REVISIONS TO IFR ALTITUDES & CHANGEOVER POINTS—Continued

[Amendment 473 effective date April 10, 2008]

From	To	MEA
§ 95.6489 VOR Federal Airway V489 Is Amended To Read in Part		
Albany, NY VORTAC *5000—GNSS MEA	Glens Falls, NY VORTAC	*7000
Glens Falls, NY VORTAC *8000—MRA	*Fairb, NY FIX	6000
*Fairb, NY FIX *8000—MRA **6000—GNSS MEA	Leafy, NY FIX	**8000

From	To	MEA	MAA
§ 95.7001 Jet Routes **§ 95.7029 Jet Route J29 Is Amended To Read in Part**			
Humble, TX VORTAC	El Dorado, AR VORTAC	18000	45000
§ 95.7101 Jet Route J101 Is Amended To Read in Part			
Lufkin, TX VORTAC	Little Rock, AR VORTAC	18300	45000

Airway segment		Changeover points	
From	To	Distance	From
§ 95.8003 VOR Federal Airway Changeover Points			
Is Amended To Delete Changeover Point V59: Beckley, WV VORTAC	Pulaski, VA VORTAC	46	Beckley
Is Amended To Add Changeover Point V59: Beckley, WV VORTAC	Parkersburg, WV VORTAC	46	Beckley

[FR Doc. E8–5372 Filed 3–17–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

New Animal Drugs; Change of Sponsor's Name; Iron Injection; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor's name from Animal Health Pharmaceuticals, LLC, to Pharmacosmos, Inc.

DATES: This rule is effective March 18, 2008.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8307, e-mail: *david.newkirk@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Animal Health Pharmaceuticals, LLC, 1805 Oak Ridge Circle, suite 101, St. Joseph, MO 64506, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 106–772 for Iron-GARD Injection 100 milligrams per milliliter (mg/mL) and NADA 134–708 for Iron-GARD Injection 200 mg/mL to Pharmacosmos, Inc., 776 Mountain Blvd., Watchung, NJ 07069. Accordingly, the regulations are amended in 21 CFR 522.1182 to reflect these changes of sponsorship.

In addition, Pharmacosmos, Inc., is not currently 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 Pharmacosmos, Inc.

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 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 parts 510 and 522 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 ''Pharmacosmos, Inc.''; and in the table in paragraph (c)(2) numerically add a new entry for ''042552'' 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
* * * * *	

Firm name and address	Drug labeler code
Pharmacosmos, Inc., 776 Mountain Blvd.,Watchung, NJ 07069.	042552
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
042552	Pharmacosmos, Inc., 776 Mountain Blvd.,Watchung, NJ 07069
* * * * *	

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.1182 [Amended]

■ 4. In § 522.1182, in paragraphs (b)(1) and (b)(7) remove ''059130 and 068718'' and add in its place ''042552 and 059130''.

Dated: March 6, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–5452 Filed 3–17–08; 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 Feed; Zilpaterol

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 Intervet, Inc. The NADA provides for use of approved, single-ingredient zilpaterol hydrochloride and monensin U.S.P. Type A medicated articles to make two-way combination Type B and Type C medicated feeds for cattle fed in confinement for slaughter.

DATES: This rule is effective March 18, 2008.

FOR FURTHER INFORMATION CONTACT: Gerald L. Rushin, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8103, e-mail: *gerald.rushin@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Intervet, Inc., P.O. Box 318, 29160 Intervet Lane, Millsboro, DE 19966, filed NADA 141–278 that provides for use of ZILMAX (zilpaterol hydrochloride) and RUMENSIN (monensin U.S.P.) Type A medicated articles to make dry and liquid, two-way combination Type B and Type C medicated feeds used for increased rate of weight gain, improved feed efficiency, and increased carcass leanness; and for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* in cattle fed in confinement for slaughter during the last 20 to 40 days on feed. The NADA is approved as of February 15, 2008, and the regulations in 21 CFR 558.665 are amended 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 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 the 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 § 558.665, add paragraph (e)(3) to read as follows:

§ 558.665 Zilpaterol.

* * * * *

(e) * * *

Zilpaterol in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	* *	* *	*
(3) 6.8 to provide 60 to 90 mg/head/day	Monensin 10 to 40	Cattle fed in confinement for slaughter: As in paragraph (e)(1) of this section; and for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*.	As in paragraph (e)(1) of this section; see paragraph § 558.355(d) of this chapter. Monensin as provided by No. 000986 in § 510.600(c) of this chapter.	057926
*	*	* *	* *	*