

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 2005 fiscal period began on January 1, 2005, and the marketing order requires that the rate of assessment for each fiscal period apply to all assessable Vidalia onions handled during such fiscal period; (2) this action changes the assessable carton size from a 50-pound bag or equivalent to the current industry standard 40-pound carton size; (3) the Committee needs to have sufficient funds to pay its expenses, which are incurred on a continuous basis; (4) handlers are aware of this action which was unanimously recommended by the Committee at a public meeting and is similar to other assessment rate actions issued in past years; and (5) 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 in 7 CFR Part 955

Onions, Marketing agreements, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, 7 CFR part 955 is amended as follows:

PART 955—VIDALIA ONIONS GROWN IN GEORGIA

■ 1. The authority citation for 7 CFR part 955 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Section 955.209 is revised to read as follows:

§ 955.209 Assessment rate.

On and after January 1, 2005, an assessment rate of \$0.10 per 40-pound carton or equivalent is established for Vidalia onions.

Dated: March 2, 2005.

Kenneth C. Clayton,
Acting Administrator, Agricultural Marketing Service.

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 987

[Docket No. FV04–987–1 FR]

Domestic Dates Produced or Packed in Riverside County, CA; Modification of the Qualification Requirements for Approved Manufacturers of Date Products

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule modifies the requirements for approved manufacturers of date products under the marketing order regulating the handling of domestic dates produced or packed in Riverside County, California. The marketing order is administered locally by the California Date Administrative Committee (committee). The committee's approved product manufacturer program helps assure that only high quality whole and pitted dates are shipped within the United States and exported to Canada. This rule clarifies the application procedures and qualification requirements for an approved manufacturer of date products. This rule also specifies that a regulated date handler must be in compliance with the marketing order to be an approved manufacturer of date products. These modifications will help safeguard the integrity of the approved date product manufacturer program, as well as the quality of whole and pitted dates marketed both domestically and in Canada.

EFFECTIVE DATE: This final rule becomes effective March 9, 2005.

FOR FURTHER INFORMATION CONTACT:

Terry Vawter, Marketing Specialist, California Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 2202 Monterey Street, suite 102B, Fresno, California 93721; telephone: (559) 487–5901, Fax: (559) 487–5906; or George Kelhart, Technical Advisor, 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.

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.

SUPPLEMENTARY INFORMATION: This final rule is issued under Marketing Agreement and Order No. 987, as amended (7 CFR part 987), regulating the handling of domestic dates produced or packed in Riverside County, 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 final 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.

Summary of the Rule Change

This final rule modifies the requirements for approved manufacturers of date products in § 987.157 of the order's administrative rules and regulations. This rule clarifies the application procedures and qualification requirements for approved manufacturers of date products. This rule also specifies that, to be an approved manufacturer of date products, a regulated date handler must be in compliance with the order. These modifications will help safeguard the integrity of the approved date product manufacturer program, as well as the quality of whole and pitted dates marketed both domestically and in

Canada. These changes were recommended unanimously by the committee at a meeting on April 23, 2004.

Authority for Approved Manufacturers

Section 987.57 of the order provides the authority for the approved date product manufacturer program. Section 987.57 states in part: "Diversion of dates pursuant to § 987.55 or § 987.56 shall be accomplished only by such persons (which may include handlers) as are approved manufacturers or feeders * * * The application and approval shall be in accordance with such rules, regulations and safeguards as may be prescribed pursuant to § 987.59." Further, § 987.59 states: "The Committee may prescribe, with the approval of the Secretary, such rules, regulations and safeguards as are necessary to prevent dates covered by §§ 987.55 and 987.56 from interfering with the objectives of this part."

Finally, § 987.157 of the order's administrative rules and regulations prescribes the application procedure and qualification requirements to become an approved manufacturer of date products.

Background Information and Committee Action Taken

At its public meeting on April 23, 2004, the committee unanimously recommended modifying the application procedures and qualification requirements for approved manufacturers of date products. The committee's approved date product manufacturer program helps assure that high quality whole and pitted dates are marketed in the United States and Canada. Whole and pitted dates shipped within the United States and to Canada must at least meet the requirements of U.S. Grade B, whereas dates for manufacture into products must meet the lower quality requirements of U.S. Grade C.

Only firms on the committee's list of approved date product manufacturers are allowed to receive dates for conversion into date products. These entities agree to alter the form and appearance of the lower quality dates so they cannot be marketed in competition with higher quality whole and pitted dates in the United States and Canada.

Based on the committee's recommendation, the procedures used to qualify an applicant as an approved manufacturer of date products have been revised in this final rule to help ensure that each applicant is treated similarly, and that an approved date product manufacturer remains qualified

to receive dates for conversion into products.

Within the regulated production area (Riverside County, California), all approved manufacturers are also date handlers regulated under the order. Conversely, approved manufacturers outside the regulated area are not regulated date handlers.

This rule also helps safeguard the integrity of the approved manufacturer program by requiring that regulated handlers be in compliance with the order—including the assessment and reporting requirements of the order—for approval as date product manufacturers. Once approved as a date product manufacturer, handlers must stay in compliance with the requirements of the order to remain on the committee's approved date product manufacturers' list.

Prior to revoking a handler's approved manufacturer status for noncompliance with the requirements of the order, the committee staff will consult with USDA. If, after consultation with USDA and notification of the handler, the approved product manufacturer continues to be in noncompliance with order requirements, the committee staff will announce the revocation of such handler's approved manufacturer status by mailing or faxing a revised approved manufacturer list to all date handlers in the regulated area.

Further, the approved manufacturers will be required to maintain accurate records regarding date product information and provide these records to the committee staff. This will enable the committee to verify that each approved date product manufacturer is operating as required. To ensure that approved manufacturers continue to be qualified, each will be required to reapply for approved manufacturer status once a year. The procedures for reapplication are the same as the procedures used for initial approval as a date product manufacturer.

Final 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 action 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 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.

Industry Profile

There are approximately 124 date producers in the production area and 10 handlers subject to regulation under the order. The Small Business Administration (SBA) (13 CFR 121.201) defines small agricultural producers as those with annual receipts of less than \$750,000, and small agricultural service firms as those with annual receipts of less than \$5,000,000.

The committee estimates approximately 7 producers (approximately 6 percent) had receipts over \$750,000 and that 4 handlers (40 percent) shipped over \$5,000,000 worth of California dates. Based on this information, a majority of handlers and producers of California dates may be classified as small entities.

Within the regulated production area all approved manufacturers are also date handlers regulated under the order. Conversely, approved manufacturers outside the regulated area are not regulated date handlers. Currently, there are three approved manufacturers outside the regulated area. We do not have information on their size, but believe most of them are small entities.

Summary of Rule Change

This final rule modifies the requirements for approved date product manufactures under § 987.157 of the order's administrative rules and regulations. This rule clarifies both the application procedures and qualification requirements for approval as a manufacturer of date products. This final rule also requires an applicant who is a date handler regulated under the order to be in compliance with the order to continue to manufacture date products. These changes help safeguard the integrity of the approved manufacturer program and help assure the quality of whole and pitted dates marketed in the United States and Canada. These changes were recommended unanimously by the committee at a meeting on April 23, 2004.

Impact of Regulation

At the meeting, the committee discussed the impact of this change on handlers and approved manufacturers. By clarifying the date product manufacturer application procedure and qualification requirements, the modifications help ensure that applicants are treated similarly. In addition, the committee believes the modifications will help safeguard the

integrity of the approved manufacturer program by requiring that participating handlers are in compliance with the order. As such, the committee believes that the impact of this rule on handlers and date product manufactures will be negligible and greatly outweighed by the improvement in the overall integrity and efficiency of the program.

Furthermore, the benefits of this rule are not expected to be disproportionately greater or less for small entities than for large entities.

Alternatives Considered

The committee discussed alternatives to these changes, including not making any changes to the requirements to become an approved date product manufacturer. The committee, however, decided that lack of action on its part could negatively impact the effectiveness of the safeguards that help ensure the quality of whole and pitted dates marketed in the United States and Canada.

A second alternative debated by the committee would have required an applicant to pay all the costs for repeated inspections to verify that the applicant can, indeed, meet the requirements of an approved manufacturer. There was some discussion about whether the committee should continue to pay for the committee staff's time for verification inspections beyond the initial visit. There is no authority to charge applicants for verification inspections under this program, thus this alternative was deemed unacceptable.

Recordkeeping and Reporting Requirements

These changes clarify the application procedures and qualification requirements to become or maintain an approved manufacturer status of date products under the date marketing order. Accordingly, this final rule does not impose any additional reporting or recordkeeping requirements on small or large California date handlers. This information collection burden has been approved by the Office of Management and Budget (OMB) under OMB No. 0581-0178. 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.

As noted in the initial regulatory flexibility analysis, USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this final rule.

In addition, the committee's meeting was widely publicized throughout the

California date industry and all interested persons were invited to attend the meeting and participate in committee deliberations on all issues. Like all committee meetings, the April 23, 2004, meeting was a public meeting and all entities, both large and small, were able to express views on this issue.

A proposed rule concerning this action was published in the **Federal Register** on January 24, 2005 (70 FR 3315). Copies of the rule were provided to all committee members and date handlers. The rule was also made available through the Internet by USDA and the Office of the Federal Register. A 15-day comment period ending on February 3, 2005, was provided to allow interested persons to respond to the proposal. No comments were received.

Accordingly, no changes will be made to the rule as proposed.

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 matter 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.

It is further found that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** (5 U.S.C. 553). Handlers are already shipping dates from the 2004-2005 crop. This action clarifies the application procedures and qualification requirements for approved manufacturers of date products. Further, handlers and approved manufacturers are aware of this rule, which was recommended at a public meeting. Also, a 15-day comment period was provided for in the proposed rule and no comments were received.

List of Subjects in 7 CFR Part 987

Dates, Marketing agreements, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, 7 CFR part 987 is amended as follows:

PART 987—DOMESTIC DATES PRODUCED OR PACKED IN RIVERSIDE COUNTY, CALIFORNIA

■ 1. The authority citation for 7 CFR part 987 continues to read as follows:

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

■ 2. Section 987.157 is revised to read as follows:

§ 987.157 Approved date product manufacturers.

Any person, including date handlers, with facilities for converting dates into products may apply to the committee, by filing CDAC Form No. 3, for listing as an approved date product manufacturer.

(a) The applicant shall indicate on such form: The products he/she intends to make; the quantity of dates he/she may use; the location of his/her facilities; and agree that all dates obtained for manufacturing into products shall be used for that purpose, none shall be resold or disposed of as whole or pitted dates.

(b) As a condition to become an approved date product manufacturer: Each applicant is subject to an inspection of his/her manufacturing plant to verify that proper equipment to convert dates into products is in place and that the plant meets appropriate sanitation requirements; the applicant also shall agree to file a report of the disposition of each lot of dates on the Committee's CDAC Form No. 8 within 24 hours of the transaction, and to file an annual usage and inventory report on CDAC Form No. 4 by October 10 of each year; and an applicant who is also a handler under the order shall be in compliance with the order, including the assessment payment and reporting requirements.

(c) The committee shall approve each such application on the basis of information furnished or its own investigation, and may revoke any approval for cause. The name and address of all approved manufacturers shall be placed on a list and made available to each date handler in Riverside County.

(d) If an application is disapproved, the committee shall notify the applicant in writing of the reasons for disapproval, and allow the applicant an opportunity to respond to the disapproval. When the applicant has complied with all the qualification requirements to become an approved manufacturer, the committee shall notify the applicant in writing of such approval. The applicant's name shall be added to the list of approved manufacturers, which shall be made

available to each date handler in Riverside County.

(e) Each approved manufacturer of date products is required to renew their approved manufacturer status with the committee by submitting an updated CDAC Form No. 3 at the end of a crop year, but no later than October 10 of the new crop year. In addition, the approved manufacturer must continue to meet the other approved manufacturer qualification requirements.

(f) In the event an approved date product manufacturer who is also a regulated date handler within the area of production does not remain in compliance with the order, or fails or refuses to submit reports or to pay assessments required by the committee, such date product manufacturer shall become ineligible to continue as an approved date product manufacturer. Prior to making a determination to remove a date product manufacturer from the approved date product manufacturer list, the committee shall notify such manufacturer in writing of its intention and the reasons for removal. The committee shall allow the date product manufacturer an opportunity to respond. In the event that a date product manufacturer's name has been removed from the list of approved date product manufacturers, a new application must be submitted to the committee and the applicant must await approval.

Dated: March 2, 2005.

Kenneth C. Clayton,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 05-4448 Filed 3-7-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor's Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor's address for Wellmark International.

DATES: This rule is effective March 8, 2005.

FOR FURTHER INFORMATION CONTACT:

David R. Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6967, e-mail: david.newkirk@fda.gov.

SUPPLEMENTARY INFORMATION: Wellmark International, 1100 East Woodfield Rd., suite 500, Schaumburg, IL 60173 has informed FDA of a change of address to 1501 East Woodfield Rd., suite 200 West, Schaumburg, IL 60173.

Accordingly, the agency is amending the regulations in 21 CFR 510.600(c) to reflect the change.

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 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

■ 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 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. Section 510.600 is amended in the table in paragraph (c)(1) by revising the entry for "Wellmark International"; and in the table in paragraph (c)(2) by revising the entry for "011536" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * *	*
Wellmark International, 1501 East Woodfield Rd., suite 200 West, Schaumburg, IL 60173	011536
* * *	*

(2) * * *

Drug labeler code	Firm name and address
* *	* * *
011536	Wellmark International, 1501 East Woodfield Rd., suite 200 West, Schaumburg, IL 60173
* *	* * *