encouraged to participate in the Committees' deliberations on all issues. Like all Committee meetings, the February 19, 2009, meetings were public meetings and entities of all sizes 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.

This action imposes no additional reporting or recordkeeping requirements on either small or large handlers. 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.

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

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/fv/moab.html.* Any questions about the compliance guide should be sent to Jay Guerber at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the information and recommendation submitted by the Committee and other available information, it is hereby found that this 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) The 2009–10 fiscal period began March 1, 2009, and the marketing orders require that the rates of assessment for each fiscal period apply to all assessable nectarines and peaches handled during such fiscal period; (2) the Committees need to have sufficient funds to pay its expenses which are incurred on a continuous basis; (3) handlers are aware of this action which was recommended by the Committees at public meetings and is similar to other assessment rate actions issued in past years; and (4) this interim final rule provides a 60-day comment period, and all comments timely received will be considered prior to finalization of this rule.

List of Subjects

7 CFR Part 916

Marketing agreements, Nectarines, Reporting and recordkeeping requirements.

7 CFR Part 917

Marketing agreements, Peaches, Pears, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, 7 CFR parts 916 and 917 are amended as follows:

■ 1. The authority citation for 7 CFR parts 916 and 917 continues to read as follows:

Authority: 7 U.S.C. 601–674.

PART 916—NECTARINES GROWN IN CALIFORNIA

■ 2. Section 916.234 is revised to read as follows:

§ 916.234 Assessment rate.

On and after March 1, 2009, an assessment rate of $0.0175 per 25-pound container or container equivalent of nectarines is established for California nectarines.

PART 917—PEACHES GROWN IN CALIFORNIA

■ 3. Section 917.258 is revised to read as follows:

§ 917.258 Assessment rate.

On and after March 1, 2009 an assessment rate of $0.0025 per 25-pound container or container equivalent of peaches is established for California peaches.

Dated: June 12, 2009.

Craig Morris,

Acting Associate Administrator.

[FR Doc. E9–14280 Filed 6–17–09; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 981

[Doc. No. AMS–FV–08–0045; FV08–981–2 IFR]

Almonds Grown in California; Revision of Outgoing Quality Control Requirements

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Interim final rule with request for comments.

SUMMARY: This rule revises the outgoing quality control regulations issued under the California almond marketing order (order). The order regulates the handling of almonds grown in California and is administered locally by the Almond Board of California (Board). This rule revises the term ''validation'' under the *Salmonella* bacteria (*Salmonella*) treatment program by specifying that validation data must be both submitted to and accepted by the Board's Technical Expert Review Panel (TERP) for all treatment equipment prior to its use under this program. This will help ensure that all treatment equipment meets a 4-log reduction of *Salmonella* in almonds.

DATES: Effective June 19, 2009; comments must be received by August 17, 2009.

ADDRESSES: Interested persons are invited to submit written comments concerning this rule. Comments must be sent to the Docket Clerk, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Washington, DC 20250–0237; *Fax:* (202) 720–8938, or *Internet: http://www.regulations.gov.* Comments should reference the document number and the date and page number of this issue of the **Federal Register** and will be available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *http://www.regulations.gov.* All comments submitted in response to this rule will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made public on the Internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Terry Vawter, Senior Marketing Specialist, or Kurt J. Kimmel, Regional Manager, California Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA; *Telephone:* (559) 487–5901, *Fax:* (559) 487–5906, or *E-mail: Terry.Vawter@ams.usda.gov,* or *Kurt.Kimmel@ams.usda.gov.*

Small businesses may request information on complying with this regulation by contacting Jay Guerber, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Washington, DC 20250–0237; *Telephone:* (202) 720–2491, *Fax:* (202) 720–8938, or *E-mail: Jay.Guerber@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This interim final rule is issued under Marketing Order No. 981, as amended (7 CFR part 981), regulating the handling of almonds grown in California, hereinafter referred to as the ''order.'' The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.''

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Order 12866.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect. This rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This interim final rule revises the outgoing quality control requirements under the *Salmonella* treatment program. This rule revises the term ''validation'' by specifying that validation data must be both submitted to and accepted by the Board's TERP for all treatment equipment prior to its use under the program. The TERP consists of four scientists, with a representative from the Food and Drug Administration serving as an ex-officio member. This will help ensure that all treatment equipment meets a 4-log reduction of *Salmonella* in almonds. This action was unanimously recommended by the Board at a meeting on May 20, 2008.

Section 981.42(b) of the order provides authority for the Board to establish, with approval of the Secretary, such minimum quality and inspection requirements applicable to almonds to be handled or to be processed into manufactured product, as will contribute to orderly marketing or be in the public interest. In such crop year, no handler shall handle or process almonds into manufactured items or products unless they meet the applicable requirements as evidenced by certification acceptable to the Board. The Board, with approval of the Secretary, may establish rules and regulations necessary and incidental to the administration of this provision.

Section § 981.442(b) of the order's administrative rules and regulations provides authority for a mandatory treatment program to reduce the potential for *Salmonella* in almonds. A mandatory program went into effect in September 2007. Specifically, handlers must subject their almonds to a treatment process that achieves a minimum 4-log reduction in *Salmonella* prior to shipment. ''Log reduction'' describes how much bacteria is reduced by a treatment process. A 4-log reduction decreases bacteria by a factor of 10,000 (4 zeros). Handlers may treat almonds themselves or transport the almonds to off-site facilities for treatment. Also, handlers may ship untreated almonds to Board-approved manufacturers within the U.S., Canada, and Mexico who agree to treat the almonds appropriately. Handlers may also ship untreated almonds to locations outside the U.S., Canada, and Mexico. Containers of untreated almonds must be labeled ''unpasteurized.''

Paragraph 3 of § 981.442(b) of the regulations specifies that treatment processes must be validated by a Board-approved process authority. Paragraph (i) of that section defines the term ''validation'' to mean that the treatment technology and equipment have been demonstrated to achieve a 4-log reduction. Process authorities run tests to ensure this parameter is met. A process authority is a person who has expert knowledge of appropriate processes for the treatment of almonds and meets criteria specified in paragraph (ii) of that section.

Currently, the regulation does not specify that process authorities submit validation data to the Board's TERP in order to ensure that the treatment equipment meets the program's 4-log requirement. Thus, the Board recommended that the regulation be revised accordingly. This will help ensure that all treatment equipment meets the program's 4-log requirement. Paragraph (3)(i) of § 981.442(b) of the regulations issued under the order is revised accordingly.

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Agricultural Marketing Service (AMS) has considered the economic impact of this rule on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 6,200 producers of almonds in the production area and approximately 100 handlers subject to regulation under the marketing order. Additionally, the Board estimates there are about 15 process authorities and 30 almond manufacturers under the *Salmonella* treatment program. Small agricultural producers are defined by the Small Business Administration (13 CFR 121.201) as those having annual receipts of less than $750,000, and small agricultural service firms are defined as those whose annual receipts are less than $7,000,000.

Data for the most recently-completed crop year indicate that about 50 percent of the handlers shipped under $7,000,000 worth of almonds. Dividing average almond crop value for 2006–07 reported by the National Agricultural Statistics Service of $2.258 billion by the number of producers (6,200) yields an average annual producer revenue estimate of about $364,190. Based on the foregoing, about half of the handlers and a majority of almond producers may be classified as small entities. While data regarding the size of the process authorities and almond manufacturers is not available, it may be assumed that some process authorities and manufacturers may be classified as small entities.

This rule revises § 981.442(b)(3)(i) of the order's administrative rules and regulations. This rule revises the term ''validation'' under the *Salmonella* treatment program to specify that validation data must be both submitted to and accepted by the TERP for each piece of treatment equipment prior to its use under the program. This revision will help ensure that all treatment equipment meets the program's 4-log requirement prior to its use. Authority for this action is provided in § 981.42(b) of the order.

Regarding the overall impact of this action on affected entities, it is expected to be minimal. Validation data is

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]

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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.