PARTIES FILING FOR REHEARING DOCKET NO. RM96–1–009

Party filing rehearing request	Abbreviation
Salt River Project Agricultural Improvement and Power District, Arizona Public Service Company, El Paso Electric Company, PEMEX Gas y Petroquimica Basica, Phelps Dodge Corporation, ASARCO, Inc., BHP Copper, Inc., Cyprus Miami Mining Corp., PNM Gas Services, El Paso Municipal Customer Group (Cities of: Mesa, AZ, Safford, AZ, Benson, AZ, Wilcox, AZ, Las Cruces, NM, Socorro, NM, Deming, NM; Town of Ignacio, CO, Navajo Tribal Utility Authority; Graham County Utilities, Inc.; Duncan Rural Service Corp.; and Black Mountain Gas Company).	East-of-California Shippers.
Eberly & Meade, Inc	Eberly & Meade.
El Paso Energy Corporation Interstate Pipelines	El Paso/Tennessee.
Engage Energy US, L.P	Engage.
Enron Capital & Trade Resources Corporation	ECT.
Enron Interstate Pipelines	Enron.
Exxon Company, U.S.A	Exxon.
Florida Cities, Southern Cities, and Louisiana Municipal Gas Association	Florida Municipals.
Florida Power Corporation	Florida Power.
Great Lakes Gas Transmission Limited Partnership	Great Lakes.
Independent Petroleum Association of America	IPAA.
Intermountain Gas Company, IGI Resources, Inc., Cascade Natural Gas Corporation, Northwest Natural Gas Company, and Washington Water Power Company.	Pacific Northwest Shippers.
Interstate Natural Gas Association of America	INGAA.
KN Interstate Pipelines	KN.
Koch Gateway Pipeline Company	Koch.
Louisville Gas & Electric Company	Louisville.
Midland Cogeneration Venture Limited Partnership	MCV.
NorAm Gas Transmission Company and Mississippi River Transmission Corporation	NGT/MRT.
Missouri Gas Energy, a Division of Southern Union Company	MGE.
National Fuel Gas Distribution Corporation	National Fuel Distribution.
National Fuel Gas Supply Corporation	National Fuel.
Natural Gas Clearinghouse	NGC.
Natural Gas Supply Association	NGSA.
Peoples Gas System	Peoples.
The Peoples Gas Light and Coke Company and North Shore Gas Company	Peoples/NorthShore.
PG&E Gas Transmission, Northwest Corporation	PG&E GT–NW.
Piedmont Natural Gas Company, Inc	Piedmont.
Public Service Company of Colorado and Cheyenne Light, Fuel and Power Company	PSCo/Cheyenne.
Reedy Creek Improvement District	Reedy Creek.
Richardson Products Company	RPC.
Southern Natural Gas Company	Southern.
TransCanada Gas Services, a Division of TransCanada Energy Limited	TCGS.
TransCapacity Limited Partnership	TransCapacity.
Western Gas Resources, Inc	Western.
Williams Gas Pipelines	WGP.
Williston Basin Interstate Pipeline Company	Williston Basin.

[FR Doc. 98–26677 Filed 10–5–98; 8:45 am]
BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Iron Dextran Injection

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 Phoenix Scientific, Inc. The ANADA provides for use of iron dextran injection in baby pigs for prevention or treatment of iron deficiency anemia.

EFFECTIVE DATE: October 6, 1998.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center For Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, filed ANADA 200–256 that provides for use of iron dextran injection-200 in baby pigs for prevention or treatment of iron deficiency anemia.

Approval of Phoenix Scientific, Inc.'s ANADA 200–256 for iron dextran injection is as a generic copy of Boehringer Ingelheim Vetmedica, Inc.'s NADA 134–708 iron dextran complex injection. The ANADA is approved as of August 17, 1998, and the regulations are amended in 21 CFR 522.1182(b)(2) to reflect the approval. 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 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 Dockets Management Branch (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.

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.

§ 522.1182 [Amended]

2. Section 522.1182 *Iron dextran complex injection* is amended in paragraph (b)(2)(i) by removing ''No. 000010'' and adding in its place ''Nos. 000010 and 059130''.

Dated: September 23, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–26648 Filed 10–5–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

Implantation or Injectable Dosage Form New Animal Drugs; Ceftiofur Hydrochloride Sterile 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 two supplemental new animal drug applications (NADA's) filed by Pharmacia & Upjohn Co. One supplemental NADA provides for veterinary prescription use of ceftiofur hydrochloride sterile suspension for intramuscular or subcutaneous injection in cattle for treatment of bovine respiratory disease and acute bovine interdigital necrobacillosis. The second supplemental NADA provides for a revised label warning against use in veal calves.

EFFECTIVE DATE: October 6, 1998.

FOR FURTHER INFORMATION CONTACT: Naba K. Das, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1659.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed two supplements to NADA 140–890. One supplement provides for veterinary prescription use of Excenel® (ceftiofur hydrochloride) Sterile Suspension for intramuscular or subcutaneous injection in cattle for treatment of bovine respiratory disease (BRD, shipping fever, pneumonia) associated with *Pasteurella haemolytica, P. multocida*, and *Haemophilus somnus* and acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*. This supplemental NADA is approved as of July 26, 1998. The second supplemental NADA provides for a revised label warning against use in veal calves and is approved as of August 18, 1998. The regulation is amended in 21 CFR part 522.314 to reflect the approvals. The basis for approval is discussed in the freedom of information summary.

In addition, due to injection site residues following subcutaneous use of this product in cattle, 21 CFR 556.113 is amended to establish tolerances for residues of ceftiofur in edible tissues of treated cattle. Also, the regulation is amended to establish an acceptable daily intake (ADI) for total ceftiofur residues. The ADI represents the total amount of drug residue that can safely be consumed by humans every day.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Dockets Management Branch (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 21 U.S.C. 360b(c)(2)(F)(iii), this approval for food producing animals qualifies for 3 years of marketing exclusivity beginning July 26, 1998, because the supplemental application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or, in the case of food producing animals, human food safety studies (other than bioequivalence or residue studies) required for the approval of the supplement and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the new species (cattle) for which the supplemental application is approved.

The agency has determined under 21 CFR 25.33(d)(5) 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.

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 522.314 is amended by adding paragraph (d)(2) to read as follows:

§ 522.314 Ceftiofur hydrochloride sterile suspension.

* * * * *

(d) * * *

(2) *Cattle*— (i) *Dosage*. 1.1 to 2.2 milligrams per kilogram (0.5 to 1.0 milligrams per pound) of body weight, at 24-hour intervals for 3 to 5 consecutive days. In addition, for bovine respiratory disease, administer 2.2 milligrams per kilogram (1.0 milligram per pound) of body weight every other day on days 1 and 3 (48-hour interval).

(ii) *Indications for use*. For treatment of bovine respiratory disease (BRD, shipping fever, pneumonia) associated with *Pasteurella haemolytica, P. multocida*, and *Haemophilus somnus* and acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*.

(iii) *Limitations*. For intramuscular or subcutaneous use only. Do not inject more than 15 milliliters at each intramuscular injection site. Do not slaughter treated cattle for 48 hours (2 days) after last treatment. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.