

Rules and Regulations

Federal Register

Vol. 74, No. 141

Friday, July 24, 2009

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 925

[Doc. No. AMS-FV-08-0107; FV09-925-2 FIR]

Grapes Grown in a Designated Area of Southeastern California; Decreased Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Affirmation of interim final rule as final rule.

SUMMARY: The Department of Agriculture (USDA) is adopting, as a final rule, without change, an interim final rule that decreased the assessment rate established for the California Desert Grape Administrative Committee (Committee), for the 2009 and subsequent fiscal periods from \$0.02 to \$0.01 per 18-pound lug of grapes handled. The Committee locally administers the marketing order for grapes grown in a designated area of southeastern California (order). The interim final rule was necessary to align the Committee's expected revenue with decreases in its proposed budget for the 2009 fiscal period, which began on January 1.

DATES: *Effective Date:* Effective July 27, 2009.

FOR FURTHER INFORMATION CONTACT: Jennifer Robinson, 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: Jen.Robinson@ams.usda.gov or Kurt.Kimmel@ams.usda.gov.

Small businesses may obtain information on complying with this and other marketing order regulations by viewing a guide at the following Web

site: <http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateN&page=MarketingOrdersSmallBusinessGuide>; or 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 rule is issued under Marketing Order No. 925, as amended (7 CFR part 925), regulating the handling of grapes grown in a designated area of southeastern 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.

Under the order, California desert grape handlers are subject to assessments, which provide funds to administer the order. Assessment rates issued under the order are intended to be applicable to all assessable desert grapes for the entire fiscal period, and continue indefinitely until amended, suspended, or terminated. The Committee's fiscal period begins on January 1, and ends on December 31.

In an interim final rule published in the **Federal Register** on February 24, 2009, and effective on February 25, 2009 (74 FR 8141, Doc. No. AMS-FV-08-0107; FV08-932-2 IFR), § 925.215 was amended by decreasing the assessment rate established for the Committee for the 2009 and subsequent fiscal periods from \$0.02 to \$0.01 per 18-pound lug or equivalent of desert grapes. The decrease in the per-unit assessment rate was possible due to significant decreases in budgeted management and administrative expenses for 2009.

Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612), the Agricultural Marketing Service (AMS) has considered the economic impact of this rule on small entities. Accordingly, AMS has prepared this final 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.

There are approximately 14 handlers of southeastern California grapes who are subject to regulation under the order and about 50 grape producers in the production area. Small agricultural service firms are defined by the Small Business Administration (13 CFR 121.201) as those having annual receipts of less than \$7,000,000, and small agricultural producers are defined as those whose annual receipts are less than \$750,000. Nine of the 14 handlers subject to regulation have annual grape sales of less than \$7 million. Based on data from the National Agricultural Statistics Service (NASS) and the Committee, the average crop value for 2008 is about \$53,040,000. Dividing this figure by the number of producers (50) yields an average annual producer revenue estimate of about \$1,060,800, which is above the SBA threshold of \$750,000. Based on the foregoing, it may be concluded that a majority of grape handlers and none of the producers may be classified as small entities.

This rule continues in effect the action that decreased the assessment rate established for the Committee and collected from handlers for the 2009 and subsequent fiscal periods from \$0.02 to \$0.01 per 18-pound lug of grapes. The Committee unanimously recommended expenditures of \$77,692 and an assessment rate of \$0.01 per 18-pound lug of grapes for the 2009 fiscal period. The assessment rate of \$0.01 is one-half of the rate currently in effect. The number of assessable grapes is estimated at 6.5 million 18-pound lug of grapes. Thus, the \$0.01 rate should provide \$65,000 in assessment income. Income derived from handler assessments, along with interest income and funds from the Committee's authorized reserve will be adequate to cover budgeted expenses.

The major expenditures recommended by the Committee for the 2009 fiscal period include \$10,500 for compliance activities, \$53,000 for salaries and payroll expenses, and

\$14,192 for other administrative expenses. In comparison, budgeted expenses for these items in 2008 were \$5,000 for compliance activities, \$61,000 for salaries, \$18,000 for research, and \$49,254 for other administrative expenses.

Decreases in management and administrative expenses are the result of management services, office rental fees and utilities being shared by the Committee and the California Date Administrative Committee (CDAC). In 2008, the Committee and the CDAC agreed to share management and administrative costs in order to streamline expenses for both programs. Additionally, the Committee recommended not renewing its budget for research in 2009 given that there were no pending research proposals at the time the budget was reviewed.

Prior to arriving at this budget, the Committee considered alternative expenditure and assessment rate levels, but ultimately decided that the recommended levels were reasonable to properly administer the order. The assessment rate recommended by the Committee was derived by the following formula: Anticipated 2009 expenses (\$77,692) plus the desired 2009 ending reserve (\$88,534), minus the 2009 beginning reserve (\$100,226) plus anticipated interest income (\$1,000), divided by the estimated 2009 shipments (6.5 million 18-pound lugs).

This rate should provide sufficient funds in combination with interest and reserve funds to meet the anticipated expenses of \$77,692 and result in a December 2009 ending reserve of \$88,534. This figure is about \$10,800 over the Committee's 2009 expenses. Section 925.41 of the order permits the Committee to maintain approximately one fiscal period's expenses in reserve. The Committee plans to continue using reserve funds to help meet its expenses and bring the reserve to a level lower than its expenses.

To calculate the percentage of grower revenue represented by the assessment rate for 2008, the assessment rate of \$0.02 per 18-pound lug is divided by the estimated average grower price (according to the NASS). This results in estimated assessment revenue for the 2008 season as a percentage of grower revenue of .245 percent (\$0.02 divided by \$8.16 per 18-pound lug). NASS data for 2009 is not yet available. However, applying the same calculations above using the average grower price for 2006–08 would result in estimated assessment revenue as a percentage of total grower revenue of .13 percent for the 2009 season (\$0.01 divided by \$7.77 per 18-pound lug). Thus, the assessment

revenue should be well below 1 percent of estimated grower revenue in 2009.

This rule continues in effect the action that decreased the assessment obligation imposed on handlers. Assessments are applied uniformly on all handlers, and some of the costs may be passed on to producers. However, decreasing the assessment rate reduces the burden on handlers, and may reduce the burden on producers. In addition, the Committee's meeting was widely publicized throughout the grape production area and all interested persons were invited to attend the meeting and participate in Committee deliberations on all issues. Like all Committee meetings, the November 14, 2008, meeting was a public meeting and all entities, both large and small, were able to express views on this issue.

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

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

Comments on the interim final rule were required to be received on or before April 27, 2009. No comments were received. Therefore, for the reasons given in the interim final rule, we are adopting the interim final rule as a final rule, without change.

To view the interim final rule, go to <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=AMS-FV-08-0107>.

This action also affirms information contained in the interim final rule concerning Executive Orders 12866 and 12988, the Paperwork Reduction Act (44 U.S.C. Chapter 35), and the E-Gov Act (44 U.S.C. 101).

After consideration of all relevant material presented, it is found that finalizing the interim final rule, without change, as published in the **Federal Register** (74 FR 8141, February 24, 2009) will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 925

Grapes, Marketing agreements, Reporting and recordkeeping requirements.

PART 925—GRAPES GROWN IN A DESIGNATED AREA OF SOUTHEASTERN CALIFORNIA—[AMENDED]

■ Accordingly, the interim final rule amending 7 CFR part 925, which was published at 74 FR 8141 on February 24, 2009, is adopted as a final rule, without change.

Dated: July 20, 2009.

Rayne Pegg,

Administrator, Agricultural Marketing Service.

[FR Doc. E9–17602 Filed 7–23–09; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket No. FDA–2009–N–0316]

New Drug Applications and Abbreviated New Drug Applications; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its new drug application (NDA) and abbreviated new drug application (ANDA) regulations to correct the address for the Orange Book Staff in the Office of Generic Drugs. This action is being taken to ensure accuracy and clarity in the agency's regulations.

DATES: This rule is effective July 24, 2009.

FOR FURTHER INFORMATION CONTACT:

Olivia A. Pritzlaff, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 51, rm. 6308, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3506.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations in part 314 (21 CFR part 314) to correct the address for Orange Book Staff in the Office of Generic Drugs in §§ 314.52(a)(2), 314.53(f), and 314.95(a)(2).

List of Subjects in 21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under