

then southeast, northeast, southeast, southwest, southeast, northeast, southeast, northeast, east, southeast, southwest, northwest, southwest, southeast, southwest, northwest, southwest, southeast, southwest, northwest, west, southeast, northwest, west, and southwest on Alum Rock Falls Road to State Highway 130; then southeast on State Highway 130 to Quimby Road; then southwest, northwest, southwest, northwest, southwest, and south on Quimby Road to Buckeye Ranch; then southeast and southwest on Buckeye Ranch to its southwesternmost point; then southwest from that point along an imaginary line to the northeasternmost point of Fowler Road; then southwest, southeast, east, southeast, northwest, southwest, southeast, south, west, northwest, and west on Fowler Road to Yerba Buena Road; then south and west on Yerba Buena Road to San Felipe Road; then southeast on San Felipe Road to Farnsworth Drive; then southwest, northwest, and southwest on Farnsworth Drive to Silver Creek Valley Road; then southwest, southeast, southwest, and west on Silver Creek Valley Road to Blossom Hill Road; then west and southwest on Blossom Hill Road to State Highway 82; then northwest on State Highway 82 to Southside Drive; then southeast from the intersection of State Highway 82 and Southside Drive along an imaginary line to the northeasternmost point of Hillsdale Drive; then southwest on Hillsdale Drive to Hillsdale Avenue; then west on Hillsdale Avenue to State Highway 87; then northwest on State Highway 87 to Interstate 880; then northeast and north on Interstate 880 to the point of beginning.

*Solano County.* That portion of Solano County in the Dixon area bounded by a line as follows: Beginning at the intersection of Boyce Road and Putah Creek Road; then northeast, southeast, and northeast on Putah Creek Road to Stevenson Bridge Road; then northeast and northwest on Stevenson Bridge Road to Putah Creek; then southeast along Putah Creek to the south fork of Putah Creek; then southeast along the south fork of Putah Creek to Old Davis Road; then south, west, and south on Old Davis Road to Tremont Road; then east on Tremont Road to Bulkley Road; then south on Bulkley Road to Midway Road; then west on Midway Road to Sikes Road; then south on Sikes Road to Swan Road; then west on Swan Road to Bunker Station Road; then south on Bunker Station Road to Binghamton Road; then west on Binghamton Road to State Highway 113;

then north on State Highway 113 to Hawkins Road; then west on Hawkins Road to Lewis Road; then north on Lewis Road to Weber Road; then west and northwest on Weber Road to North Meridian Road; then northwest and north on North Meridian Road to Sweeney Road; then west on Sweeney Road to Halley Road; then north, southwest, and northwest on Halley Road to Wolfskill Road; then southwest on Wolfskill Road to Boyce Road; then northwest on Boyce Road to the point of beginning.

Done in Washington, DC, this 30th day of November 2007.

**Kevin Shea,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. E7-23770 Filed 12-6-07; 8:45 am]

**BILLING CODE 3410-34-P**

## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

#### 7 CFR Part 983

[Docket No. AMS-FV-07-0082; FV07-983-1 IFR]

#### Pistachios Grown in California; Changes in Handling Requirements

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Interim final rule with request for comments.

**SUMMARY:** This rule changes the handling requirements currently authorized under the California pistachio marketing order (order). The order regulates the handling of pistachios grown in California and is administered locally by the Administrative Committee for Pistachios (committee). This rule suspends the minimum quality requirements, including maximum defects and minimum sizes, for California pistachios. This will reduce handler costs and provide handlers more flexibility in meeting customer needs.

**DATES:** Effective December 10, 2007; comments received by February 5, 2008 will be considered prior to issuance of a final rule.

**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://](http://www.regulations.gov)

[www.regulations.gov](http://www.regulations.gov). All comments should reference the docket number and the date and page number of this issue of the **Federal Register** and will be made available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: <http://www.regulations.gov>.

#### 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 Email: [Terry.Vawter@usda.gov](mailto:Terry.Vawter@usda.gov) or [Kurt.Kimmel@usda.gov](mailto:Kurt.Kimmel@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@usda.gov](mailto:Jay.Guerber@usda.gov).

**SUPPLEMENTARY INFORMATION:** This rule is issued under Marketing Order No. 983 (7 CFR part 983), regulating the handling of pistachios 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. A 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 rule changes the handling requirements for pistachios currently authorized under the order. This rule suspends the minimum quality requirements, including maximum defects and minimum sizes, for California pistachios. This will reduce handler costs and provide handlers more flexibility in meeting customer needs. This action was recommended by the committee.

Section 983.39 establishes minimum quality levels for pistachios, including maximum defects and minimum sizes permitted under the order. Under § 983.46, the Secretary may modify, suspend, or make rules and regulations to implement §§ 983.38 through 983.45 based upon a recommendation by seven concurring committee members or other available information.

The quality and size requirements have been in effect for California pistachios since the order's inception in 2004. Evidence provided at the promulgation hearing suggested that there was a direct link between lower-quality pistachios and the incidence of aflatoxin contamination (see 68 FR 45990). Aflatoxin is one of a group of mycotoxins produced by the molds *Aspergillus flavus* and *Aspergillus parasiticus*. Aflatoxins are naturally-occurring in the field and can be further spread in improperly processed and stored nuts, dried fruits, and grains. The data presented at the hearing was based on aflatoxin analyses of pistachios with different defects. Although the data also indicated that the levels of aflatoxin associated with each defect varied widely, researchers attributed this to variability among the samples.

As further data was collected in 2005 and 2006, University of California researchers concluded that variability in aflatoxin levels seen in previous studies may have been due to geographic variability<sup>1,2</sup>. Aflatoxin contamination is more prevalent in pistachios produced in the northern San Joaquin Valley, while quality defects, largely due to insect damage, are less prevalent. The opposite is true for the southern San Joaquin Valley. It is now believed

that these differences in aflatoxin contamination between the growing areas are due to differences in climate. The northern San Joaquin Valley has more aflatoxin contamination because its cooler temperatures and greater moisture are more conducive to *Aspergillus* and aflatoxin development, but less conducive to insect population and damage. However, in the southern San Joaquin Valley, there is a higher incidence of insect damage and a much lower incidence of aflatoxin contamination because of the drier environment and higher temperatures. Thus, recent research suggests that aflatoxin occurrence in pistachios may be attributable to climatic factors.

Additionally, growers and handlers are reporting unexpected problems with the size of pistachios this season, as well as with staining of the nut shell from the hull. Pistachios are smaller than usual, and the large crop has resulted in a large percentage of pistachios which may not meet the requirements of the order because the sizes are smaller than currently authorized, which is 30/64ths of an inch. Staining is a problem this season due to unseasonable humidity and spotty rains on August 26th and 30th. The moisture wet the outer hull, and the hull then stained the pistachio shell. Dark stains are an external defect, which affects overall pistachio quality.

Thus, the committee recommended suspending the minimum quality requirements, which include maximum defects and minimum sizes, under the order. This will reduce handler costs and provide handlers more flexibility in meeting customer needs. Suspending these requirements also necessitates modifications to other sections of the order and regulations that reference minimum quality and size requirements. Accordingly, this rule partially suspends or amends language in §§ 983.6, 983.7, 983.31, 983.38, 983.40, 983.41, 983.42, 983.45, 983.138, 983.143, and 983.147 of the order; and suspends §§ 983.19, 983.20, 983.39, and 983.141 in their entirety.

Additionally, the third sentence in § 983.11(b), and all of § 983.71 are removed because the committee's State counterpart, the California Pistachio Commission, has been terminated and there is currently no relationship between the two organizations.

#### Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), Agricultural Marketing Service (AMS) has considered the economic impact of this action 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 would 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.

There are approximately 740 producers in the production area, and 50 handlers of California pistachios subject to regulation. The Small Business Administration (SBA) (13 CFR 121.201) defines small agricultural producers as those having annual receipts less than \$750,000, and defines small agricultural service firms those whose annual receipts are less than \$6,500,000. Of the 740 producers, approximately 722 have annual receipts of less than \$750,000. Forty-two of the 50 handlers subject to regulation have annual pistachio receipts of less than \$6,500,000. Thus, the majority of producers and handlers of California pistachios may be classified as small entities.

This rule changes the handling requirements authorized under the order. This rule suspends the minimum quality requirements, including maximum defects and minimum sizes, for California pistachios. Authority for this action is provided in § 983.46.

Regarding the impact on affected entities, suspending the minimum quality requirements will decrease handler inspection costs. The committee currently estimates that the direct costs to obtain inspection average approximately \$50.00 per lot. The average lot is approximately 44,000 pounds. With over 100,000,000 pounds shipped domestically, the direct costs for inspection for approximately 2,300 lots could total \$115,000 for the industry. The direct costs do not include handler staff time in preparing samples, and handler storage and recordkeeping costs associated with inspected pistachios.

The committee considered alternatives to suspending the minimum quality requirements. Some producers were concerned that this could give handlers too much latitude in their operations. Other producers commented that handlers' customers would likely dictate product quality and prevent shipment of substandard pistachios into the market. Ultimately, the majority of committee members supported the changes.

<sup>1</sup> Doster, M.A., T.J. Michailides, L.D. Boeckler, and D.P. Morgan, 2006. Development of expert systems and predictive models for aflatoxin contamination in pistachios. In California Pistachio Industry Annual Report Crop Year 2005–2006, pg. 101–102.

<sup>2</sup> Doster, M.A., T.J. Michailides, L.D. Boeckler, and D.P. Morgan, 2007. Prediction of aflatoxin contamination and a survey of fungi producing Ochratoxin A in California pistachios. In California Pistachio Industry Annual Report Crop Year 2006–2007, pg. 109–110.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the form ACP-5, "Minimal Testing" being suspended by this rule was previously approved by the Office of Management and Budget and assigned OMB No. 0581-0215, Pistachios Grown in California, for 1 burden hour. 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.

Further, the committee meetings where this action was discussed were widely publicized throughout the pistachio industry and all interested persons were encouraged to attend the meetings and participate in the committee's deliberations. Like all committee meetings, these were public meetings, and entities of all sizes were encouraged to express their views on these issues. Finally, interested persons are invited to submit comments on this interim final rule, including 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/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.

This rule invites comments on changes to the handling requirements currently prescribed under the order. Any comments received will be considered prior to finalization of this rule.

The order provisions suspended by this action no longer tend to effectuate the declared policy of the Act. Accordingly, after consideration of all relevant material presented, including the committee's recommendation, and other information, it is found that this interim final rule, as hereinafter set forth, will 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) It relaxes quality requirements currently in effect; (2) handlers are already receiving 2007-08 crop pistachios, and this rule should apply to as much of the 2007-08 crop as possible; (3) handlers are aware of these changes, which were discussed at two public meetings; and (4) this rule has 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 983

Pistachios, Marketing agreements and orders, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, 7 CFR part 983 is amended as follows:

#### PART 983—PISTACHIOS GROWN IN CALIFORNIA

■ 1. The authority citation for 7 CFR part 983 continues to read as follows:

Authority: 7 U.S.C. 601-674.

#### §§ 983.19, 983.20, 983.39, 983.141 [Amended]

■ 2. In part 983, §§ 983.19, 983.20, 983.39, and 983.141 are suspended indefinitely.

#### § 983.6 [Amended]

■ 3. In § 983.6, the words "free of internal defects as defined in § 983.39(b)(4) and (5)" are suspended indefinitely.

#### § 983.7 [Amended]

■ 4. In § 983.7, the words "and minimum quality" are suspended indefinitely.

#### § 983.11 [Amended]

■ 5. In § 983.11, paragraph (b), the third sentence is removed.

#### § 983.31 [Amended]

■ 6. In § 983.31, the words "and/or minimum quality" are suspended indefinitely.

#### § 983.38 [Amended]

■ 7. In § 983.38, paragraph (d)(1), the words "and divided between those pistachios for aflatoxin testing and those for minimum quality testing" are suspended indefinitely.

■ 8. In § 983.38, paragraph (d)(4), the word " , grade" is suspended from the penultimate sentence indefinitely.

#### § 983.40 [Amended]

■ 9. Paragraph (a) of § 983.40 is suspended indefinitely.

■ 10. In § 983.40, paragraph (b), the words "and/or the minimum quality" are suspended from the first sentence indefinitely, the words "either" and "or the minimum quality" are suspended from the second sentence indefinitely, and the words " , and the handler, under the supervision of an inspector, shall send the failed lot notification reports for the lots that do not meet the minimum quality requirements to the committee" are suspended from the third sentence indefinitely.

■ 11. In § 983.40, paragraph (c), the fifth sentence is suspended indefinitely.

■ 12. Paragraph (e) of § 983.40 is suspended indefinitely.

#### § 983.41 [Amended]

■ 13. Paragraph (b) of § 983.41 is suspended indefinitely.

#### § 983.42 [Amended]

■ 14. In § 983.42, the words "and minimum quality certificate" are suspended indefinitely.

#### § 983.45 [Amended]

■ 15. In § 983.45, the words "and minimum quality requirements," the first "\$," and "and 983.39" are suspended indefinitely.

#### § 983.71 [Removed]

■ 16. Section 983.71 is removed.

■ 17. Section 983.138 is revised to read as follows:

#### § 983.138 Samples for testing.

Prior to testing, a sample shall be drawn from each lot to be used to test pistachios for aflatoxin. The lot sample shall be of sufficient weight to comply with Tables 1 and 2 of § 983.38.

#### § 983.143 [Amended]

■ 18. Section 983.143 is amended by revising paragraph (b) to read as follows:

#### § 983.143 Reinspection.

(a) \* \* \*

(b) Each handler who handles pistachios shall cause any lot or portion of a lot initially certified for aflatoxin, and subsequently materially changed, to be reinspected for aflatoxin and certified as a new lot or new lots: *Provided*, That, handlers exempted from order requirements under § 983.170 are exempt from all reinspection requirements.

■ 19. In § 983.147, paragraph (a) is revised to read as follows:

**§ 983.147 Reports.**

(a) *ACP-2, Failed Lot Notification.* Each handler shall notify the Administrative Committee for Pistachios (committee) of all lots that fail to meet the order's maximum aflatoxin requirements by completing section A of this form. Handlers shall furnish this report to the committee no later than 10 days after completion of the aflatoxin test. Each USDA-approved aflatoxin testing laboratory shall complete section C of this report, and forward this report and the failing aflatoxin test results to the committee and to the handler within 10 days of the test failure.

\* \* \* \* \*

**§ 983.147 [Amended]**

■ 20. Paragraph (d) of § 983.147 is suspended indefinitely.

Dated: December 4, 2007.

**Lloyd C. Day,**

*Administrator, Agricultural Marketing Service.*

[FR Doc. 07-5989 Filed 12-5-07; 10:02 am]

BILLING CODE 3410-02-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 522

#### Implantation or Injectable Dosage Form New Animal Drugs; Erythromycin

**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 supplemental new animal drug application (NADA) filed by Cross Vetpharm Group Ltd. The supplemental NADA provides for use of a 100 milligram per milliliter (mg/mL) strength erythromycin injectable solution in cattle for the treatment of bovine respiratory disease.

**DATES:** This rule is effective December 7, 2007.

**FOR FURTHER INFORMATION CONTACT:** John K. Harshman, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0169, e-mail: [john.harshman@fda.hhs.gov](mailto:john.harshman@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed a supplement to NADA 12-123 for GALLIMYCIN-100 (erythromycin)

Injection. The supplemental NADA provides for use of a 100 mg/mL strength erythromycin injectable solution in cattle for the treatment of bovine respiratory disease. The supplemental NADA is approved as of November 15, 2007, and the regulations in 21 CFR 522.820 are amended to reflect the approval and a current format.

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.

The agency has determined under 21 CFR 25.33(a)(1) 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 Subject 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:** 21 U.S.C. 360b.

■ 2. Revise § 522.820 to read as follows:

#### § 522.820 Erythromycin.

(a) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(b) *Specifications*—(1) Each milliliter (mL) of solution contains 100 milligrams (mg) erythromycin base.

(2) Each mL of solution contains 200 mg erythromycin base.

(c) *Related tolerances.* See § 556.230 of this chapter.

(d) *Conditions of use*—(1) *Dog.* Administer product described in paragraph (b)(1) of this section as follows:

(i) *Amount.* 3 to 5 mg per pound (lb) body weight, intramuscularly, two to three times daily, for up to 5 days.

(ii) *Indications for use.* For the treatment of bacterial pneumonia, upper respiratory infections (tonsillitis, bronchitis, tracheitis, pharyngitis, pleurisy), endometritis and metritis, and bacterial wound infections caused by *Staphylococcus* spp., *Streptococcus* spp., and *Corynebacterium* spp., sensitive to erythromycin.

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

(2) *Cats.* Administer product described in paragraph (b)(1) of this section as follows:

(i) *Amount.* 3 to 5 mg/lb body weight, intramuscularly, two to three times daily, for up to 5 days.

(ii) *Indications for use.* For the treatment of bacterial pneumonia, upper respiratory infections (rhinitis, bronchitis), secondary infections associated with panleukopenia, and bacterial wound infections caused by *Staphylococcus* spp. and *Streptococcus* spp., susceptible to erythromycin.

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

(3) *Cattle.* Administer products described in paragraph (b) of this section as follows:

(i) *Amount.* 4 mg/lb body weight by deep intramuscular injection once daily for up to 5 days.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (shipping fever complex and bacterial pneumonia) associated with *Pasteurella multocida* susceptible to erythromycin.

(iii) *Limitations.* Do not use in female dairy cattle over 20 months of age. Do not slaughter treated animals within 6 days of last treatment. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. To avoid excess trim, do not slaughter within 21 days of last injection.

Dated: November 30, 2007.

**Bernadette Dunham,**

*Deputy Director, Center for Veterinary Medicine.*

[FR Doc. E7-23763 Filed 12-6-07; 8:45 am]

BILLING CODE 4160-01-S