Proposed Rules

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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-