

(3) For which you fail to meet the requirements contained in section 13(h); or

(4) That is damaged solely by uninsured causes.

(n) Acreage for which a Winter Coverage Option payment has been made is no longer insurable under the Crop Provisions for the current crop year. Any mint production subsequently harvested from uninsured acreage for the crop year and not kept separate from production from insured acreage will be considered production to count.

(o) Acreage for which a Winter Coverage Option payment has been made will receive an amount of production of zero when computing subsequent year's approved yield.

(p) Sections 11(e), (f), and (g) of these Crop Provisions do not apply to this option.

Signed in Washington, DC, on April 25, 2007.

**Eldon Gould,**

*Manager, Federal Crop Insurance Corporation.*

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BILLING CODE 3410-08-P

## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

#### 7 CFR Part 966

[Docket No. AMS-FV-06-0208; FV07-966-1 FIR]

#### Tomatoes Grown in Florida; Change in Handling Requirements

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

**ACTION:** Final rule.

**SUMMARY:** The Department of Agriculture (USDA) is adopting, as a final rule, without change, an interim final rule changing the handling requirements currently prescribed under the Florida Tomato marketing order (order). The order regulates the handling of tomatoes grown in Florida, and is administered locally by the Florida Tomato Committee (Committee). This rule continues in effect the action that limited the use of inverted lids on tomato containers to the handler whose information initially appeared on the lid. This rule helps ensure that lids do not contain the information for more than one active handler and aids in maintaining the positive identification and traceability of Florida tomatoes.

**EFFECTIVE DATE:** June 4, 2007.

**FOR FURTHER INFORMATION CONTACT:**

William Pimental, Marketing Specialist; or Christian Nissen, Regional Manager,

Southeast Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA; Telephone: (863) 324-3375, Fax: (863) 325-8793, or E-mail: [William.Pimental@usda.gov](mailto:William.Pimental@usda.gov) or [Christian.Nissen@usda.gov](mailto:Christian.Nissen@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 Agreement No. 125 and Order No. 966, both as amended (7 CFR part 966), regulating the handling of tomatoes grown in Florida, 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."

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 continues in effect the action that changed the handling requirements currently prescribed under the order. This rule continues to limit the use of inverted lids on tomato containers to the handler whose information initially appeared on the lid. This rule helps ensure that lids do not contain the information for more

than one active handler and aids in maintaining the positive identification and traceability of Florida tomatoes. This action was unanimously recommended by the Committee at a meeting on October 4, 2006.

Section 966.52 of the order provides the authority to establish pack and container requirements for tomatoes grown under the order. This includes fixing the size, weight, capacity, dimensions, markings, or pack of the container or containers which may be used in the handling of tomatoes.

Section 966.323 of the order's administrative rules prescribes the handling regulations for Florida tomatoes. Section 966.323(a)(3) delineates the requisite container requirements for weight, markings, and appearance. The section specifies, in part, that each container or lid must show the name and address of the registered handler.

The majority of Florida tomatoes are packed in containers that have a separate lid. Most lids are preprinted with the handler's name and address. In addition, most lids can be inverted by reversing the lid so the blank side is on the outside, and the preprinted information is flipped to the underside of the lid. This is done so new information can be printed on the lid. This rule amends § 966.323(a)(3) by limiting the use of inverted lids on tomato containers to the handler whose information first appeared on the lid.

Inverted lids have been used in minimal quantities in past seasons, usually when a tomato packing operation was purchased by another entity. Any containers included in the purchase could be used by the purchasing handler by inverting the lids so the purchaser's information could be affixed on the clean side. Usually there were not many containers remaining, so the containers requiring inverted lids were fairly limited in quantity.

Recently, container sales companies have started offering their container overruns at discounted prices to tomato handlers. These containers usually have preprinted handler and product information on the lids. The Committee is concerned this could significantly increase the number of inverted lids being used by the industry and could pose problems with the positive identification and traceability of tomatoes.

In their discussion of this issue, the Committee agreed the ability to positively identify product is a necessity in today's marketplace. The Committee expressed concern that the practice of

inverting lids could result in misidentification and confusion in cases where tomatoes need to be traced back to their origin. The Committee recognized that in the past, most of the containers being used with an inverted lid were associated with a handler purchasing another operation. Consequently, the original owner of the lid was no longer in business, and the container was only printed with the information for one active handler.

This would not be the case with handlers using overrun containers. The overrun containers being made available are containers produced in excess of orders, with the majority preprinted with handler information. Therefore, once inverted, the lids on the overrun containers would be printed with the information for two active handlers. The Committee is concerned that having multiple handler information on a container, even with the lid inverted, could pose problems when trying to track tomatoes back to the original handler.

The Committee believes it is of critical importance that Florida tomatoes can be traced from the farm to the end-user. Proper handler identification on a container is an important part of this traceability. Allowing the use of containers with an active registered handler's information on the exterior of the lid and another on the interior could allow for misidentification and confusion in product identification. The Committee believes by limiting the use of inverted lids to the handler whose name originally appeared on the lid, positive identification and traceability is better maintained.

In addition, in cases related to marketing order compliance, it is also important to be able to identify the original source of tomatoes. Allowing the use of inverted lids could result in the intentional misrepresentation of the origin of the tomatoes. The box lids could be re-inverted to display the handler information originally printed on the box without that handler's knowledge. Limiting the use of inverted lids on tomato containers by anyone other than the handler whose information first appeared on the lid helps alleviate any misidentification or uncertainty in product identification.

Section 8e of the Act provides that when certain domestically produced commodities, including tomatoes, are regulated under a Federal marketing order, imports of that commodity must meet the same or comparable grade, size, quality, and maturity requirements. As this rule changes the container requirements under the domestic

handling regulations, no corresponding change to the import regulations is required.

#### 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 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 100 producers of tomatoes in the production area and approximately 70 handlers subject to regulation under the marketing order. Small agricultural producers are defined by the Small Business Administration (SBA) as those having annual receipts less than \$750,000, and small agricultural service firms are defined as those whose annual receipts are less than \$6,500,000 (13 CFR 121.201).

Based on industry and Committee data, the average annual price for fresh Florida tomatoes during the 2005–06 season was approximately \$10.27 per 25-pound container, and fresh shipments totaled 47,880,303 25-pound cartons of tomatoes. Committee data indicates approximately 27 percent of the handlers handle 95 percent of the total volume shipped outside the regulated area. Based on the average price, about 75 percent of handlers could be considered small businesses under SBA's definition. In addition, based on production, grower prices as reported by the National Agricultural Statistics Service, and the total number of Florida tomato growers, the average annual grower revenue is below \$750,000. Thus, the majority of handlers and producers of Florida tomatoes may be classified as small entities.

This rule continues in effect the action that changed the handling requirements currently prescribed under the order. This rule continues to limit the use of inverted lids on tomato containers to the handler whose information initially appeared on the lid. This rule helps ensure that lids do not contain the information for more than one active handler and aids in maintaining the positive identification

and traceability of Florida tomatoes. This rule revises § 966.323(a)(3), which specifies the requisite container requirements. Authority for this action is provided in § 966.52 of the order. The Committee unanimously recommended this change at a meeting held on October 4, 2006.

At the meeting, the Committee discussed the impact of this change on handlers in terms of cost. This rule could result in a slight increase in cost for handlers that were considering purchasing the container overruns. However, Committee members stated that plain containers are readily available on the market at reasonable prices. Consequently, the difference in cost between a discounted overrun container and a plain blank container should be minimal.

In addition, last season the industry packed more than 47 million cartons of tomatoes. The available quantities of overrun containers are limited, confining the cost benefit to those containers available. When compared to the total containers needed, the overall cost savings associated with using overrun cartons would be negligible. Also, in previous seasons, overrun containers were not available for purchase. Therefore, container cost for all handlers should be similar to those in previous seasons.

Further, this rule provides the benefit of helping to maintain the traceability and proper identification of Florida tomatoes, which outweighs the minor cost savings associated with using overrun containers. The costs and benefits of this rule are not expected to be disproportionately different for small or large entities.

One alternative to this action was to allow the use of inverted lids. However, Committee members agreed that having the information for more than one active handler appear on a carton was confusing and could make traceability and proper identification difficult. Therefore, this alternative was rejected.

The 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.

This action will not impose any additional reporting or recordkeeping requirements on either small or large tomato 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. In addition, as noted in the initial regulatory flexibility analysis,

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

Further, the Committee's meeting was widely publicized throughout the Florida tomato industry and all interested persons were invited to attend the meeting and participate in Committee deliberations. Like all Committee meetings, the October 4, 2006, meeting was a public meeting and all entities, both large and small, were able to express views on this issue.

An interim final rule concerning this action was published in the **Federal Register** on February 6, 2007. Copies of the rule were mailed by the Committee's staff to all Committee members and tomato handlers. In addition, the rule was made available through the Internet by USDA and the Office of the **Federal Register**. That rule provided for a 60-day comment period which ended April 9, 2007. No comments were received.

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 Committee's recommendation, and other information, it is found that finalizing the interim final rule, without change, as published in the **Federal Register** (72 FR 5327, February 6, 2007) will tend to effectuate the declared policy of the Act.

#### List of Subjects in 7 CFR Part 966

Marketing agreements, Reporting and recordkeeping requirements, Tomatoes.

#### PART 966—TOMATOES GROWN IN FLORIDA

■ Accordingly, the interim final rule amending 7 CFR part 966 which was published at 72 FR 5327 on February 6, 2007, is adopted as a final rule without change.

Dated: April 27, 2007.

**Lloyd C. Day,**

*Administrator, Agricultural Marketing Service.*

[FR Doc. E7-8459 Filed 5-2-07; 8:45 am]

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1308

[Docket No. DEA-301F]

#### Schedules of Controlled Substances: Placement of Lisdexamfetamine Into Schedule II

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Final Rule.

**SUMMARY:** With the issuance of this final rule, the Deputy Administrator of the Drug Enforcement Administration (DEA) places the substance lisdexamfetamine, including its salts, isomers and salts of isomers into schedule II of the Controlled Substances Act (CSA). As a result of this rule, the regulatory controls and criminal sanctions of schedule II will be applicable to the manufacture, distribution, dispensing, importation and exportation of lisdexamfetamine and products containing lisdexamfetamine.

**EFFECTIVE DATE:** June 4, 2007.

#### FOR FURTHER INFORMATION CONTACT:

Christine A. Sannerud, PhD, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, (202) 307-7183.

#### SUPPLEMENTARY INFORMATION:

Lisdexamfetamine is a central nervous system stimulant drug. On February 23, 2007, the Food and Drug Administration (FDA) approved lisdexamfetamine for marketing under the trade name Vyvanse™. Lisdexamfetamine will be marketed as a prescription drug product for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

Lisdexamfetamine is an amide ester conjugate comprised of the amino acid L-lysine covalently bound to the amino group of d-amphetamine. The chemical name of its dimesylate salt form is (2S)-2,6-diamino-N-[(1S)-1-methyl-2-phenethyl]hexanamide dimethanesulfonate (CAS number 608137-32-3). Lisdexamfetamine per se is pharmacologically inactive and its effects are due to its in vivo metabolic conversion to d-amphetamine.

Lisdexamfetamine is a new molecular entity and has not been marketed in the United States or other countries. Therefore, there has been no evidence of diversion, abuse, or law enforcement encounters involving lisdexamfetamine.

On November 14, 2006, the Assistant Secretary for Health, Department of Health and Human Services (DHHS), sent the Deputy Administrator of DEA a

scientific and medical evaluation and a letter recommending that lisdexamfetamine be placed into schedule II of the CSA. Enclosed with the November 14, 2006, letter was a document prepared by the FDA entitled, "Basis for the Recommendation for Control of Lisdexamfetamine in Schedule II of the Controlled Substances Act (CSA)." The document contained a review of the factors which the CSA requires the Secretary to consider (21 U.S.C. 811(b)).

After a review of the available data, including the scientific and medical evaluation and the scheduling recommendation received from DHHS, the Deputy Administrator of the DEA, in a February 22, 2007, Notice of Proposed Rulemaking (72 FR 7945), proposed placement of lisdexamfetamine into schedule II of the CSA. The proposed rule provided an opportunity for all interested persons to submit their written comments to be postmarked and electronic comments be sent on or before March 26, 2007.

#### Comments Received

The DEA received two comments in response to the Notice of Proposed Rulemaking. One commenter stated that monthly visits to obtain refills for Concerta [supreg]—like drugs used in children are very expensive and the law needs to be changed. DEA notes that statutory requirements for schedule II drugs do not permit prescription refills. DEA does not regulate the size of each prescription or the frequency of medical visits; these matters are within the purview of prescribing physician. DEA has no authority regarding either the cost of medical care or the cost of the medications a prescribing practitioner may prescribe. Another commenter requested the name of the company that filed the New Drug Application for lisdexamfetamine in order to obtain standard analytical reference material and/or analytical data from the company. This comment is not relevant to the present scheduling action.

#### Scheduling of Lisdexamfetamine

Relying on the scientific and medical evaluation and the recommendation of the Acting Assistant Secretary for Health, received in accordance with section 201(b) of the Act (21 U.S.C. 811(b)), and the independent review of the available data by DEA, and after a review of the comments received in response to the Notice of Proposed Rulemaking, the Deputy Administrator of DEA, pursuant to sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), finds that: