Wine, Distilled Spirits and Malt Beverages, which delegates certain of these authorities to the appropriate organizational level. The effect of these changes is to consolidate all delegations of authority in parts 4, 5 and 7 into one delegation instrument. This action both