

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0230]

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21 CFR Part 110

Food; Current Good Manufacturing Practice Regulations; Public Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meetings.

SUMMARY: The Food and Drug Administration (FDA) is announcing three public meetings to solicit comments, data, and scientific information about the current state of quality management techniques, quality systems approaches, and voluntary industry standards concerning current good manufacturing practices and other controls used by food manufacturers and processors to prevent, reduce, control, or eliminate food borne hazards that can occur during food production or processing. The meetings are intended to elicit information about FDA's current good manufacturing practice (CGMP) in manufacturing, packing, or holding human food regulations. This information will be useful in determining appropriate revisions to these regulations. We ask that those who speak at the meetings or otherwise provide FDA with their comments focus on our questions given in section II of this document about the CGMP regulations and other quality management techniques. There also will be an opportunity to address small business concerns at the meetings.

DATES: The public meetings will be held in College Park, MD, on Friday, June 11, 2004, from 9 a.m. to 12 noon; in Monterey, CA, on Friday, July 2, 2004,

from 1 p.m. to 4 p.m.; and in Chicago, IL, on Wednesday, July 21, 2004, from 2 p.m. to 5 p.m. You should register for any of the meetings by fax or e-mail (see **FOR FURTHER INFORMATION CONTACT**). For security reasons and due to space limitations, we recommend that you register at least 5 days prior to the meeting you wish to attend. You may register by fax or e-mail until close of business 5 days before the meeting you wish to attend, provided that space is available. In addition to participating at the public meetings, you may submit written or electronic comments until September 10, 2004.

ADDRESSES: The public meeting on Friday, June 11, 2004, will be held at the Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740-3835. The public meeting on Friday, July 2, 2004, will be held at the Monterey Conference Center, One Portola Plaza, Monterey, CA 93940. The public meeting on Wednesday, July 21, 2004, will be held at the Marriott Chicago Downtown, 540 North Michigan Ave., Chicago, IL 60611.

You may submit comments, identified with Docket No. 2004N-0230, by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>.

Follow the instructions for submitting comments.

- Agency Web site: <http://www.fda.gov/dockets/ecomments>.

Follow the instructions for submitting comments on the agency Web site.

- E-mail: fdadockets@oc.fda.gov. Include Docket No. 2004N-0230 in the subject line of your e-mail message.

- FAX: 301-827-6870.

- Mail/Hand delivery/Courier (For paper, disk, or CD-ROM submissions):

Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. for this rulemaking. All comments received will be posted without change to <http://www.fda.gov/dockets/ecomments>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.fda.gov/dockets/ecomments> and/or the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Peter J. Vardon, Center for Food Safety and Applied Nutrition (HFS-726), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD, 301-436-1830, FAX 301-436-2626, or e-mail: pvardon@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA last revised its CGMP regulations for food (part 110 (21 CFR part 110)) in 1986 (51 FR 22458, June 19, 1986). The primary purpose of the revision was to establish new, updated, or more detailed provisions concerning food industry personnel; plants and grounds; sanitary facilities, controls, and operations; equipment and utensils, warehousing, and distribution; and natural or unavoidable defect levels. FDA designed the revised CGMP regulations to

help ensure the safe and sanitary manufacturing, processing, and holding of food for human consumption.

In the almost 20 years since the food CGMPs were revised, the food industry has undergone considerable change, and the agency believes that it is now time to revisit these regulations and determine appropriate revisions to better ensure a safe and sanitary food supply. FDA believes that a good first step is to obtain the views of the industry and the public generally by holding a series of public meetings. The three public meetings are intended to provide interested parties an opportunity to comment on what revisions to the CGMPs FDA should consider. The meetings are also intended to fulfill part of the outreach requirement of the Small Business Regulatory Enforcement Fairness Act of 1996.

FDA has drafted the questions set out in this document to help focus comments presented at the public meetings or otherwise communicated to the agency. One area of particular agency focus is potential hazards in the food supply. Generally speaking, there are three categories of hazards that may be present during the production or warehousing of food: Physical hazards (such as the presence of glass fragments in food), chemical hazards (such as the unintended presence of a cleaning solution in food), and microbiological hazards (such as the presence of *Listeria monocytogenes* in ready-to-eat foods).

In responding to the questions set out in this document, please address, to the extent you are able, each of the three types of hazards discussed in the previous paragraph. FDA is particularly interested in receiving comments about food manufacturing practices and other controls used by small food manufacturing and processing entities.

II. Questions

In general, do the current good manufacturing regulations (part 110) need to be revised or otherwise modernized? If yes, please describe generally the shortcomings of the current regulations.

1. Which practices specified in current part 110 are most effective at preventing each type of food hazard? Which practices are least effective at such prevention?

2. In today's food manufacturing environment, what conditions, practices, or other factors are the principal contributors to each type of food hazard?

3. If the CGMP regulations were revised, which type or types of food hazards could be most readily prevented through CGMP-type controls?

4. Are there preventive controls, in addition to those set out in part 110, needed to reduce, control, or eliminate each of the three types of food hazards? If yes, please identify the specific hazard and the particular controls, that would reduce, control, or eliminate the hazard.

5. What concepts or underlying principles should guide FDA's adoption of new preventive controls?

6. How should the effectiveness of preventive controls for each of the three types of hazards be most accurately measured?

7. In today's food manufacturing environment, what are the principal contributors to the presence of undeclared allergens in food? For example, do labeling errors or cross-contamination contribute? Which preventive controls could help reduce, control, or eliminate the presence of undeclared allergens in food?

8. Are there existing quality systems or standards (such as international standards) that FDA should consider as part of the agency's exploration of food

CGMP modernization? Please identify these systems or standards and explain what their consideration might contribute to this effort.

9. There is a broad variation within the food manufacturing and processing industry, including variations in size of establishments, the nature of the food produced, the degree to which the food is processed, and the vulnerability of a particular operation to physical, chemical, or microbial hazards. How, if at all, should the CGMP regulations be revised to take into account such variation? For example, should there be different sets of preventive controls for identifiable segments of the food industry, such as different storage temperature limits?

10. There are a number of measures, procedures, and programs that help to ensure that preventive controls are carried out adequately. These include the following items:

- Training programs for managers and/or workers;
- Audit programs;
- Written records, e.g., batch records, sanitation records;
- Validation of control measures;
- Written sanitation standard operating procedures;
- Food label review and control program; and
- Testing of incoming raw materials, inprocess materials, or finished products.

Which (if any) of these should be required practices for food and manufacturers and why? Which (if any) of these should be recommended practices for food manufacturers and processors and why?

11. Are there preventive controls in addition to those already set out in part 110 for food distributors, wholesalers, and warehouseers that are needed

to help ensure the safe and sanitary holding of food? If yes, please identify the controls by hazard and sector of the industry.

III. Registration

You should register for any of the meetings by fax or e-mail (see **FOR FURTHER INFORMATION CONTACT**). For security reasons and due to space limitations, we recommend that you register at least 5 days prior to the meeting you wish to attend. Registration will be accepted on a space-available basis. You may register until close of business June 4, 2004, for the College Park meeting, close of business on June 25, 2004, for the Monterey meeting, and close of business July 15, 2004, for the Chicago meeting. If you need special accommodations due to a disability, please inform the contact person at least 7 days in advance (see **FOR FURTHER INFORMATION CONTACT**). Please include your name, title, firm name, address, telephone number, and e-mail address (if available) when you register. FDA encourages individuals or firms with relevant data or information to present such information at the meeting or in written comments to the record. If you would like to make oral comments at one of the meetings, please specify your interest in speaking when you register. The amount of time for each oral presentation may be limited due to the number of requests to speak.

IV. Transcripts

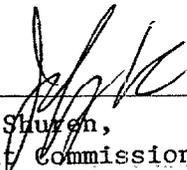
A transcript will be made of the proceedings of each meeting. You may request a copy of a meeting transcript in writing from FDA's Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 30 working days after the public meetings at a cost of 10 cents per page. The transcript of each public meeting and all comments submitted will be available for public examination

at the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

V. Comments

In addition to presenting oral comments at a public meeting, interested persons may submit (see **ADDRESSES**) written or electronic comments on the subject of these meetings. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 5/18/04
May 18, 2004.


Jeffrey Shuren,
Assistant Commissioner for Policy.

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