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Docket No. [AO-FV-09-0138;
AMS-FV-09-0029; FV09-970-1 E]
Leafy Green Vegetables Handled in the
United States; Extension of Time for First
Session of Hearing on Proposed Marketing
Agreement No. 970

I, Jimmie Turner, hereby certify that on the twenty-second day of September, 2009, by authority vested in me by the Administrator and in accordance with §900.4(b)(1)(iii) (23 F.R. 4027) of the applicable rules of practice and procedure (7 CFR Part 900), as amended, I made available a press release to such newspapers and television and radio stations in the area subject to regulation as reasonably will tend to bring to the attention of interested persons the notice of extension of time for a USDA hearing on a proposed national marketing agreement regulating the handling of leafy green vegetables.

Date:



Jimmie Turner
Public Affairs Specialist
Information Staff

Exhibit 18



PROGRAM ANNOUNCEMENT

AGRICULTURAL MARKETING SERVICE

United States Department of Agriculture ♦ 1400 Independence Ave., SW ♦ Room 2632-S
Washington, DC 20250 ♦ (202) 720-8998 ♦ World Wide Web: <http://www.ams.usda.gov>

AMS No. 186-09

Jimmie Turner (202) 720-8998
jimmie.turner@usda.gov
Billy Cox (202) 720-8998
billy.cox@usda.gov

USDA EXTENDS DATES FOR HEARING ON PROPOSED NATIONAL MARKETING AGREEMENT FOR LEAFY GREEN VEGETABLES

WASHINGTON, Sept. 22, 2009 -- The U.S. Department of Agriculture today announced that it may allow an additional day for a public hearing related to a proposed national marketing agreement for leafy green vegetables.

A hearing session previously scheduled for Sept. 22 – 24, 2009, in Monterey, Calif., may be extended by adding a fourth day, Sept. 25, if deemed necessary by the presiding administrative law judge. This session is the first of seven hearings scheduled throughout the United States to consider a proposal from representatives of the fresh produce industry regarding the establishment of a national marketing agreement for handlers of leafy green vegetables.

The administrative law judge presiding at the hearing will determine whether an additional day for the receipt of testimony and evidence in Monterey is necessary. If extended, the Sept. 25 session, as with all other sessions of the hearing, would be open to the public and scheduled to begin at 8:30 a.m. and conclude at 5 p.m. PST, or as determined by the judge. The hearing will be held in the Hyatt Regency Monterey at 1 Old Golf Course Road.

Information about the proposal and the schedule of hearings were published in the Sept. 3, 2009, *Federal Register*.

Copies may be obtained in writing from Antoinette Carter, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue SW, Stop 0237, Washington, DC 20250-0237; by calling (202) 720-2491; or faxing (202) 720-8938; or Melissa Schmaedick, Marketing Order Administration Branch, Fruit and Vegetable Programs, Northwest Marketing Field Office, AMS, USDA, 1220 SW Third Avenue, Room 385, Portland, OR 97204; (503) 326-2724; fax, (503) 326-7440.

An electronic version of this news release can be obtained via the Internet at <http://www.ams.usda.gov/news/newsrel.html>.

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UNITED STATES DEPARTMENT OF AGRICULTURE
Agricultural Marketing Service
Fruit and Vegetable Programs
14th and Independence Ave., SW
Washington, D.C. 20250

CERTIFICATE OF)
OFFICIALS NOTIFIED)
_____)

Docket No. [AO-FV-09-0138; AMS-FV-09-0029; FV09-970-1 E]
Leafy Green Vegetables Handled in the United States;
Extension of Time for First Session of Hearing on Proposed
Marketing Agreement No. 970

I, Anne M. Dec, hereby certify that on the twenty-third day of September, 2009, by authority vested in me, and in accordance with the applicable rules of practice and procedure governing proceedings to formulate marketing agreements and marketing orders, as amended (7 CFR Part 900), I mailed a true copy of the notice of "Leafy Green Vegetables Handled in the United States; Extension of Time for First Session of Hearing on Proposed Marketing Agreement No. 970" (74 FR 48423) to the Governors and the Secretaries of the Department of Food and Agriculture of each state in the nation and the District of Columbia.

Dated:



Anne M. Dec
Assistant Branch Chief
Marketing Order Administration Branch
Fruit and Vegetable Programs

Exhibit 18

Second Letter Mailed to Governors for Whom Email Addresses Not Obtained
Mailed September 3, 2009

Recipients are the following:

Jan Brewer (AZ), Jim Ritter (CO), Jennifer Granholm (MI), Bill Richardson (NM), Mike Pounds (SD), Rick Perry (TX), Jack Markell (DE), Tim Kaine (VA), Felix Camacho (Guam), Chris Gregoire (WA) and
Jim Douglas (VT)

Dear Governor _____:

On September 3, 2009, we notified you that the Department of Agriculture (USDA) would be holding hearings to consider a proposed national marketing agreement covering the handling of leafy green vegetables. The first of seven hearings began yesterday, September 22, 2009, in California, and we are notifying you today that an additional day may be added to the three-day hearing in Monterey, CA, if deemed necessary by the presiding administrative law judge. Enclosed is the notice that appeared in the Federal Register.

USDA determined that additional time may be needed to receive testimony and evidence at the Monterey hearing. Subsequent hearings will be held in Jacksonville, FL, on September 30-October 1, 2009; Columbus, OH, on October 6, 2009; Denver, CO, on October 8, 2009; Yuma, AZ, on October 14-15, 2009; Syracuse, NY, on October 20, 2009; and Charlotte, NC, on October 22, 2009.

Sincerely,

Anne M. Dec, Assistant Chief
Marketing Order Administration Branch
Fruit and Vegetable Programs

UNITED STATES DEPARTMENT OF AGRICULTURE
Agricultural Marketing Service
Fruit and Vegetable Programs
14th and Independence
Room 1406-South
Washington, DC 20250

_____)
CERTIFICATE OF MAILING)
_____)

Docket No. AO-FV-09-0138; AMS-FV-09-0029;
FV09-970-1 E]
Leafy Green Vegetables Handled in the United
States; Extension of Time for First Session of
Hearing on Proposed Marketing Agreement No. 970

I, Anne M. Dec, hereby certify that on the twenty-third day of September, 2009, by authority vested in me, and in accordance with the applicable rules of practice and procedure governing proceedings to formulate marketing agreements and marketing orders, as amended (7 CFR Part 900), I mailed a true copy of the notice of "Leafy Green Vegetables Handled in the United States; Extension of Time for First Session of Hearing on Proposed Marketing Agreement No. 970" (74 FR 48423) to each of the persons known to be interested therein.

Dated:



Anne M. Dec
Assistant Branch Chief
Marketing Order Administration Branch
Fruit and Vegetable Programs

Exhibit 18

Second Message to Interested Persons
Emailed September 23, 2009

On September 3, 2009, we notified you that the Department of Agriculture (USDA) would be holding hearings to consider a proposed national marketing agreement covering the handling of leafy green vegetables. The first of seven hearings began yesterday, September 22, 2009, in California, and we are notifying you today that an additional day may be added to the three-day hearing in Monterey, CA, if deemed necessary by the presiding administrative law judge. Enclosed is the notice that appeared in the Federal Register.

USDA determined that additional time may be needed to receive testimony and evidence at the Monterey hearing. Subsequent hearings will be held in Jacksonville, FL, on September 30-October 1, 2009; Columbus, OH, on October 6, 2009; Denver, CO, on October 8, 2009; Yuma, AZ, on October 14-15, 2009; Syracuse, NY, on October 20, 2009; and Charlotte, NC, on October 22, 2009.

Sincerely,

Anne M. Dec, Assistant Chief
Marketing Order Administration Branch
Fruit and Vegetable Programs

Proposed Rules

Federal Register

Vol. 74, No. 183

Wednesday, September 23, 2009

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 970

[Docket No. AO-FV-09-0138; AMS-FV-09-0029; FV09-970-1E]

Leafy Green Vegetables Handled in the United States; Extension of Time for First Session of Hearing on Proposed Marketing Agreement No. 970

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule; notice of additional time for public hearing on proposed national marketing agreement for leafy green vegetables.

SUMMARY: This notice announces that the scheduled hearing date for the Monterey, California session of a public hearing to consider a proposed marketing agreement for the handling of leafy green vegetables in the United States may be extended by one day, if deemed necessary by the presiding administrative law judge.

DATES: The Monterey, California session for the public hearing is currently scheduled for September 22 through 24, 2009. This hearing session may be extended by an additional day, September 25, 2009, if deemed necessary. As with the other scheduled sessions, this session would begin at 8:30 a.m. and conclude at 5 p.m., or any other time as determined by the presiding administrative law judge.

ADDRESSES: The hearing location in Monterey is: Hyatt Regency Monterey, 1 Old Golf Course Road, Monterey, California, (831) 372-1234.

FOR FURTHER INFORMATION CONTACT: Antoinette Carter, 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: Antoinette.Carter@ams.usda.gov; or Melissa Schmaedick, Marketing Order Administration

Branch, Fruit and Vegetable Programs, Northwest Marketing Field Office, AMS, USDA, 1220 SW. Third Avenue, Room 385, Portland, OR 97204; Telephone: (503) 326-2724, Fax: (503) 326-7440, or e-mail: Melissa.Schmaedick@ams.usda.gov.

SUPPLEMENTARY INFORMATION:

Prior documents in this proceeding: Notice of Hearing issued August 31, 2009; published September 3, 2009 (74 FR 45565).

Notice is hereby given that the scheduled hearing date for the Monterey, California session of a public hearing to consider a proposed marketing agreement for the handling of leafy green vegetables in the United States may be extended by one day, if deemed necessary by the presiding administrative law judge.

The Department of Agriculture (USDA) previously announced a hearing to consider a proposed marketing agreement for the handling of leafy green produce in the United States. Hearing dates have been scheduled for various locations throughout the United States, including Monterey, California. However, an additional day may be required to receive testimony and evidence in Monterey. This notice announces the addition of September 25, 2009 to the first session, if deemed necessary by the presiding administrative law judge.

Information regarding the hearing and the proposed marketing agreement is contained in the Notice of Hearing, which may be viewed at: <http://www.regulations.gov/search/Regs/home.html#documentDetail?R=0900006480a1c313>.

List of Subjects in 7 CFR Part 970

Marketing agreements, Reporting and recordkeeping requirements, Vegetables.

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

Dated: September 18, 2009.

Rayne Pegg,

Administrator, Agricultural Marketing Service.

[FR Doc. E9-22992 Filed 9-21-09; 11:15 am]

BILLING CODE 3410-02-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 4

[Docket No. FDA-2008-D-0409]

Current Good Manufacturing Practice Requirements for Combination Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or agency) proposes to codify the current good manufacturing practice (cGMP) requirements applicable to combination products. This proposed rule is intended to promote the public health by clarifying which cGMP requirements apply when drugs, devices, and biological products are combined to create a combination product. In addition, the proposed rule sets forth a transparent and streamlined regulatory framework for firms to use when demonstrating compliance with cGMP requirements for "single-entity" and "co-packaged" combination products.

DATES: Submit written or electronic comments on this proposed rule by December 22, 2009. See section IX of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2008-D-0409 (formerly Docket No. 2004D-0431), by any of the following methods: *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-