already submitted to the Board's TERP for review. This action simply specifies that such data must be accepted by the TERP for all treatment equipment prior to its use under the program.

The Board's Food Quality and Safety Committee (committee) met on April 22, 2008, to consider this change. The committee considered maintaining the status quo whereby equipment could be used under the program that had completed validation testing, but had not been accepted by the TERP. The committee concluded that acceptance by the TERP was important in order to help ensure that all treatment equipment consistently meets the 4-log requirement of the program. The Board agreed with the committee and ultimately recommended that the term ''validation'' be revised accordingly.

This action does not impose any additional reporting and recordkeeping requirements on California almonds handlers, process authorities, or almond manufacturers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

In addition, USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

Further, the committee and Board meetings where this issue was discussed were widely publicized throughout the California almond industry and all interested persons were invited to attend the meetings and participate in deliberations on all issues. The issue was discussed at two committee meetings in April 2008 and at two Board meetings, one in April and one in May 2008. All of these meetings were public meetings, and all entities, both large and small, were able to express views on this issue. Finally, interested persons are invited to submit information on the regulatory and informational impacts of this action on small businesses.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateN&page=MarketingOrdersSmallBusinessGuide*. Any questions about the compliance guide should be sent to Jay Guerber at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

This rule invites comments on a revision to the outgoing quality control requirements currently prescribed under the almond marketing order. Any comments received will be considered prior to finalization of this rule.

After consideration of all relevant material presented, including the Board's recommendation, and other information, it is found that this interim final rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it is also found and determined upon good cause that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this rule into effect and that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** because: (1) This rule makes a revision to the requirements concerning validation contained in the current regulations to help ensure that all treatment equipment meets a 4-log reduction in *Salmonella* in almonds; (2) handlers are aware of this action since the Board unanimously recommended this revision at a public meeting, and interested parties had an opportunity to provide input; and (3) this rule provides a 60-day comment period and any comments received will be considered prior to finalization of this rule.

List of Subjects in 7 CFR Part 981

Almonds, Marketing agreements, Nuts, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, 7 CFR part 981 is amended as follows:

PART 981—ALMONDS GROWN IN CALIFORNIA

■ 1. The authority citation for 7 CFR part 981 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Paragraph (b)(3)(i) in § 981.442 is revised to read as follows:

§ 981.442 Quality control.

* * * * *

(b) * * *

(3) * * *

(i) Validation means that the treatment technology and equipment have been demonstrated to achieve in total a minimum 4-log reduction of *Salmonella* bacteria in almonds. Validation data prepared by a Board-approved process authority must be submitted to and accepted by the TERP for each piece of equipment used to treat almonds prior to its use under the program.

* * * * *

Dated: June 12, 2009.

Craig Morris,

Acting Associate Administrator.

[FR Doc. E9–14281 Filed 6–17–09; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA–2009–N–0665]

Oral Dosage Form New Animal Drugs; Toceranib

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the original approval of a new animal drug application (NADA) filed by Pharmacia & Upjohn Co., a Division of Pfizer, Inc. The NADA provides for the veterinary prescription use of toceranib phosphate tablets in dogs for treatment of recurrent, cutaneous mast cell tumors.

DATES: This rule is effective June 18, 2009.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8337, email: *melanie.berson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed NADA 141–295 that provides for veterinary prescription use of PALLADIA (toceranib phosphate) Tablets in dogs for the treatment of Patnaik grade II or III, recurrent, cutaneous mast cell tumors with or without regional lymph node involvement. The NADA is approved as of May 22, 2009, and the regulations are amended in 21 CFR part 520 to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Division of Dockets Management (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 section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning on the date of approval.

FDA 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 520

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Add § 520.2475 to read as follows:

§ 520.2475 Toceranib.

(a) *Specifications*. Each tablet contains 10, 15, or 50 milligrams (mg) toceranib as toceranib phosphate.

(b) *Sponsor*. See No. 000009 in § 510.600 of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. Administer an initial dose of 3.25 mg per kilogram (1.48 mg per pound) body weight, orally every other day.

(ii) *Indications for use*. For the treatment of Patnaik grade II or III, recurrent, cutaneous mast cell tumors with or without regional lymph node involvement.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved].

Dated: June 12, 2009.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E9–14299 Filed 6–17–09; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 55

[OAR–2004–0091; FRL–8912–7]

Outer Continental Shelf Air Regulations Consistency Update for California

AGENCY: Environmental Protection Agency (''EPA'').

ACTION: Final rule—consistency update.

SUMMARY: EPA is finalizing the update of the Outer Continental Shelf (''OCS'') Air Regulations proposed in the **Federal Register** on March 17, 2009. Requirements applying to OCS sources located within 25 miles of states' seaward boundaries must be updated periodically to remain consistent with the requirements of the corresponding onshore area (''COA''), as mandated by section 328(a)(1) of the Clean Air Act Amendments of 1990 (''the Act''). The portion of the OCS air regulations that is being updated pertains to the requirements for OCS sources for which the Ventura County Air Pollution Control District (Ventura County APCD) is the designated COA. The intended effect of approving the requirements contained in the ''Ventura County Air Pollution Control District Requirements Applicable to OCS Sources'' (May 2009) is to regulate emissions from OCS sources in accordance with the requirements onshore.

DATES: *Effective Date:* This rule is effective on July 20, 2009.

The incorporation by reference of certain publications listed in this rule is approved by the Director of the Federal Register as of July 20, 2009.

ADDRESSES: EPA has established docket number OAR–2004–0091 for this action. The index to the docket is available electronically at *http://www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (*e.g.*, copyrighted material), and some may not be publicly available in either location (*e.g.*, CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Cynthia G. Allen, Air Division, U.S. EPA Region IX, (415) 947–4120, *allen.cynthia@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document, the terms ''we,'' ''us,'' or ''our'' refer to U.S. EPA.

Organization of this document: The following outline is provided to aid in locating information in this preamble.

Table of Contents

I. Background

On March 17, 2009 (74 FR 11330), EPA proposed to approve requirements into the OCS Air Regulations pertaining to Ventura County APCD. These requirements are being promulgated in response to the submittal of rules from this California air pollution control agency. EPA has evaluated the proposed requirements to ensure that they are rationally related to the attainment or maintenance of federal or state ambient air quality standards or Part C of title I of the Act, that they are not designed expressly to prevent exploration and development of the OCS and that they are applicable to OCS sources. 40 CFR 55.1. EPA has also evaluated the rules to ensure that they are not arbitrary or capricious. 40 CFR 55.12(e). In addition, EPA has excluded administrative or procedural rules.

Section 328(a) of the Act requires that EPA establish requirements to control air pollution from OCS sources located within 25 miles of states' seaward boundaries that are the same as onshore requirements. To comply with this statutory mandate, EPA must incorporate applicable onshore rules into 40 CFR part 55 as they exist onshore. This limits EPA's flexibility in deciding which requirements will be incorporated into part 55 and prevents EPA from making substantive changes to the requirements it incorporates. As a result, EPA may be incorporating rules into part 55 that do not conform to all of EPA's state implementation plan (SIP) guidance or certain requirements of the Act. Consistency updates may result in the inclusion of state or local rules or regulations into part 55, even though the same rules may ultimately be disapproved for inclusion as part of the SIP. Inclusion in the OCS rule does not imply that a rule meets the requirements of the Act for SIP approval, nor does it imply that the rule will be approved by EPA for inclusion in the SIP.

II. Public Comment

EPA's proposed actions provided a 30-day public comment period. During this period, we received no comments on the proposed actions.