

in NADA 30-314. The ANADA is approved as of October 20, 1995, and the regulations are amended in 21 CFR 522.2100(d)(2) 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 part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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 Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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 522.2100 is amended by revising paragraph (d)(2) to read as follows:

§ 522.2100 Selenium, vitamin E injection.

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(d) * * *

(2) *Sponsors.* See Nos. 000061 and 000856 in § 510.600(c) of this chapter.

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Dated: November 13, 1995.

Stephen F. Sundlof,
 Director, Center for Veterinary Medicine.
 [FR Doc. 95-28543 Filed 11-21-95; 8:45 am]
 BILLING CODE 4160-01-F

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Sarafloxacin Hydrochloride

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 Abbott Laboratories. The NADA provides for use of sarafloxacin hydrochloride solution for injection in day-old broiler chickens for control of early mortality associated with *Escherichia coli* organisms susceptible to sarafloxacin.

EFFECTIVE DATE: November 22, 1995.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center For Veterinary Medicine (HFV-133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1644.

SUPPLEMENTARY INFORMATION: Abbott Laboratories, 1401 Sheridan Rd., North Chicago, IL 60064-4000, filed NADA 141-018, which provides for use of SaraFlox® Injection (sarafloxacin hydrochloride solution for injection) to be used in day-old broiler chickens for control of early mortality associated with *E. coli* organisms susceptible to sarafloxacin. The NADA is approved as of October 12, 1995, and the regulations are amended in part 522 (21 CFR part 522) by adding new § 522.2095 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 part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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 Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning October 12, 1995, because the NADA contains reports of new clinical or field investigations and new human food safety studies essential to the approval and conducted or sponsored by the applicant.

The agency has carefully considered the potential environmental effects of

this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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. New § 522.2095 is added to read as follows:

§ 522.2095 Sarafloxacin solution for injection.

(a) *Specifications.* Each milliliter contains sarafloxacin hydrochloride equivalent to 50 milligrams of sarafloxacin in a 20 percent propylene glycol solution.

(b) *Sponsor.* See No. 000074 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.594 of this chapter.

(d) *Conditions of use.* Day-old broiler chickens:

(1) *Amount.* 0.1 milligram sarafloxacin per 0.2 milliliter dose.

(2) *Indications for use.* For control of early mortality in day-old broiler chickens associated with *Escherichia coli* organisms susceptible to sarafloxacin.

(3) *Limitations.* A single subcutaneous 0.2 milliliter injection in the neck. Dilute 1 milliliter of SaraFlox® with 100 milliliters of sterile water or physiologic saline to provide 0.1 milligram sarafloxacin in a 0.2 milliliter dose. Use entire contents of diluted solution within 24 hours. No preslaughter drug withdrawal period is required when the product is used as directed. Use in a manner other than that indicated or with dosages in excess of that recommended may result in illegal drug residues in edible tissues. Do not use in laying hens producing eggs for human consumption. Do not use in replacement layers or fowl intended for breeding

purposes. The effects of sarafloxacin on the reproductive function of treated fowl have not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: November 13, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[IL135-1-7205(a); FRL-5332-7]

Approval of Section 112(l) Program of Delegation; Illinois

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving, through "direct final" procedure, a request for delegation of the Federal air toxic program pursuant to section 112(l) of the Clean Air Act of 1990. The State's mechanism of delegation involves the straight delegation of all existing and future section 112 standards unchanged from the Federal standards. The actual delegation of authority will occur automatically upon EPA's promulgation of the standards. This request for approval of a mechanism of delegation encompasses all sources not covered by the part 70 program.

DATES: This action is effective January 22, 1996, unless adverse or critical comments not previously addressed by the State or EPA are received by December 22, 1995, in which case this rulemaking action will be taken as the proposed rule published in the proposed rules section of this Federal Register. If the effective date is delayed, timely notice will be published in the Federal Register.

ADDRESSES: Copies of the State's submittal and other supporting information used in developing the approval are available for inspection during normal business hours at the following location: EPA Region 5, 77 West Jackson Boulevard, AR-18J, Chicago, Illinois 60604. Please contact Jennifer Buzecky at (312) 886-3194 to arrange a time if inspection of the submittal is desired.

FOR FURTHER INFORMATION CONTACT: Jennifer Buzecky, AR-18J, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886-3194.

SUPPLEMENTARY INFORMATION:

I. Background and Purpose

Section 112(l) of the CAA enables the EPA to approve state air toxic programs or rules to operate in place of the Federal air toxic program. The Federal air toxic program implements the requirements found in section 112 of the CAA pertaining to the regulation of hazardous air pollutants. Approval of an air toxic program is granted by the EPA if the Agency finds that the State program: (1) Is "no less stringent" than the corresponding Federal program or rule, (2) the State has adequate authority and resources to implement the program, (3) the schedule for implementation and compliance is sufficiently expeditious, and (4) the program is otherwise in compliance with Federal guidance. Once approval is granted, the air toxic program can be implemented and enforced by State or local agencies, as well as EPA. Implementation by local agencies is dependent upon appropriate subdelegation.

On August 17, 1995, Illinois submitted to EPA a request for delegation of authority to implement and enforce the air toxic program under section 112 of the CAA. On September 8, 1995, EPA found the State's submittal complete. In this document EPA is taking final action to approve the program of delegation for Illinois.

II. Review of State Submittal

A. Program Summary

Requirements for approval, specified in section 112(l)(5), require that a State's program contain adequate authorities, adequate resources for implementation, and an expeditious compliance schedule. These requirements are also requirements for an adequate operating permits program under part 70 (40 CFR 70.4). On March 7, 1995, EPA promulgated a final interim approval under part 70 of the State of Illinois' Operating Permit Program. 60 FR 12478. Included in that notice was the approval of a mechanism for delegation of all section 112 standards for sources subject to the part 70 program. Sources subject to the part 70 program are those sources that are operating pursuant to a part 70 permit issued by the State, local agency or EPA. Sources not subject to the part 70 program are those sources that are not required to obtain a part 70 permit from either the State, local agency or EPA. Because Illinois' August 17, 1995, request for delegation encompasses all existing and future standards as they apply to sources NOT subject to part 70, this action

supplements the earlier part 70 rulemaking in that Illinois can now implement and enforce the section 112 air toxic program regardless of a source's part 70 applicability.

The Illinois program of delegation for sources not subject to part 70 will not include delegation of section 112(r) authority. The program will, however, include the delegation of the 40 CFR part 63 general provisions to the extent that they are not reserved to the EPA and are delegable to the State. Furthermore, Illinois' request for delegation includes the delegation of all existing National Emission Standards for Hazardous Air Pollutants (NESHAP) standards, 40 CFR part 61, with the exception of radionuclides.

An example of an existing NESHAP is the asbestos standard, 40 CFR part 61, subpart M. Implementation of this standard includes the primary responsibility for accepting asbestos notifications. Sources in Illinois subject to the asbestos standard should henceforth submit their notification forms to the Illinois Environmental Protection Agency (IEPA).

As stated above, this document constitutes EPA's approval of Illinois' program of straight delegation of all existing and future air toxic standards, except for section 112(r) standards as they pertain to non-part 70 sources. Straight delegation means that the State will not promulgate individual State rules for each section 112 standard promulgated by EPA, but will implement and enforce without changes the section 112 standards promulgated by EPA. The Illinois program of straight delegation will operate as follows: Upon promulgation of a section 112 standard, the State of Illinois automatically receives the authority and assumes responsibility for the timely implementation and enforcement required by the standard, as well as any further activities agreed to by IEPA and EPA. Some activities necessary for effective implementation of the standard include receipt of initial notifications, recordkeeping, reporting and generally assuring that sources subject to the standard are aware of its existence. When deemed appropriate, IEPA will utilize the resources of its Small Business Assistance Program to assist in general program implementation. The details of this delegation mechanism are set forth in a series of letters between EPA and IEPA, copies of which are located in the docket associated with this rulemaking.

B. Criteria for Approval

On November 26, 1993, EPA promulgated regulations to provide