

Q62 NOLNN, OH to SARAA, PA [New]

NOLNN, OH	WP	(Lat. 41°14'04" N., long. 84°38'12" W.)
WEEVR, OH	WP	(Lat. 41°13'21" N., long. 84°13'04" W.)
PSKUR, OH	WP	(Lat. 41°09'16" N., long. 82°42'57" W.)
FAALS, OH	WP	(Lat. 41°02'51" N., long. 80°52'40" W.)
ALEEE, OH	WP	(Lat. 41°00'28" N., long. 80°31'54" W.)
QUARM, PA	WP	(Lat. 40°49'45" N., long. 79°04'39" W.)
BURNI, PA	FIX	(Lat. 40°39'25" N., long. 77°48'14" W.)
MCMAN, PA	FIX	(Lat. 40°38'16" N., long. 77°34'14" W.)
VALLO, PA	FIX	(Lat. 40°37'37" N., long. 77°26'18" W.)
Ravine, PA (RAV)	VORTAC	(Lat. 40°33'12" N., long. 76°35'58" W.)
SUZIE, PA	FIX	(Lat. 40°27'12" N., long. 75°58'22" W.)
SARAA, PA	FIX	(Lat. 40°26'22" N., long. 75°53'16" W.)

Q406 Broadway, NJ (BWZ) to Barnes, MA (BAF) [New]

Broadway, NJ (BWZ)	VOR/DME	(Lat. 40°47'54" N., long. 74°49'19" W.)
DBABE, NY	WP	(Lat. 41°08'30" N., long. 74°05'46" W.)
BASYE, NY	FIX	(Lat. 41°20'37" N., long. 73°47'55" W.)
TRIBS, CT	WP	(Lat. 41°39'29" N., long. 73°19'03" W.)
BIGGO, CT	FIX	(Lat. 41°57'21" N., long. 73°04'05" W.)
Barnes, MA (BAF)	VORTAC	(Lat. 42°09'43" N., long. 72°42'58" W.)

Q448 Pottstown, PA (PTW) to Barnes, MA (BAF) [New]

Pottstown, PA (PTW)	VORTAC	(Lat. 40°13'20" N., long. 75°33'37" W.)
LANNA, NJ	FIX	(Lat. 40°33'35" N., long. 75°01'40" W.)
DBABE, NY	WP	(Lat. 41°08'30" N., long. 74°05'46" W.)
BASYE, NY	FIX	(Lat. 41°20'37" N., long. 73°47'55" W.)
TRIBS, CT	WP	(Lat. 41°39'29" N., long. 73°19'03" W.)
BIGGO, CT	FIX	(Lat. 41°57'21" N., long. 73°04'05" W.)
Barnes, MA (BAF)	VORTAC	(Lat. 42°09'43" N., long. 72°42'58" W.)

Q480 ZANDR, OH to Kennebunk, ME (ENE) [New]

ZANDR, OH	FIX	(Lat. 40°00'19" N., long. 81°31'58" W.)
Bellaire, OH (AIR)	VOR/DME	(Lat. 40°01'01" N., long. 80°49'02" W.)
LEJOY, PA	FIX	(Lat. 40°00'12" N., long. 79°24'54" W.)
VINSE, PA	FIX	(Lat. 39°58'16" N., long. 77°57'21" W.)
BEETS, PA	WP	(Lat. 39°57'20" N., long. 77°26'59" W.)
HOTEE, PA	WP	(Lat. 40°20'36" N., long. 76°29'37" W.)
BTRIX, PA	WP	(Lat. 40°36'06" N., long. 75°49'11" W.)
SPOTZ, PA	WP	(Lat. 40°45'55" N., long. 75°22'59" W.)
CANDR, NJ	WP	(Lat. 40°57'59" N., long. 74°57'29" W.)
JEFFF, NJ	WP	(Lat. 41°14'46" N., long. 74°27'43" W.)
Kingston, NY (IGN)	VOR/DME	(Lat. 41°39'56" N., long. 73°49'20" W.)
LESWL, CT	WP	(Lat. 41°53'31" N., long. 73°19'20" W.)
Barnes, MA (BAF)	VORTAC	(Lat. 42°09'43" N., long. 72°42'58" W.)
Kennebunk, ME (ENE)	VORTAC	(Lat. 43°25'32" N., long. 70°36'49" W.)

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Paragraph 6010 VOR Federal Airways**V-16 [Amended]**

From Los Angeles, CA; Paradise, CA; Palm Springs, CA; Blythe, CA; Buckeye, AZ; Phoenix, AZ; INT Phoenix 155° and Stanfield, AZ, 105° radials; Tucson, AZ; Cochise, AZ; Columbus, NM; El Paso, TX; Salt Flat, TX; Wink, TX; INT Wink 066° and Big Spring, TX, 260° radials; Big Spring; Abilene, TX; Bowie, TX; Bonham, TX; Paris, TX; Texarkana, AR; Pine Bluff, AR; Marvell, AR; Holly Springs, MS; Jacks Creek, TN; Shelbyville, TN; Hinch Mountain, TN; Volunteer, TN; Holston Mountain, TN; Pulaski, VA; Roanoke, VA; Lynchburg, VA; Flat Rock, VA; Richmond, VA; INT Richmond 039° and Patuxent, MD, 228° radials; Patuxent; Smyrna, DE; Cedar Lake, NJ; Coyle, NJ; INT Coyle 036° and Kennedy, NY, 209° radials; Kennedy; INT Kennedy 040° and Calverton, NY, 261° radials; Calverton; Norwich, CT;

Boston, MA. The airspace within Mexico and the airspace below 2,000 feet MSL outside the United States is excluded. The

airspace within Restricted Areas R-5002A, R-5002C, and R-5002D is excluded during their times of use. The airspace within Restricted Areas R-4005 and R-4006 is excluded.

V-229 [Amended]

From Patuxent, MD; INT Patuxent 036° and Atlantic City, NJ, 236° radials; Atlantic City; INT Atlantic City 055° and Colts Neck, NJ, 181° radials; INT Colts Neck 181° and Kennedy, NY, 209° radials; Kennedy; INT Kennedy 040° and Calverton, NY, 261° radials; INT Calverton 261° and Kennedy 053° radials; INT Kennedy 053° and Bridgeport, CT, 200° radials; Bridgeport; Hartford, CT; INT Hartford 040° and Gardner, MA, 195° radials; Gardner; Keene, NH; INT Keene 336° and Burlington, VT, 160° radials; to Burlington. The airspace within R-5002B is excluded during times of use. The airspace below 2,000 feet MSL outside the United States is excluded.

V-449 [Amended]

From Milton, PA; INT Milton 064° and Williamsport, PA 109° radials; Lake Henry, PA; DeLancey, NY; Albany, NY.

Issued in Washington, DC on September 12, 2011.

Gary A. Norek,

Acting Manager, Airspace, Regulations and ATC Procedures Group.

[FR Doc. 2011-23839 Filed 9-16-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

[Docket No. FDA-2011-N-0003]

Implantation or Injectable Dosage Form New Animal Drugs; Ivermectin

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 Cross Vetpharm Group Ltd. The ANADA provides for use of an ivermectin injectable solution for treatment and control of various internal and external parasites in cattle, swine, reindeer, and American bison.

DATES: This rule is effective September 19, 2011.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV-170), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8197, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed ANADA 200-447 for the use of BIMECTIN (ivermectin) Injection for Cattle and Swine for treatment and control of various internal and external parasites in cattle, swine, reindeer, and American bison. Cross Vetpharm Group Ltd.'s BIMECTIN Injection for Cattle and Swine is approved as a generic copy of Merial Ltd.'s IVOMEK (ivermectin) Injection for Cattle and Swine, approved under NADA 128-409. The ANADA is approved as of July 5, 2011, and the regulations in 21 CFR 522.1192 are amended to reflect the approval.

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 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 OR 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. In § 522.1192, revise paragraph (b)(2) to read as follows:

§ 522.1192 Ivermectin.

* * * * *

(b) * * *

(2) Nos. 055529, 058005, 059130, and 061623 for use of the product described in paragraph (a)(2) of this section as in paragraphs (e)(2), (e)(3), (e)(4), and (e)(5) of this section.

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Dated: September 13, 2011.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2011-23865 Filed 9-16-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

[Docket No. FDA-2011-N-0003]

New Animal Drugs; Gamithromycin

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 original new animal drug application (NADA) filed by Merial, Ltd. The NADA provides for the veterinary prescription use of gamithromycin injectable solution for the management of bovine respiratory disease (BRD). FDA is also amending the regulations to add the established tolerances for residues of gamithromycin in edible tissues of cattle.

DATES: This rule is effective September 19, 2011.

FOR FURTHER INFORMATION CONTACT:

Cindy L. Burnsteel, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8341, e-mail: cindy.burnsteel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640 filed NADA 141-328 that provides for the veterinary prescription use of ZACTRAN

(gamithromycin), an injectable solution, in beef and non-lactating dairy cattle for the treatment of BRD associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*; and for the control of respiratory disease in beef and non-lactating dairy cattle at high risk of developing BRD associated with *M. haemolytica* and *P. multocida*. The application is approved as of June 16, 2011, and the regulations are amended in 21 CFR parts 522 and 556 to reflect the approval.

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)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning on the date of approval.

The Agency has determined under 21 CFR 25.33 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 522

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

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 522 and 556 are amended as follows:

PART 522—IMPLANTATION OR 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. Section 522.1014 is added to read as follows: