FDC date	State	City	Airport	FDC No.	Subject
07/11/09	MT	HELENA	HELENA REGIONAL	9/8260	RNAV (RNP) Z RWY 9, ORIG.
07/11/09	AL	HAMILTON	MARION COUNTY–RANKIN FITE	9/8352	RNAV (GPS) RWY 18, ORIG.
07/13/09	CA	IMPERIAL	IMPERIAL COUNTY	9/8666	TAKEOFF MINIMUMS AND OBSTACLE DP, AMDT 2.
07/14/09	WY	NEWCASTLE	MONDELL FIELD	9/8931	TAKEOFF MINIMUMS AND OBSTACLE DP, AMDT 3.
07/14/09	OK	ALTUS	ALTUS/QUARTZ MOUNTAIN RGNL	9/8941	VOR A, AMDT 4C.
07/15/09	NV	RENO	RENO/TAHOE INTL	9/9101	ILS RWY 16R, AMDT 10D.
07/17/09	NY	ISLIP	LONG ISLAND MACARTHUR	9/9568	RNAV (GPS) RWY 6, ORIG.
07/17/09	CA	OROVILLE	OROVILLE MUNI	9/9700	GPS RWY 1, ORIG.
07/17/09	CA	OROVILLE	OROVILLE MUNI	9/9701	VOR OR GPS–A, AMDT 6.
07/21/09	OR	REDMOND	ROBERTS FIELD	9/0045	ILS OR LOC RWY 22, AMDT 2A.
07/21/09	OR	REDMOND	ROBERTS FIELD	9/0046	VOR/DME RWY 22, AMDT 3.
07/21/09	OR	REDMOND	ROBERTS FIELD	9/0047	VOR A, AMDT 5.
07/21/09	CA	OROVILLE	OROVILLE MUNI	9/0053	TAKEOFF MINIMUMS AND OBSTACLE DP, AMDT 2.
07/21/09	WV	MORGANTOWN	MORGANTOWN MUNI–WALTER L. BILL HART FLD.	9/0093	ILS OR LOC RWY 18, AMDT 13.
07/22/09	OR	PORTLAND	PORTLAND INTL	9/0161	ILS ROR LOC RWY 28L, AMDT 1A.
07/22/09	FL	MELBOURNE	MELBOURNE INTL	9/0262	RNAV (GPS) RWY 27L, ORIG–A.
07/22/09	WY	DOUGLAS	CONVERSE COUNTY	9/0323	RNAV (GPS) RWY 29, ORIG.
07/22/09	WY	DOUGLAS	CONVERSE COUNTY	9/0324	VOR RWY 29, AMDT 1

[FR Doc. E9–18661 Filed 8–12–09; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA–2009–N–0665]

New Animal Drugs for Use in Animal Feeds; Oxytetracycline; Neomycin

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 supplemental new animal drug application (NADA) filed by Pennfield Oil Co. The supplemental NADA provides for the use of fixed-combination Type A medicated articles containing oxytetracycline and neomycin sulfate to formulate two-way, fixed-combination drug Type B and Type C medicated feeds for chickens, turkeys, swine, cattle, and sheep. This approval reflects FDA's effectiveness conclusions which relied on the National Academy of Sciences/National Research Council (NAS/NRC) Drug Efficacy Study Group's evaluation of the effectiveness of these drugs when used in animal feed as single ingredients.

DATES: This rule is effective August 13, 2009.

FOR FURTHER INFORMATION CONTACT: Harlan Howard, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8111, e-mail: *harlan.howard@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 8, 2003 (68 FR 47332), as corrected October 7, 2003 (68 FR 57911), as part of the Drug Efficacy Study Implementation (DESI) program, CVM announced the effective conditions of use for several drug products and use combinations that were listed in § 558.15 (21 CFR 558.15). CVM proposed to withdraw the NADAs for those products or use combinations lacking substantial evidence of effectiveness following a 90-day opportunity to supplement the NADAs with labeling conforming to the relevant findings of effectiveness.

In response to that notice, Pennfield Oil Co., (Pennfield) 14040 Industrial Rd., Omaha, NE 68144, filed a hearing request for its approved NADA 138–939 NEO–OXY 50/50, NEO–OXY 100/100, and NEO–OXY 100/100 MR (oxytetracycline and neomycin sulfate). These products are two-way, fixed-combination Type A medicated articles used to make two-way combination drug Type C medicated feeds. Pennfield subsequently filed a supplement to NADA 138–939 to revise the labeling of these products to comply with these findings of effectiveness. The supplemental NADA provided for use of these fixed-combination Type A medicated articles to formulate two-way, fixed-combination drug Type B and Type C medicated feeds containing oxytetracycline and neomycin sulfate, in a 1:1 ratio, for several production and therapeutic indications in chickens, turkeys, swine, cattle, and sheep. The supplemental NADA is approved as of July 2, 2009, and the regulations are amended in 21 CFR 558.455 to reflect the approval. Pennfield has since withdrawn its hearing request for NDA 138–939.

Approval of this supplemental NADA did not require review of any new safety or effectiveness data. Therefore, a freedom of information summary was not prepared.

The DESI evaluation was concerned only with the effectiveness of the drug products and use combinations. Nothing in this document constitutes a bar to further proceedings with respect to questions of safety of the subject drugs in treated animals or of the drugs or their metabolites in food products derived from treated animals.

Products that comply with FDA's findings of effectiveness are eligible for copying, as described in the *Generic Animal Drug and Patent Term Restoration Act Policy Letter Eight*, August 21, 1991 (56 FR 41561). Accordingly, sponsors may now obtain approval of abbreviated NADAs for this fixed combination Type A medicated article.

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 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. Amend § 558.455 as follows:
■ a. Revise paragraph (b);
■ b. Redesignate paragraph (d) as paragraph (e);
■ c. Add new paragraph (d); and
■ d. Revise newly redesignated paragraph (e).

The redesignation, additions, and revisions read as follows:

§ 558.455 Oxytetracycline and neomycin.

* * * * *

(b) *Sponsors.* See Nos. 048164 and 066104 in § 510.600(c) of this chapter.

* * * * *

(d) *Special considerations.* Cattle feeds shall bear the following warning statement: ''Use of more than one product containing neomycin or failure to follow withdrawal times may result in illegal drug residues.''

(e) *Indications for use*—(1) *Chickens.* It is used in feed as follows:

Oxytetracycline and neomycin sulfate amount in grams per ton of feed	Indications for use	Limitations	Sponsors
(i) 10 to 50	Chickens: For increased rate of weight gain and improved feed efficiency.	Feed continuously; do not feed to chickens producing eggs for human consumption; in low calcium feeds withdraw 3 days before slaughter.	048164 066104
(ii) 100 to 200	Chickens: For control of infectious synovitis caused by *Mycoplasma synoviae*; control of fowl cholera caused by *Pasteurella multocida* susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption; in low calcium feed, withdraw 3 d before slaughter.	048164 066104
(iii) 400	Chickens: For control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *Escherichia coli* susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption; in low calcium feeds, withdraw 3 d before slaughter.	048164 066104
(iv) 500	Chickens: For reduction of mortality due to air sacculitis (air-sac- infection) caused by *E. coli* susceptible to oxytetracycline.	Feed continuously for 5 d; do not feed to chickens producing eggs for human consumption; withdraw 24 hours before slaughter; in low calcium feeds withdraw 3 d before slaughter.	048164 066104

(2) *Turkeys.* It is used in feed as follows:

Oxytetracycline and neomycin sulfate amount	Indications for use	Limitations	Sponsors
(i) 10 to 50 grams per ton (g/ton) of feed	Growing turkeys: For increased rate of weight gain and improved feed efficiency.	Feed continuously; do not feed to turkeys producing eggs for human consumption.	048164 066104
(ii) 100 g/ton of feed	Turkeys: For control of hexamitiasis caused by *Hexamita meleagridis* susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption.	048164 066104
(iii) 200 g/ton of feed	Turkeys: For control of infectious synovitis caused by *M. synoviae* susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter; do not feed to turkeys producing eggs for human consumption.	048164 066104
(iv) To provide 25 milligrams per pound (mg/lb) of body weight daily.	Turkeys: For control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter; do not feed to turkeys producing eggs for human consumption.	048164 066104

(3) *Swine.* It is used in feed as follows:

Oxytetracycline and neomycin sulfate amount	Indications for use	Limitations	Sponsors
(i) 10 to 50 g/ton of feed	Swine: For increased rate of weight gain and improved feed efficiency.	Feed continuously.	048164 066104
(ii) To provide 10 mg/lb of body weight daily.	1. Swine: For treatment of bacterial enteritis caused by *E. coli* and *Salmonella choleraesuis* and treatment of bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin.	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter.	048164 066104
	2. Breeding swine: For control and treatment of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to oxytetracycline.	Feed continuously for not more than 14 d; withdraw 5 d before slaughter.	048164 066104

(4) *Cattle and sheep.* It is used in feed as follows:

Oxytetracycline and neomycin sulfate amount	Indications for use	Limitations	Sponsors
(i) 10 to 20 g/ton of feed	Sheep: For increased rate of weight gain and improved feed efficiency.	Feed continuously.	048164 066104
(ii) To provide 0.05 to 0.1 mg/lb of body weight daily.	Calves (up to 250 lb): For increased rate of weight gain and improved feed efficiency.	Feed continuously; in milk replacers or starter feed.	048164 066104
(iii) To provide 10 mg/lb of body weight daily.	1. Calves and beef and nonlactating dairy cattle: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia (shipping fever complex) caused by *P. multocida* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin.	Feed continuously for 7 to 14 d; in feed or milk replacers. If symptoms persist after using for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older. Withdraw 5 d before slaughter.	048164 066104
	2. Calves (up to 250 lb): For treatment of bacterial enteritis caused by *E. coli* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin.	Feed continuously for 7 to 14 d; in milk replacers or starter feed. If symptoms persist after using for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older. Withdraw 5 d before slaughter.	048164 066104

Oxytetracycline and neomycin sulfate amount	Indications for use	Limitations	Sponsors
	3. Sheep: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin.	Feed continuously for 7 to 14 d. If symptoms persist after using for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. Withdraw 5 d before slaughter.	048164 066104
(iv) To provide 25 mg/head/day	Calves (250 to 400 lb): For increased rate of weight gain and improved feed efficiency.	Feed continuously.	048164 066104
(v) To provide 75 mg/head/day	Growing cattle (over 400 lb): For increased rate of weight gain; improved feed efficiency, and reduction of liver condemnation due to liver abscesses.	Feed continuously.	048164 066104
(vi) To provide 0.5 to 2.0 g/head/ day	Cattle: For prevention and treatment of the early stages of shipping fever complex.	Feed 3 to 5 d before and after arrival in feedlots. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older.	048164 066104

Dated: August 7, 2009.

William T. Flynn,

Acting Director, Center for Veterinary Medicine.

[FR Doc. E9–19414 Filed 8–12–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 251

[Docket ID: MMS–2008–OMM–0006]

RIN 1010–AD41

Geological and Geophysical (G&G) Explorations of the Outer Continental Shelf—Changing Proprietary Term of Certain Geophysical Information

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Final rule.

SUMMARY: This final rule extends the proprietary term of certain reprocessed geophysical information submitted to MMS under a permit. The rule gives up to 5 years of additional protection to reprocessed vintage geophysical information that MMS retains and, without an extension, is subject to release by MMS 25 years after issuing the permit. The extension provides incentives to permittees and third parties to reprocess, market, or in other ways use geophysical information that may not otherwise be reprocessed without the term extension. The extension does not apply to geological data or information.

DATES: *Effective Date:* This rule becomes effective on September 14, 2009.

FOR FURTHER INFORMATION CONTACT: David Zinzer, Geophysicist, Offshore Energy and Minerals Management, Resource Evaluation Division, at (703) 787–1628.

SUPPLEMENTARY INFORMATION: This final rule implements changes put forward by our proposed rulemaking published June 18, 2007 (72 FR 33417). The comment period ended August 17, 2007. The MMS received four sets of written comments. One set of comments and recommendations was from an industry association; two sets were from third party users of geophysical data and information collected on the Outer Continental Shelf (OCS); and one set was from the public.

Summary of Proposed Rulemaking

The MMS proposed to extend, upon successful application to MMS, the proprietary term of geophysical information that a permittee or third party reprocessed 20 or more years after MMS issued the germane permit under which the originating data were collected. The rule proposed to give up to 5 years of additional protection to reprocessed vintage geophysical information that MMS retains and, without an extension, is subject to release by MMS 25 years after issuing the permit. The extension provides incentives to permittees and third parties to reprocess, market, or in other ways use geophysical information that may not otherwise be reprocessed without the term extension.

Analysis of Comments and Recommendations

The MMS has decided to proceed with the final rule after carefully considering all written comments on the proposed rulemaking.

Comment: One commenter continued to comment about issues and changes put forward by our proposed rulemaking, published July 17, 2002 (67 FR 46942), and the subsequent related final rulemaking, published March 30, 2006 (71 FR 16033).

Response: Changes put forth by the June 18, 2007, proposed rulemaking are directly addressed in this final rulemaking. However, MMS has clarified, where necessary, certain points or matters that pertain to all of 30 CFR part 251.

Comment: Three comments cited the substantial costs that can be incurred in reprocessing existing geophysical information. One estimated costs of reprocessing exclusive 2–D data of $5–10 million for a project of 5,000 sq. km (1,930 sq./mi.). The second comment