Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 522.1222a [Amended]

2. Section 522.1222a *Ketamine hydrochloride injection* is amended in paragraph (c) by removing the number ''057319'' and adding in its place ''059130''.

Dated: March 31, 1997.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 97–10914 Filed 4–25–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Flunixin Meglumine

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 Agri Laboratories, Ltd. The ANADA provides for use of flunixin meglumine injection in horses for alleviation of inflammation and pain associated with musculoskeletal disorders and visceral pain associated with colic.

EFFECTIVE DATE: April 28, 1997.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1617.

SUPPLEMENTARY INFORMATION: Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503, filed ANADA 200–061, which provides for intravenous or intramuscular use of flunixin meglumine injection in horses for alleviation of inflammation and pain associated with musculoskeletal disorders and visceral pain associated with colic. Flunixin meglumine is for veterinary prescription use only.

Approval of ANADA 200–061 for Agri Laboratories' flunixin meglumine injection is as a generic copy of Schering-Plough's Banamine® (flunixin meglumine) Solution (injection) NADA 101–479. The ANADA is approved as of September 11, 1996, and the regulations are amended in 21 CFR 522.970(b) to reflect the approval. The basis for 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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The firm has submitted an abbreviated environmental assessment. In response, FDA has prepared a finding of no significant impact. The agency has determined under 21 CFR 25.24(d)(1)(i) 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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 522.970 is amended by revising paragraph (b) to read as follows:

§ 522.970 Flunixin meglumine solution.

* * * * *

(b) *Sponsors.* See Nos. 000061, 000856, 057561, and 059130 in § 510.600(c) of this chapter.

* * * * *

Dated: April 8, 1997.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 97–10910 Filed 4–25–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 529

Certain Other Dosage Form New Animal Drugs; Gentamicin Sulfate

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 Med-Pharmex, Inc. The ANADA provides for the use of gentamicin sulfate solution in the dipping treatment of turkey hatching eggs as an aid in the reduction or elimination of certain organisms.

EFFECTIVE DATE: April 28, 1997.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767, has filed ANADA 200–191, which provides for use of Gentasol (gentamicin sulfate solution) in the dipping treatment of turkey hatching eggs as an aid in the reduction or elimination of the following organisms from turkey hatching eggs: *Arizona hinshawii* (paracolon), *Salmonella st. paul*, and *Mycoplasma meleagridis*.

The ANADA is approved as a generic copy of Schering Plough's NADA 92–523, Garasol® Solution (gentamicin sulfate veterinary). ANADA 200–191 is approved as of March 24, 1997, and the regulations are amended in 21 CFR 529.1044b to reflect the approval. The basis for 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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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 529

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 529 is amended as follows:

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 529 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 529.1044b [Amended]

2. Section 529.1044b *Gentamicin sulfate solution* is amended in paragraph (b) by removing ''No. 000061'' and adding in its place ''Nos. 000061 and 051259''.

Dated: April 8, 1997.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 97–10913 Filed 4–25–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 934

[SPATS No. ND–034–FOR]

North Dakota Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: Office of Surface Mining Reclamation and Enforcement (OSM) is approving a proposed amendment to the North Dakota regulatory program (hereinafter referred to as the ''North Dakota program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). North Dakota proposed revisions to rules pertaining to: Permit application requirements for the disposal of noncoal wastes; performance standards concerning soil redistribution; revegetation success standards on lands developed for use as prime farmland, recreation, and on previously-mined areas to be developed for water, residential, industrial, and/or commercial uses. The amendment is intended to revise the North Dakota program to be consistent with the corresponding Federal regulations, clarify ambiguities, and improve operational efficiencies.

EFFECTIVE DATE: April 28, 1997.

FOR FURTHER INFORMATION CONTACT: Guy Padgett, Director, Casper Field Office, Telephone: (307) 261–6550.

SUPPLEMENTARY INFORMATION:

I. Background on the North Dakota Program

On December 15, 1980, the Secretary of the Interior conditionally approved the North Dakota program. General background information on the North Dakota program, including the Secretary's findings, the disposition of comments, and conditions of approval of the North Dakota program can be found in the December 15, 1980 **Federal Register** (45 FR 82214). Subsequent actions concerning North Dakota's program and program amendments can be found at 30 CFR 934.15, 934.16, and 934.30.

II. Proposed Amendment

By letter dated March 20, 1996, North Dakota submitted a proposed amendment (Amendment No. XXIII, administrative record No. ND–Y–01) to its program pursuant to SMCRA (30 U.S.C. 1201 *et seq.*). North Dakota submitted the proposed amendment on its own initiative and in response to required program amendments at 30 CFR 934.16 (aa) and (bb). OSM announced receipt of the proposed amendment in the April 24, 1996, **Federal Register** (61 FR 18100; administrative record No. ND–Y–05), provided an opportunity for a public hearing or meeting on its substantive adequacy, and invited public comment on its adequacy. The public comment period ended May 24, 1996. Because no one requested a public hearing or meeting, none was held.

III. Director's Findings

As discussed below, the Director, in accordance with SMCRA and 30 CFR 732.15 and 732.17, finds that the proposed program amendment submitted by North Dakota on March 20, 1996, is no less effective than the corresponding Federal regulations and no less stringent than SMCRA. Accordingly, the Director approves the proposed amendment.

1. Nonsubstantive Revisions to North Dakota's Rules

North Dakota proposed revisions to its approved program that are nonsubstantive in nature and consist of editorial changes. North Dakota proposed to replace, throughout its program, the name of the U.S. ''Soil Conservation Service''with its new name, the ''National Resource Conservation Service.'' North Dakota also proposed to replace the name of the North Dakota ''Department of Health and Consolidated Laboratories,'' with its new name, the ''Department of Health.''

Because these editorial revisions have no significant impact on the substance of the requirements of the program, other than to correctly identify the appropriate Federal and State agencies, the Director finds that the proposed revisions are consistent with and no less effective than the Federal program and approves them.

2. Substantive Revisions to North Dakota's Rules That Are Substantively Identical to the Corresponding Provisions of the Federal Regulations

North Dakota proposed revisions to the following rules that are substantive in nature and contain language that is substantively identical to the requirements of the corresponding Federal regulations (listed in parentheses).

NDAC 69–05.2–19–04.3 (30 CFR 816.89(b)), concerning design and construction of noncoal waste disposal sites to ensure that leachate and drainage from the noncoal waste areas does not degrade surface or underground water.

NDAC 69–05.2–26–05.3.e (30 CFR 823.15(b)(5)), concerning the demonstration of restoration of prime farmland productivity, to require an average annual yield rather than yields from three consecutive growing seasons.

Because these proposed revisions to North Dakota rules are substantively identical to the corresponding provisions of the Federal regulations, the Director finds that they are no less effective than the corresponding Federal regulations. The Director approves these proposed revisions.

3. NDAC 69–05.2–09–02.8, Permit Applications Requirements for Noncoal Waste Disposal

North Dakota proposed to revise NDAC 69–05.2–09–02.8, which currently provides that the required maps and plans of the proposed permit and adjacent areas show each coal storage, cleaning, and loading area, and each coal waste and noncoal waste storage area. Under the proposed revisions, for noncoal wastes that will be disposed of in the proposed permit area, the applicant would be required to provide a description of: (1) Any wastes listed under NDAC 33–20–02.1–01.2.i and (2) ''any other wastes requiring a permit from the state department of