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 522.955 is amended by revising paragraph (d)(1)(i) and the first four sentences of paragraph (d)(1)(iii) to read as follows:

§ 522.955 Florfenicol solution.

* * * * *

(d) * * *

(1) * * *

(i) *Amount.* For intramuscular injection use 20 milligrams per kilogram of body weight (3 milliliters per 100 pounds). A second dose should be given 48 hours later. Alternatively, a single subcutaneous injection of 40 milligrams per kilogram of body weight (6 milliliters per 100 pounds) may be used.

* * * * *

(iii) *Limitations.* For intramuscular or subcutaneous use only. Do not inject more than 10 milliliters at each site. Injection should be given in the neck only. Do not slaughter within 28 days of last intramuscular treatment or within 38 days of subcutaneous treatment.

* * *

* * * * *

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

4. Section 556.283 is revised to read as follows:

§ 556.283 Florfenicol.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of florfenicol is 10 micrograms per kilogram of body weight per day.

(b) *Cattle.* A tolerance of 3.7 parts per million (ppm) for florfenicol amine (marker residue) in liver (target tissue) is established. A tolerance of 0.3 ppm for florfenicol amine in cattle muscle is established.

Dated: July 10, 1998.

Margaret Ann Miller,

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

[FR Doc. 98–20534 Filed 7–31–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Melengestrol Acetate and Oxytetracycline

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 original new animal drug applications (NADA's) filed by Pharmacia & Upjohn Co. The NADA's provide for the use of separately approved Type A medicated articles containing melengestrol acetate (dry and liquid form) and oxytetracycline (dry form) to make dry combination drug Type C medicated feeds. The Type C medicated feeds are for heifers fed in confinement for slaughter for increased rate of weight gain, improved feed efficiency, suppression of estrus, and reduced incidence of liver abscesses.

EFFECTIVE DATE: August 3, 1998.

FOR FURTHER INFORMATION CONTACT: Jack Caldwell, Center For Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1638.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed original NADA's 46–718 and 46–719 that provide for combining separately approved melengestrol acetate (MGA) (dry and liquid form) and oxytetracycline (dry form) Type A medicated articles to make dry Type C medicated feeds for heifers fed in confinement for slaughter for increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and reduced incidence of liver abscesses. The NADA's are approved as of May 6, 1998, and 21 CFR 558.342(d)(8) and 558.450(d)(3)(iii) are added to reflect the approvals.

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.

FDA has determined under 21 CFR 25.33(a)(2) 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 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. Section 558.342 is amended by adding paragraph (d)(8) to read as follows:

§ 558.342 Melengestrol acetate.

* * * * *

(d) * * *

(8) *Amount.* Melengestrol acetate, 0.25 to 0.5 milligram per head per day, plus oxytetracycline, 75 milligrams per head per day.

(i) *Indications for use.* For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and reduction of liver condemnation due to liver abscesses.

(ii) *Limitations.* Heifers fed in confinement for slaughter. Add at the rate of 0.5 to 2.0 pounds per head per day a medicated feed (liquid or dry) containing 0.125 to 1.0 milligram of melengestrol acetate per pound to a feed containing 6 to 10 grams of oxytetracycline per ton; or add at the rate of 0.5 to 2.0 pounds per head per day a dry medicated feed containing 0.125 to 1.0 milligram of melengestrol acetate plus 37.5 to 150 milligrams of oxytetracycline per pound to provide 0.25 to 0.5 milligram of melengestrol acetate and 75 milligrams of oxytetracycline per head per day. Liquid melengestrol acetate may not be mixed

with oxytetracycline in a common liquid feed supplement. Melengestrol acetate as provided by 000009, oxytetracycline by 000069, in § 510.600(c) of this chapter.

3. Section 558.450 is amended by adding paragraph (d)(3)(iii) to read as follows:

§ 558.450 Oxytetracycline.

* * * * *

(d) * * *

(3) * * *

(iii) Melengestrol acetate as in § 558.342.

Dated: June 30, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–20535 Filed 7–31–98; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 159

[OPP–60010K; FRL–6016–2]

RIN 2070–AB50

Pesticide Reporting Requirements for Risk/Benefit Information

AGENCY: Environmental Protection Agency (EPA).

ACTION: Deferral of compliance date; amendment to final rule.

SUMMARY: EPA is amending its recent reporting requirements for risk/benefit information for pesticides to defer the compliance date. EPA is taking this action because it recently published technical corrections to the final rule as well as detailed guidance on reporting procedures. EPA believes that registrants who are required to comply with the rule should have time to adjust their procedures and train personnel to comply with the rule, the corrections, and new guidance in their entirety. Registrants who wish to comply with the final rule immediately may do so after notifying the Agency.

DATES: Effective August 3, 1998. The complaince date for the final rule amending 40 CFR part 159, issued on September 19, 1997 at 62 FR 49388 is deferred from June 16, 1998 until August 17, 1998.

FOR FURTHER INFORMATION CONTACT: By mail: Kathryn Bouve, Office of Pesticide Programs (7502C), U.S. Environmental Protection Agency, 401 M St., SW, Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, Room 224, 1921 Jefferson Davis Highway, Arlington, VA 22202; (703) 305–5032; Bouve.Kate@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. Does This Document Apply to You?

You are affected by this action if you are a pesticide producer who is now or ever has been the registrant of a pesticide product. Regulated categories and entities may include, but is not limited to:

Category	Examples of regulated entities
Industry	Pesticide producers.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. To determine whether you or your business is regulated by this action, you should carefully examine the applicability provisions in the rule at 40 CFR 159.152.

II. Background

On September 19, 1997, EPA published in the **Federal Register** (62 FR 9388 *et seq.*) (FRL–5739–1) new regulations governing the reporting by pesticide registrants of information under section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). That section requires registrants to report to EPA additional factual information in their possession related to whether a pesticide causes unreasonable adverse effects in the environment. Among other things, the new regulations provided registrants with detailed instructions on whether, when, and how to report information in the possession of the registrant or its agents. Until the new rule is effective, registrants are required to comply with Agency guidance issued in 1979 (44 FR 40716, July 12, 1979).

At the time the regulations were promulgated, the Agency was sensitive to the significant need for training and other implementation issues raised by the regulations. The Agency therefore established an effective date for the regulations of June 16, 1998. At the time the regulations were published, the Agency also announced its intention to provide assistance to registrants in implementing the regulations. In addition to providing speakers at seminars and conferences, the Agency commenced preparation of guidance documents to help explain to registrants their responsibilities under the new regulations.

On April 3, 1998, the Agency issued Pesticide Registration (PR) Notice 98–3 which provided guidance to registrants on a broad range of issues. In addition, the Agency promulgated a direct final rule and technical corrections to the regulations, which were published on June 19, 1998 in the **Federal Register** (63 FR 33580) (FRL–5792–2). The June 1998 document corrects the definition of registrants which identifies the parties subject to the regulations, specifies time frames for reporting certain types of adverse effects information, and specifies information to be submitted to the Agency about reportable detections of pesticides in food, feed, and water.

On June 10, 1998, seven pesticide trade associations requested that the effective date of the regulation be deferred for 120 days after issuance of the technical corrections and other guidance. The seven trade associations observed that the new regulations impose extensive new reporting obligations on pesticide registrants which must train numerous individuals to implement their compliance programs. Because of Agency delays in issuing all needed technical corrections and guidance, the trade associations believed that registrants did not have sufficient time to address all requirements before the effective date of the regulations.

The Agency has considered the issues raised by the trade associations and has determined that, given the timing of the issuance of the guidance documents and the technical corrections, it would be appropriate to defer the compliance date of the regulations for an additional 60 days in order to allow registrants the opportunity to incorporate the material included in the guidance documents into their training and implementation programs in an orderly fashion. Accordingly, the Agency is hereby extending the adjustment period and changing the compliance date of the final rule published at 62 FR 49388, September 19, 1997 from June 16, 1998, to August 17, 1998. EPA is also modifying § 159.159 to reflect this new date.

While EPA is deferring the compliance date for the new regulations for a brief period, EPA is also aware that some registrants may wish to comply with the new regulations immediately rather than continue to comply with the pre-existing requirements for another 2 months. Any registrant that wishes to comply with the new regulations immediately may do so provided that the registrant first informs the Agency in writing of its desire to be bound by the new regulations effective June 16, 1998. Such notice should be submitted to Kathryn Bouve, the Agency contact person, at the address given above