

EFFECTIVE DATE: 0901 UTC, October 25, 2007.

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Airspace and Rules Group, Office of System Operations Airspace and AIM, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267-8783.

SUPPLEMENTARY INFORMATION:

History

On April 26, 2007, the FAA published in the **Federal Register** a notice of proposed rulemaking to amend R-3702A and R-3702B at Fort Campbell, KY (72 FR 20787). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received. With the exception of editorial changes, this amendment is the same as that proposed in the notice of proposed rulemaking.

Section 73.37 of 14 CFR part 73 was published in the FAA Order 7400.8N, Special Use Airspace, dated February 16, 2007. The restricted area listed in this document will be published subsequently in the Order.

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) part 73 to realign the designated altitudes separating restricted areas R-3702A and R-3702B at Fort Campbell, KY. This rule changes the designated altitudes for R-3702A from "surface to 6,000 feet MSL," to "surface to 10,000 feet MSL." In addition, the designated altitudes for R-3702B are changed from "6,000 feet MSL to FL 220," to "10,000 feet MSL to FL 220." This change will allow Fort Campbell to conduct hazardous activities that do not exceed 10,000 feet MSL without unnecessarily restricting the airspace up to FL 220. This change also allows air traffic control to provide better service to nonparticipating aircraft in the area.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation: (1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic

procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has reviewed the above referenced action according to Department of Transportation Order 5610.1C, "Procedures for Considering Environmental Impacts" and FAA Order 1050.1E, "Environmental Impacts: Policies and Procedures." In accordance with FAA Order 1050.1E paragraphs 311d and 401p(5) it is determined that the action qualifies for categorical exclusion from further environmental review. Additionally, the implementation of this action will not result in any extraordinary circumstances in accordance with Order 1050.1E paragraph 304. Therefore, on July 27, 2007 the FAA issued a categorical exclusion declaration for the change in the internal boundaries for R-3702A and R-3702B.

List of Subjects in 14 CFR Part 73

Airspace, Prohibited areas, Restricted areas.

The Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73 as follows:

PART 73—SPECIAL USE AIRSPACE

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 73.37 [Amended]

■ 2. Section 73.37 is amended as follows:

* * * * *

**R-3702A Fort Campbell, KY
[Amended]**

Under Designated altitudes, by removing the words "Surface to 6,000 feet MSL," and inserting the words "Surface to 10,000 feet MSL."

* * * * *

**R-3702B Fort Campbell, KY
[Amended]**

Under Designated altitudes, by removing the words "6,000 feet MSL to FL 220," and inserting the words "10,000 feet MSL to FL 220."

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Issued in Washington, DC, on August 6, 2007.

Edith V. Parish,

Manager, Airspace and Rules Group.

[FR Doc. E7-15747 Filed 8-10-07; 8:45 am]

BILLING CODE 4910-13-P

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Food and Drug Administration

21 CFR Parts 510 and 529

**Certain Other Dosage Form New
Animal Drugs; Formalin**

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 an abbreviated new animal drug application (ANADA) filed by B.L. Mitchell, Inc. The ANADA provides for the use of formalin in a water bath for the control of certain external parasites on finfish and shrimp and for the control of certain fungi on finfish eggs.

DATES: This rule is effective August 13, 2007.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0169, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: B.L. Mitchell, Inc., 103 Hwy. 82 E., Leland, MS 38756, filed ANADA 200-414 that provides for use of Formacide-B (formalin) in a water bath for the control of certain external parasites on finfish and shrimp and for the control of certain fungi on finfish eggs. B.L. Mitchell, Inc.'s Formacide-B is approved as a generic copy of Parasite-S, sponsored by Western Chemical, Inc., under NADA 140-989. The ANADA is approved as of July 17, 2007, and the regulations are amended in § 529.1030 to reflect the approval.

In addition, B.L. Mitchell, Inc., has not been previously listed in the animal drug regulations as a sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to add entries for this firm.

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)(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.

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

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 529

Animal drugs.

■ 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 parts 510 and 529 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600, in the table in paragraph (c)(1) alphabetically add a new entry for “B.L. Mitchell, Inc.”; and in the table in paragraph (c)(2) numerically add a new entry for “067188” to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * *				
(c) * * *				
(1) * * *				
Firm name and address				Drug labeler code
* * * *				*
B.L. Mitchell, Inc., 103 Hwy. 82 E., Leland, MS 38756.				067188
* * * *				*

(2) * * *

Drug labeler code		Firm name and address		
* *		* * *		
067188		B.L. Mitchell, Inc., 103 Hwy. 82 E., Leland, MS 38756		
* *		* * *		

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 529 continues to read as follows:

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

§ 529.1030 [Amended]

■ 4. In paragraph (b)(1) of § 529.1030, remove “Nos. 049968 and 050378” and add in its place “Nos. 049968, 050378, and 067188”.

Dated: August 1, 2007.

Stephen F. Sundlof,
Director, Center for Veterinary Medicine.
[FR Doc. E7–15763 Filed 8–10–07; 8:45 am]
BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Ampicillin Sodium

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 an abbreviated new animal drug application (ANADA) filed by G. C. Hanford Manufacturing Co. The ANADA provides for the use of ampicillin sodium powder in aqueous solution by injection in horses for the treatment of various bacterial infections.

DATES: This rule is effective August 13, 2007.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0169, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: G. C. Hanford Manufacturing Co., P.O. Box 1017, Syracuse, NY 13201, filed ANADA 200–335 that provides for use of ampicillin sodium as a constituted solution by injection in horses for the treatment of various bacterial infections.

G. C. Hanford Manufacturing Co.’s Ampicillin Sodium is approved as a generic copy of Pfizer, Inc.’s, AMP-EQUINE, approved under NADA 55–084. The ANADA is approved as of July 12, 2007, and the regulations are amended in 21 CFR 522.90c to reflect the approval and a current format. 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 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.

FDA 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.

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 522

Animal drugs.

■ 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 522 is amended as follows:

PART 522—IMPLANTATION AND INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 2. Revise § 522.90c to read as follows:

§ 522.90c Ampicillin sodium.

(a) Specifications. Each milliliter of aqueous solution constituted from ampicillin sodium powder contains 300 milligrams (mg) ampicillin equivalents.

(b) Sponsors. See Nos. 000069 and 010515 in § 510.600(c) of this chapter.

(c) Conditions of use in horses—(1) Amount: 3 mg per pound of body weight twice daily by intravenous or intramuscular injection.

(2) Indications for use. For the treatment of respiratory tract infections (pneumonia and strangles) due to