

Authority: 21 U.S.C. 331, 333, 337, 351, 352, 355, 360, 360c, 360f, 360i, 360j, 371; 42 U.S.C. 262, 263b, 300aa-28; 5 U.S.C. 554, 555, 556, 557.

■ 2. In § 17.2, revise the introductory text to read as follows:

§ 17.2 Maximum penalty amounts.

The following table shows maximum civil monetary penalties associated with the statutory provisions authorizing civil monetary penalties under the act or the Public Health Service Act:

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Dated: March 18, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8-6082 Filed 3-25-08; 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; Bacitracin Methylene Disalicylate and Nicarbazine

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 Type A medicated articles containing bacitracin methylene disalicylate and nicarbazine to formulate two-way combination drug Type C medicated feeds for broiler chickens.

DATES: This rule is effective March 26, 2008.

FOR FURTHER INFORMATION CONTACT: Timothy Schell, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8116, e-mail: *timothy.schell@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Alpharma, Inc., 440 Rt. 22, Bridgewater, NJ 08807, filed NADA 141-279 that provides for use of BMD (bacitracin methylene disalicylate) and NICARB (nicarbazine) Type A medicated articles to formulate two-way combination drug Type C medicated feeds for broiler chickens. The NADA is approved as of February 21, 2008, and the regulations are amended in 21 CFR 558.366 to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 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 Division of Dockets Management (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. In the table in paragraph (d) of § 558.366, alphabetically add new entries for “Bacitracin methylene disalicylate 4 to 50” and “Bacitracin methylene disalicylate 50” to read as follows:

§ 558.366 Nicarbazine.

* * * * *

(d) * * *

Nicarbazine in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
113.5 (0.0125 pct)	*	* *	* *	*
	Bacitracin methylene disalicylate 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; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for outbreaks of coccidiosis; do not use in flushing mashers; do not feed to laying hens; withdraw 4 days before slaughter.	046573
	Bacitracin methylene disalicylate 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; as an aid in the prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for outbreaks of coccidiosis; do not use in flushing mashers; do not feed to laying hens; withdraw 4 days before slaughter.	046573

Dated: March 12, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8-6063 Filed 3-25-08; 8:45 am]

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DEPARTMENT OF STATE

22 CFR Part 123

[Public Notice: 6147]

Amendment to the International Traffic in Arms Regulations: North Atlantic Treaty Organization (NATO)

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State is amending the International Traffic in Arms Regulations (ITAR), to clarify United States policy to allow for reexports or retransfers of U.S.-origin components incorporated into a foreign defense article to the North Atlantic Treaty Organization (NATO), and its agencies, as well as to NATO member governments.

DATES: *Effective Date:* This rule is effective March 26, 2008.

ADDRESSES: Interested parties may submit comments at any time by any of the following methods:

- *E-mail:*

DDTCResponseTeam@state.gov with an appropriate subject line.

- *Mail:* Department of State,

Directorate of Defense Trade Controls, Office of Defense Trade Controls Policy, ATTN: Regulatory Change, ITAR Part 123, SA-1, 12th Floor, Washington, DC 20522-0112.

Persons with access to the Internet may also view this notice by going to the regulations.gov Web site at <http://regulations.gov/index.cfm>.

FOR FURTHER INFORMATION CONTACT:

Director Ann Ganzer, Office of Defense Trade Controls Policy, Department of State, Telephone (202) 663-2792 or Fax (202) 261-8199; E-mail *DDTCResponseTeam@state.gov*. ATTN: Regulatory Change, Part 123.

SUPPLEMENTARY INFORMATION: To clarify the current regulation, it is necessary to explicitly provide that NATO and its agencies, in addition to the government of a NATO country, or the governments of Australia or Japan, are authorized without the prior written approval of the Directorate of Defense Trade Controls, upon meeting certain conditions, to reexport or retransfer U.S.-origin components incorporated into a foreign defense article.

Regulatory Analysis and Notices

Administrative Procedure Act

This amendment involves a foreign affairs function of the United States and, therefore, is not subject to the procedures required by 5 U.S.C. 553 and 554.

Regulatory Flexibility Act

Since this amendment involves a foreign affairs function of the United States, it does not require analysis under the Regulatory Flexibility Act.

Unfunded Mandates Reform Act of 1995

This amendment does not involve a mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This amendment has been found not to be a major rule within the meaning of the Small Business Regulatory Enforcement Fairness Act of 1996.

Executive Orders 12372 and 13132

This amendment will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this amendment does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on federal programs and activities do not apply to this amendment.

Executive Order 12866

This amendment is exempt from review under Executive Order 12866, but has been reviewed internally by the Department of State to ensure consistency with the purposes thereof.

Paperwork Reduction Act

This rule does not impose any new reporting or recordkeeping requirements subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

List of Subjects in 22 CFR Part 123

Arms and munitions, Exports.

■ Accordingly, for the reasons set forth above, Title 22, Chapter I, Subchapter M, part 123 is amended as follows:

PART 123—LICENSES FOR THE EXPORT OF DEFENSE ARTICLES

■ 1. The authority citation for part 123 continues to read as follows:

Authority: Secs. 2, 38, and 71, Pub. L. 90-629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2797); 22 U.S.C. 2753; E.O. 11958, 42 FR 4311; 3 CFR, 1977 Comp., p. 79; 22 U.S.C. 2651a; 22 U.S.C. 2776; Pub. L. 105-261, 112 Stat. 1920; Sec. 1205(a), Pub. L. 107-228.

■ 2. Section 123.9 is amended by revising paragraph (e) introductory text to read as follows:

§ 123.9 Country of ultimate destination and approval of reexports or retransfers.

* * * * *

(e) Reexports or retransfers of U.S.-origin components incorporated into a foreign defense article to NATO, NATO agencies, a government of a NATO country, or the governments of Australia or Japan, are authorized without the prior written approval of the Directorate of Defense Trade Controls, provided:

* * * * *

Dated: March 10, 2008.

John C. Rood,

Acting Under Secretary for Arms Control and International Security, Department of State.

[FR Doc. E8-6019 Filed 3-25-08; 8:45 am]

BILLING CODE 4710-25-P

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Parts 203, 206, 210, 216, 218, and 227

[Docket No. MMS-2008-MRM-0021]

RIN 1010-AD20

Reporting Amendments

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Final rule.

SUMMARY: The MMS is amending existing regulations for reporting production and royalties on oil, gas, coal and other solid minerals, and geothermal resources produced from Federal and Indian leases in order to align the regulations with current MMS business practices. These amendments reflect changes that were implemented as a result of major reengineering of MMS financial systems and other legal requirements.

DATES: Effective Date: April 25, 2008.