Guides reach small and very small establishments. The team also suggested that, to be useful to small and very small plants, the guidelines be simplified.

Retail Team

Finally, the Retail team focused on possible means of controlling *L. monocytogenes* in RTE products at retail establishments. This team found that slicing and packaging deli meats at retail establishments represents a significant source of exposure of *L. monocytogenes.* The team suggested two possible strategies for dealing with this problem: (1) education and outreach, and (2) use of antimicrobial agents in products to be sliced and sold at retail establishments. The team also pointed to efforts already underway in the Agency to compare the risk of listeriosis from product sliced in plants with the risk from those sliced at retail establishments. The results of this assessment will be used by the Agency in developing its strategy for retail establishments.

Availability of the Complete Team Report

The report on ''Assessing the Effectiveness of the *Listeria monocytogenes* Interim Final Rule'', with each of the Project Assessment Team's individual reports, is available on the Agency Web site at *http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/Docs_97–013F.htm*.

The complete report may also be viewed in the FSIS Docket Room, 300 12th Street, SW., Room 102 Cotton Annex, Washington, DC, 20250 between 8:30 a.m. to 4:30 p.m.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that the public and in particular minorities, women, and persons with disabilities, are aware of this notice, FSIS will announce it on-line through the FSIS Web page located at *http://www.fsis.usda.gov.*

FSIS also will make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and other types of information that could affect or would be of interest to our constituents and stakeholders. The update is communicated via Listserv, a free e-mail subscription service consisting of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The update also is available on the FSIS Web page. Through Listserv and the Web page, FSIS is able to provide information to a much broader, more diverse audience.

Done in Washington, DC, on October 29, 2004.

Barbara J. Masters,

Acting Administrator.

[FR Doc. 04–26515 Filed 12–1–04; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2004–18827; Airspace Docket No. 04–ACE–53]

Modification of Class E Airspace; Hannibal, MO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: This document confirms the effective date of the direct final rule which revises Class E airspace at Hannibal, MO.

DATES: *Effective* 0901 UTC, January 20, 2005.

FOR FURTHER INFORMATION CONTACT: Brenda Mumper, Air Traffic Division, Airspace Branch, ACE–520A, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust, Kansas City, MO 64106; telephone: (816) 329–2524.

SUPPLEMENTARY INFORMATION: The FAA published this direct final rule with a request for comments in the **Federal Register** on October 8, 2004 (69 FR 60286). The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on January 20, 2005. No adverse comments were received, and thus this notice confirms that this direct final rule will become effective on that date.

Issued in Kansas City, MO, on November 16, 2004.

Anthony D. Roetzel,

Acting Area Director, Western Flight Services Operations.

[FR Doc. 04–26524 Filed 12–1–04; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

Oral Dosage Form New Animal Drugs; Sulfadiazine/Pyrimethamine Suspension

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 Animal Health Pharmaceuticals, LLC. The NADA provides for veterinary prescription use of an oral suspension of sulfadiazine and pyrimethamine for the treatment of equine protozoal myeloencephalitis (EPM).

DATES: This rule is effective December 2, 2004.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7543, e-mail: *melanie.berson@fda.gov*.

SUPPLEMENTARY INFORMATION: Animal Health Pharmaceuticals, LLC, 1805 Oak Ridge Circle, suite 101, St. Joseph, MO 64506, filed NADA 141–240 for veterinary prescription use of REBALANCE (sulfadiazine/pyrimethamine) Antiprotozoal Oral Suspension for the treatment of EPM caused by *Sarcocystis neurona*. The NADA is approved as of November 5, 2004, and 21 CFR part 520 is amended by adding new § 520.2215 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, Animal Health Pharmaceuticals, LLC, is not currently listed in the animal drug regulations as a sponsor of an approved application. At this time, 21 CFR 510.600(c) is being amended to add entries for the 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.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning November 5, 2004.

The agency has determined under 21 CFR 25.33(d)(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 520

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 520 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. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding an entry for ''Animal Health Pharmaceuticals, LLC''; and in the table in paragraph (c)(2) by numerically adding an entry for ''068718'' 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
* * * * *	
Animal Health Pharmaceuticals, LLC, 1805 Oak Ridge Circle, suite 101, St. Joseph, MO 64506	068718
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* *	* * * *
068718	Animal Health Pharmaceuticals, LLC, 1805 Oak Ridge Circle, suite 101, St. Joseph, MO 64506
* *	* * * *

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 520 continues to read as follows:

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

■ 4. Section 520.2215 is added to read as follows:

§ 520.2215 Sulfadiazine/pyrimethamine suspension.

(a) *Specifications.* Each milliliter (mL) of suspension contains 250 milligrams (mg) sulfadiazine (as the sodium salt) and 12.5 mg pyrimethamine.

(b) *Sponsor.* See No. 068718 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer orally 20 mg sulfadiazine per kilogram (kg) body weight and 1 mg/kg pyrimethamine daily.

(2) *Indications for use.* For the treatment of equine protozoal myeloencephalitis (EPM) caused by *Sarcocystis neurona.*

(3) *Limitations.* Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: November 23, 2004.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 04–26528 Filed 12–1–04; 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; Progesterone and Estradiol Benzoate

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 supplemental new animal drug applications (NADAs) filed by Fort Dodge Animal Health, Division of Wyeth, and Ivy Laboratories, Division of Ivy Animal Health, Inc. The supplemental NADAs provide for the addition of statements to labeling of subcutaneous implants containing progesterone and estradiol benzoate warning against the use of these products in calves to be processed for veal.

DATES: This rule is effective December 2, 2004.

FOR FURTHER INFORMATION CONTACT: Eric S. Dubbin, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0232, e-mail: *edubbin@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501, filed a supplement to NADA 009–576 for SYNOVEX C and SYNOVEX S (progesterone and estradiol benzoate). Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed a supplement to NADA 110–315 for COMPONENT E–C and COMPONENT E–S (progesterone and estradiol benzoate), and COMPONENT E–C with TYLAN and COMPONENT E–S with TYLAN (progesterone and estradiol benzoate with tylosin tartrate). The supplemental NADAs provide for the addition of statements to labeling warning against the use of these products in calves to be processed for veal. The supplemental applications are approved as of October 28, 2004, and the regulations are amended in 21 CFR 522.1940 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), summaries of safety and effectiveness