

(Lat 35°30'26" N, long 98°20'33" W)

That airspace extending upward from 700 feet above the surface within a 6.45-mile radius of Hinton Muni Airport.

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Issued in Fort Worth, TX, on March 13, 2008.

Gene L. Kasson,

Acting Manager, System Support Group, ATO Central Service Center.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA-2008-N-0160] (formerly Docket No. 2002N-0276)

Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to change the fax number to which food facility registration forms under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) can be sent. This action is editorial in nature and is intended to improve the accuracy of the agency's regulations.

DATES: This rule is effective March 26, 2008.

FOR FURTHER INFORMATION CONTACT:

Catherine Copp, Center for Food Safety and Applied Nutrition (HFS-4), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2379.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations in part 1 (21 CFR part 1). Several sections in part 1 cite a fax number to which food facility registration forms under the Bioterrorism Act (Public Law 107-188) can be sent. This rule replaces the obsolete information with correct information.

The final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Publication of this document constitutes final action on these changes

under the Administrative Procedure Act (5 U.S.C. 553). These amendments remove obsolete information and are not substantive. FDA therefore, for good cause, finds under 5 U.S.C. 553(b)(3)(B) and (d)(3) that notice and comment are unnecessary.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1 is amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

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

Authority: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. Section 1.231 is amended by revising paragraph (b)(2) to read as follows:

§ 1.231 How and where do you register?

* * * * *

(b) * * *

(2) When you receive the form, you must fill it out completely and legibly and either mail it to the address in paragraph (b)(1) of this section or fax it to 301-436-2804 or 1-800-573-0846.

* * * * *

■ 3. Section 1.234 is amended by revising paragraph (d)(2) to read as follows:

§ 1.234 How and when do you update your facility's registration information?

* * * * *

(d) * * *

(2) When you receive the form, you must legibly fill out the sections of the form reflecting your updated information and either mail it to the address in paragraph (d)(1) of this section or fax it to 301-436-2804 or 1-800-573-0846.

* * * * *

■ 4. Section 1.235 is amended by revising paragraph (d)(2) to read as follows:

§ 1.235 How and when do you cancel your facility's registration information?

* * * * *

(d) * * *

(2) When you receive the form, you must completely and legibly fill out the form and either mail it to the address in

paragraph (d)(1) of this section or fax it to 301-436-2804 or 1-800-573-0846.

* * * * *

Dated: March 18, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8-6052 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 17

Civil Money Penalties Hearings; Maximum Penalty Amounts; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its civil money penalties regulations to correct an inadvertent typographical error. This action is editorial in nature and is intended to improve the accuracy of the agency's regulations.

DATES: This rule is effective March 26, 2008.

FOR FURTHER INFORMATION CONTACT:

Joyce Strong, Office of Policy, Planning, and Preparedness (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7010.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations in 21 CFR part 17 to correct an inadvertent typographical error.

Publication of this document constitutes final action on this change under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedures are unnecessary because FDA is merely correcting a nonsubstantive error.

List of Subjects in 21 CFR Part 17

Administrative practice and procedure, Penalties.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 17 is amended as follows:

PART 17—CIVIL MONEY PENALTIES HEARINGS

■ 1. The authority citation for 21 CFR part 17 continues to read as follows:

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:

* * * * *

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
* * * * *				