Rules and Regulations

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 993

[AMS-FV-90-115FR]

Dried Prunes Produced in California; Changes in Producer District Boundaries

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: The Agricultural Marketing Service is adopting as a final rule, without modification, the provisions of an interim final rule which revised the administrative rules and regulations established under the Federal marketing order for dried prunes produced in California. The interim final rule changed the boundaries of the districts established for independent producer representation on the Prune Marketing Committee (PMC). The marketing order requires that these districts be divided as equally as practicable in terms of the number of independent producers and their collective dried prune production. Some producer and production shifts had occurred within the California production area which required changes in the district boundaries to bring them in line with order requirements. This action was recommended by the PMC, which is responsible for local administration of the order, and other available information.

EFFECTIVE DATE: May 10, 1990.

FOR FURTHER INFORMATION CONTACT: Allen Belden, Marketing Specialist, Marketing Order Administration Branch, F&V, AMS, USDA, room 2525-S, P.O. Box 96456, Washington, DC 20050-6456; telephone: (202) 475-3923.

SUPPLEMENTARY INFORMATION: This final rule is issued under marketing agreement and Order No. 993 (7CFR Part 993), both as amended, hereinafter referred to as the "order," regulating the handling of dried prunes produced in California. 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."

This rule has been reviewed by the Department in accordance with Departmental Regulation 1512-1 and the criteria contained in Executive Order 12291 and has been determined to be a "non-major" rule.

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

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 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 the RFA and the Act have small entity orientation and compatibility.

There are approximately 15 handlers of dried prunes who are subject to regulation under the dried prune marketing order and approximately 1,200 producers in the regulated area. Small agricultural producers have been defined by the Small Business Administration (13 CFR 121.2) as those having annual receipts of less than $500,000, and small agricultural service firms are defined as those whose annual receipts are less than $3,500,000. The majority of handlers and producers of California dried prunes may be classified as small entities.

This final rule adopts an interim final rule which revised the boundaries of the seven districts established for independent producer representation on the PMC to ensure that, as far as practicable, each district represents an equal number of producers and an equal volume of prunes grown by such producers. It is the view of AMS that the change will not impose any additional regulatory, informational, or cost requirements on handlers or producers.

The interim final rule adopted by this action without modification revised § 993.128 of Subpart—Administrative Rules and Regulations and was based on a unanimous recommendation of the PMC and other available information.

Section 993.24 of the order provides that the PMC shall consist of 22 members, of which 14 shall represent producers, seven shall represent handlers, and one shall represent the public. The 14 producer member positions are apportioned between cooperative producers and independent producers in the same proportion, as nearly as practicable, as the percentage of the total prune tonnage handled by the respective cooperative or independent handler group during the year preceding the year in which nominations are made is to the total handled by all handlers. In recent years, the cooperative producers and the independent producers have each been eligible to nominate seven members.

Section 993.28 of the order provides that, for independent producers, the PMC shall, with the approval of the Secretary of Agriculture, divide the production area into districts, giving, insofar as practicable, equal representation throughout the production area by numbers of independent producers and production of prune tonnage by such producers. When revisions are required, the PMC must make its recommendations to the Secretary of Agriculture to change the district boundaries prior to January 31 of any year in which nominations are to be made. Nominations are made in all even-numbered years, including 1990.

The PMC made a recommendation to change the independent producer district boundaries at its November 30, 1989, meeting. The recommendation was made because, since the last redistricting in 1982, the number of producers and volume of production in most districts had changed, causing imbalances among some of the districts. Thus, redistricting was needed to bring current districts in line with order requirements.

The interim final rule removed Colusa County from District No. 7 and added it to District No. 2. Lake, Mendocino, Napa, and Sonoma counties were removed from District No. 3 and added to District No. 4. Sutter County, which had been divided between Districts No. 1 and No. 2, was divided among Districts No. 1, No. 2, and No. 3. The boundaries of Districts No. 5 and No. 6

remained the same. The counties of Humboldt, Trinity, Del Norte, and Siskiyou, which had been named in District No. 3, were not named in the redistricting because they were no longer significant prune-producing counties. Unspecified counties continued to be included in District No. 4.

In arriving at its recommendation, the PMC calculated the percentage of total independent prune growers for each proposed district and the percentage of total independent prune tonnage for each proposed district. These two percentages were averaged for each district to determine a representation factor for each district. The optimal representation factor for each of the seven districts was determined to be 14.29 percent (100 percent ÷ seven).

The representation factors for each of the seven new districts are shown below based on the 1988–89 crop year. The representation factors for the old districts based on the 1988–89 crop year are shown as a basis for comparison.

[In percent]

	Representation factor	
	Old districts	New districts
District:		
1	17.38	13.10
2	17.38	13.10
3	6.89	13.10
4	12.85	16.91
5	12.03	12.03
6	16.59	16.59
7	16.90	15.19

The recommended method for redistricting was deemed to be desirable as it allowed each district to approximate the optimal representation factor, while maintaining a continuous geographic boundary for each district. In addition, several of the districts whose representation factors are below the optimum are expected to experience production increases in the next few years which are likely to be above the industry average.

The interim final rule which changed the boundaries of the districts established for independent producer representation on the PMC was published in the **Federal Register** on February 16, 1990 [55 FR 5571]. That rule provided that interested persons could file written comments through March 19, 1990. No comments were received.

Based on the above, the Administrator of the MAS has determined that the issuance of this final rule will not have a significant economic impact on a substantial number of small entities.

After consideration of all available information, it is found that the issuance of a final rule to change the boundaries of the districts established for independent producer representation on the PMC, 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 that good cause exists for not postponing the effective date of this action until 30 days after publication in the **Federal Register** because: (1) This action does not impose additional regulatory requirements on handlers or producers and, therefore, neither handlers nor producers need additional time to comply; (2) the industry is aware of this action, which was recommended by the PMC at an open meeting; and (3) this final rule is an adoption, without modification, of an interim final rule which became effective February 16, 1990.

List of Subjects in 7 CFR Part 993

Marketing agreements, Plums, Prunes, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 993 is amended as follows:

PART 993—DRIED PRUNES PRODUCED IN CALIFORNIA

1. The authority citation for 7 CFR part 993 continues to read as follows:

Authority: Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–74.

Subpart—Administrative Rules and Regulations

2. Accordingly, the interim final rule amending 7 CFR part 993 which was published at 55 FR 5570–5571 on February 16, 1990, is adopted as a final rule without change.

Note: This action will be published in the annual Code of Federal Regulations.

Dated: May 7, 1990.

William J. Doyle,

Deputy Director, Fruit and Vegetable Division.

[FR Doc. 90–10928 Filed 5–9–90; 8:45 am]

BILLING CODE 3410–02–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Adminstration

21 CFR Part 74

[Docket No. 89C–0304]

Listing of Color Additives for Coloring Sutures: [Phthalocyaninato(2-)] Copper

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use of [phthalocyaninato(2-)] copper to color nonabsorbable monofilament sutures composed of polybutylene terephthalate for general and ophthalmic surgery. This action responds to a petition filed by Davis & Geck.

DATES: Effective May 11, 1990. Except as to any provisions that may be stayed by the filing of proper objections: written objections by June 11, 1990.

ADDRESSES: Written objections may be sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Sandra L. Varner, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of August 10, 1989 (54 FR 32850, FDA announced that a color additive petition (CAP 8C0213) had been filed by Davis & Geck, One Casper St., Danbury, CT 06810, proposing that 21 CFR 74.3045 be amended to provide for the safety use of [phthalocyaninato(2-)] copper to color nonabsorbable monofilament sutures composed of polybutylene terephthalate for general and ophthalmic surgery. The petition was filed under section 706 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 376).

II. Applicability of the Act

With the passage of the Medical Device Admendments of 1976 (Pub. L. 94–295), Congress mandated the listing of color additives for use in medical devices when the color additive comes into contact with the body for a

significant period of time (21 U.S.C. 376(a)). [Phthalocyaninato(2-)] copper is added to nonabsorbable monofilament sutures composed of polybutylene terephthalate in such a way that at least some of the additive will come into contact with the body when the sutures are in place. In addition, the sutures are intended to remain in the body at least until healing is complete. Thus, the color additive will be in direct contact with the body for a significant period of time. Consequently, the use of the color additive currently before the agency is subject to the statutory listing requirement.

III. Safety Evaluation

FDA concludes from the data submitted in the petition and from other relevant information that the upper limit of exposure to [phthalocyaninato(2-)] copper from its use in coloring nonabsorable monofilament sutures composed of polybutylene terephthalate is 0.33 microgram per person per day. The agency-calculated upper limit was based on the following two factors. First, the color additive will be used at levels not to exceed 0.5 percent by weight of the polybutylene terephthalate suture. Second, the agency made four worst-case assumptions that: (1) Five meters is the maximum total length of suture likely to be used in a single surgical operation, and that 10 meters of suture would be needed to accommodate multiple operations over a person's lifetime, (2) a lifespan of 50 years follows initial suture implantation, (3) a size 2/0 suture is used, and (4) 100 percent of the color additive migrates from the suture into the body (Ref. 1). Because these are highly conservative assumptions, exposure to [phthalocyaninato(2-)] copper from its use for coloring nonabsorbable monofilament sutures composed of polybutylene terephthalate is likely to be far less than 0.33 microgram per person per day.

To establish that the color additive [phthalocyaninato(2-)] copper is safe for use in coloring polybutylene terephthalate sutures, the petitioner conducted a 120-day implantation toxicity study to compare the breaking strength and tissue reaction of the firm's suture to a polybutester suture containing this same color additive that is listed under § 74.3045. In addition, the petitioner has relied upon the fact that: (1) The agency has adequate toxicity studies in its files on this color additive, and (2) the firm's suture material is chemically similar to the polybutester suture material that is currently regulated under § 74.3045 for which the agency has comparable safety data in its files.

The agency has evaluated the comparative 120-day implantation study in rats that was submitted by the petitioner and finds that there was no gross tissue reaction to the petitioner's polybutylene terephthalate suture colored with [phthalocyaninato(2-)] copper. The study also demonstrated that the petitioner's suture had slightly greater strength up to 120 days after implantation in rats when compared to the polybutester suture. In addition, the agency finds that there will be no significant increase in exposure to [phthalocyaninato(2-)] copper from its use in polybutylene terephthalate sutures, because this suture material is expected to compete with other authorized suture materials containing [phthalocyaninato(2-)] copper. The agency also finds that there is sufficient toxicological information in its files on [phthalocyaninato(2-)] copper to permit the new use of this color additive in polybutylene terephthalate sutures. The studies previously submitted to support the safety of this color additive include 6-month implantation toxicity studies in rats and dogs; studies on the effect of implantation on reproduction and teratogenesis in rats and rabbits; sensitization studies, including skin irritation studies on suture extracts in rabbits; and cytotoxicity studies, including in vitro agar overlay tests with mouse fibroblast cells. The agency also finds that the polybutylene terephthalate suture is sufficiently similar, physically and chemically, to the currently regulated polybutester suture and therefore, that the localized effects from the migration of the color additive to surrounding tissue will be similar for these two suture materials.

Therefore, based upon the petitioner's submitted implantation study demonstrating the lack of tissue reaction to the use of the color additive in polybutylene terephthalate nonabsorbable sutures, the available toxicity data of the polybutester suture containing this color additive, and the estimated exposure calculation, FDA finds that the color additive [phthalocyaninato(2-)] copper is safe for use in polybutylene terephthalate nonabsorbable monofilament sutures for general and ophthalmic surgey at a level not to exceed 0.5 percent by weight of the suture material.

IV. Specifications and Certification

[Phthalocyaninato(2-)] copper is currently regulated as a color additive, subject to certification, for use in coloring contact lenses and for use in coloring certain sutures for general and ophthalmic surgery at levels not to exceed 0.5 percent by weight of the suture. The agency concludes that the specifications currently established for [phthalocyaninato(2-)] copper for these uses under § 74.3045 are adequate to ensure the safe use of this color additive in medical devices.

V. Conclusions

Based on data contained in the petition and other relevant material, FDA concludes that there is a reasonable certainty that no harm will result from the petitioned use of [phthalocyaninato(2-)] copper for coloring polybutylene terephthalate nonabsorbable monofilament sutures for general and ophthalmic surgery when used at a maximum level of 0.5 percent by weight of the suture. The agency also concludes that the color additive will perform its intended coloring effect in the nonabsorbable monofilament suture material, polybutylene terphthalate, and thus, is suitable for this use. The agency, therefore, is amending the color additive regulations by revising the introductory text in 21 CFR 74.3045(c)(1) to provide for use of the color additive at a maximum level of 0.5 percent in polybutylene terephthalate sutures.

VI. Inspection of Documents

In accordance with 21 CFR 71.15, the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 71.15, the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

VII. Environmental Impact

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.

VIII. Objections

Any person who will be adversely affected by this regulation may at any time on or before June 11, 1990, file with the Dockets Management Branch

(address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. FDA will publish a notice of the objections that the agency has received, or lack thereof in the Federal Register.

IX. Reference

The following reference has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum dated August 19, 1988, from the Food and Color Additives Review Section to the Indirect Additives Branch, "CAP 8CO213—Davis & Geck. Phthalocyaninato (2-) copper to color nonabsorbable sutures. Submission dated December 21, 1987."

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 74 is amended as follows:

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

1. The authority citation for 21 CFR part 74 continues to read as follows:

Authority: Secs. 201, 401, 402, 403, 409, 501, 502, 505, 601, 602, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 376).

2. Section 74.3045 is amended by revising the introductory text of paragraph (c)(1) to read as follows:

§ 74.3045 [Phthalocyaninato(2-)] copper.

* * * * *

(c) * * * (1) The color additive [phthalocyaninato(2-)] copper may be safely used to color polypropylene sutures, polybutester (the generic designation for the suture fabricated from 1,4-benzenedicarboxylic acid, polymer with 1,4-butanediol and *alpha*-hydro-*omega*-hydroxypoly(oxy-1,4-butanediyl), CAS Reg. No. 37282-12-5) nonabsorbable sutures for use in general and ophthalmic surgery, polybutylene terephthalate nonabsorbable monofilament sutures for general and ophthalmic surgery, and polymethylmethacrylate monofilament used as supporting haptics for intraocular lenses, subject to the following restrictions:

* * * * *

Dated: May 3, 1990.

Ronald G. Chesemore,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 90-10911 Filed 5-9-90; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 143

RIN: 1076-AC29

Charges for Goods and Services Provided to Non-Federal Users

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Interim rule.

SUMMARY: The Independent Office Appropriations Act (31 U.S.C. 9701) requires that Federal agencies charge for those goods/services provided to members of the public (called "non-Federal users" in these regulations) above and beyond the goods/services provided to the public at large. The statute also requires that regulations be promulgated in order for the Bureau of Indian Affairs (BIA) to charge for goods/services provided to non-Federal users. The intent of these regulations is to enable the BIA to continue to provide goods/services and to bill and collect for such goods/services.

EFFECTIVE DATE: May 10, 1990.

FOR FURTHER INFORMATION CONTACT: Joe Christie, Bureau of Indian Affairs, 18th & C Street NW., MS-4513-MIB, Washington, DC 20240, FTS 343-5831 or (202) 343-5831 or, Joseph Gourneau, Billings Area Office, Bureau of Indian Affairs, 316 North 26th Street, Billings, MT 59101, FTS 585-6315 or (406) 657-6315.

SUPPLEMENTARY INFORMATION: The authority for these regulations is 31 U.S.C. 9701 and 25 U.S.C. 2, 13, 413. This interim rule is published in exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by 209 DM 8.

Goods/services have been provided to non-Federal users and payments for these goods/services have been collected for many years. These regulations are being promulgated to permit the BIA to continue to charge for the goods/services. Not collecting fees for the goods/services may cause the provision of the goods/services to be discontinued.

A proposal to adopt this interim rule as a final rule appears elsewhere in the Proposed Rules portion of this issue of the Federal Register. Comments may be submitted in accordance with that proposal.

Executive Order 12291 and the Regulatory Flexibility Act

This rulemaking affects only a limited amount of locations (less than 90), where the BIA is delivering goods/services to non-Federal users, and no other groups will be affected. As the BIA billed and collected for these goods/services prior to the promulgation of the rule, the rule will not cause any increased economic effect. Further, this rule will not adversely affect or impact tribal organizations or other forms of small entities as the rule will not result in increases or decreases in charges to non-Federal users.

Accordingly, the Department of the Interior has determined that this document is not a major rule under Executive Order 12291 and that it will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Paperwork Reduction Act

This rule does not contain information collection requirements which require approval by the Office of Management and Budget under 44 U.S.C. 3401 *et seq.* See 5 CFR 1320.7(j).

Environmental Effects

The Department of the Interior has determined that this rule is categorically excluded from the National Environmental Policy Act (NEPA) process because it is of an administrative, routine financial, legal, technical and procedural nature, and therefore neither an environmental