TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	FDA Form Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1040.11(a)(2)		190	1.00	190	10	1,900
1040.20(d)(1)(ii) through (d)(1)(vi) and (e)(1) and (e)(2)		110	1.00	110	10	1,100
1040.30(c)(1)(ii)		1	1.00	1	1	1
1040.30(c)(2)		7	1.00	7	1	7
1050.10(d)(1) through (d)(4) and (f)(1) through (f)(2)(iii)		10	1.00	10	56	560
Total						107,209

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
1002.30 and 1002.31(a)	1,150	1,655.5	1,903,825	198.7	228,505
1002.40 and 1002.41	2,950	49.2	145,140	2.4	7,080
1020.30(g)	22	1	22	0.5	11
1040.10(a)(3)(ii)	83	1	83	1.0	83
Totals					235,679

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The information collection requirements under OMB control number 0910–0564 and Form FDA 3626, the data collection instrument for this collection, have been consolidated under the information collection activity of OMB control number 0910–0025, thus resulting in an adjustment (increase) in the current burden estimate.

The burden estimates were derived by consultation with FDA and industry personnel and actual data collected from industry. An evaluation of the type and scope of information requested was also used to derive some time estimates. For example, disclosure information primarily requires time only to update and maintain existing manuals. Initial development of manuals has been performed except for new firms entering the industry. When information is generally provided to users, assemblers, or dealers in the same manual, they have been grouped together in the ''Estimated Annual Reporting Burden'' table (table 1 of this document).

The following information collection requirements are not subject to review by OMB because they do not constitute a ''collection of information'' under the PRA: Sections 1002.31(c); 1003.10(a), (b), and (c); 1003.11(a)(3) and (b); 1003.20(a) through (h); 1003.21(a) through (d); 1003.22(a) and (b); 1003.30(a) and (b); 1003.31(a) and (b); 1004.2(a) through (i); 1004.3(a) through (i); 1004.4(a) through (h); 1005.21(a) through (c); and 1005.22(b). These requirements ''apply to the collection of information during the conduct of general investigations or audits'' (5 CFR 1320.4(b)). The following labeling requirements are also not subject to review under the PRA because they are a public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (1410.10 of the FDA Staff Manual Guide and §§ 1020.10(c)(4), 1030.10(c)(6), 1040.10(g), 1040.30(c)(1), and 1050.10(d)(1)).

Dated: February 20, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–3258 Filed 2–26–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0051]

Safety of Fresh Produce; Public Hearings; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearings; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing two public hearings concerning the safety of fresh produce. The purpose of the hearings is for FDA to share information about recent outbreaks of foodborne illness associated with microbial contamination of fresh produce, and to solicit comments, data, and other scientific information about current agricultural and manufacturing practices used to produce, harvest, pack, cool, process, and transport fresh produce; risk factors for contamination of fresh produce associated with these practices; and possible measures by FDA to enhance the safety of fresh produce.

DATES: The first public hearing will be held on March 20, 2007, from 9 a.m. to

5 p.m. The second public hearing will be held on April 13, 2007, from 9 a.m. to 5 p.m. See section V of this document for additional dates on how to participate in the hearings. Submit written or electronic comments (i.e., submissions other than notices of participation and the text, comprehensive outline, or summary of an oral presentation) by June 13, 2007.

ADDRESSES: The first public hearing will be held at the Ronald V. Dellums Federal Building, Edward Roybal Auditorium, 1301 Clay St., 3d floor, Oakland, CA 94612. The second public hearing will be held at the Harvey W. Wiley Federal Building, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD, 20740–3835 (Metro stop: College Park on the Green Line).

Submit electronic notices of participation for either hearing to *http://www.cfsan.fda.gov/~comm/register.html*. We encourage you to use this method of registration, if possible. You may also submit oral or written notices of participation by phone, by fax, or by e-mail, or submit the written full text, comprehensive outline, or summary of any oral presentation by fax or by e-mail to Isabelle Howes, U.S. Department of Agriculture Graduate School, 202–314–4713, FAX: 202–479–6801, or e-mail: *Isabelle_Howes@grad.usda.gov*.

Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

Instructions: All submissions and comments received must include the agency name and docket number found in brackets in the heading of this document. All submissions and comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments, see section VI in the **SUPPLEMENTARY INFORMATION** section of this document.

Transcripts of the hearings will be available for review at the Division of Dockets Management and on the Internet at *http://www.fda.gov/ohrms/dockets/default.htm* approximately 30 days after the hearing.

FOR FURTHER INFORMATION CONTACT:

To submit an oral or written notice of participation by phone, by fax, or by e-mail, or the written full text, comprehensive outline, or summary of any oral presentation by fax or by e-mail: Isabelle Howes, U.S. Department of Agriculture Graduate School, 202–314–4713, FAX: 202–479–6801, or e-mail: *Isabelle_Howes@grad.usda.gov*. All participants must complete registration. Following registration, you will receive a confirmation notice which also includes hotel and parking information.

For all other questions about the hearings or if you need special accommodations due to a disability: Juanita Yates, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 301–436–1731, e-mail: *Juanita.Yates@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

A. Food Safety and Fresh Produce

FDA is responsible for ensuring the safety of all domestic and imported fresh and fresh-cut fruits and vegetables consumed in the United States. Fresh fruits and vegetables are those that are likely to be sold to consumers in an unprocessed or minimally processed (i.e., raw) form. Fresh fruits and vegetables may be intact and whole, such as whole apples, or cut in the act of harvest, such as heads of lettuce and bunches of broccoli. As used in this document, the term ''fresh-cut produce'' refers to minimally processed fruits and vegetables that have been altered in form by peeling, slicing, chopping, shredding, coring, or trimming, with or without washing or other treatment, prior to being packaged for use by the consumer or retail establishment. Examples of fresh-cut products are shredded lettuce, sliced tomatoes, salad mixes, peeled baby carrots, broccoli florets, and cut melons. Fresh-cut produce does not require additional preparation, processing, or cooking before consumption, with the possible exception of washing or the addition of salad dressing or seasoning. In this document, we use the term ''fresh produce'' to describe all fresh and fresh-cut fruits and vegetables consumed in the United States.

Because most fresh produce is grown in a natural environment, it is vulnerable to contamination with pathogens (i.e., bacteria or other organisms that can cause disease). Factors that may affect the occurrence of such contamination include agricultural and/or processing water quality, the use of manure as fertilizer, the presence of wild or domestic animals in or near fields or packing areas, worker health and hygiene, environmental conditions, production activities, and equipment and facility sanitation. Consequently, the manner in which fresh produce is grown, harvested, packed, processed, transported, distributed, and prepared is crucial to minimizing the risk of microbial contamination. (We use the term ''microbial contamination'' to refer to contamination with any microorganism.)

Data reported to the U.S. Centers for Disease Control and Prevention (CDC) indicate that between 1973 and 1997 reported outbreaks of foodborne illness in the United States associated with fresh produce increased in absolute numbers and as a proportion of all reported foodborne outbreaks (Ref. 1). (By ''outbreak,'' we mean the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food.) Unpublished data compiled by FDA indicate that from 1996 to 2006 there were approximately 72 reported outbreaks of foodborne illness associated with approximately 20 fresh produce commodities. Of this total, 12 outbreaks were associated with tomatoes, 11 outbreaks were associated with melons, and 24 outbreaks were associated with leafy greens such as lettuce and spinach (Ref. 2). These outbreaks involved a number of pathogens, including *Escherichia coli* (*E. coli*) O157:H7 and *Salmonella* species, and both domestic and imported produce. These totals include only those outbreaks in which our investigation has indicated that the contamination of the produce was not a result of exposure to an infected food handler or other unsafe food handling practice at the place of preparation and consumption (i.e., home or restaurant).

When there is an outbreak of foodborne illness, we work with Federal, State, and local agencies to identify the source of the outbreak and minimize the public health impact. For example, on September 14, 2006, we issued a news release alerting consumers about an outbreak of *E. coli* O157:H7 in multiple States and advising the public not to eat bagged fresh spinach because it had been implicated in the outbreak (Ref. 3). We continued to issue updated press releases for approximately four weeks. During the course of the outbreak, approximately 200 illnesses were reported to the CDC, including more than 30 cases of hemolytic uremic syndrome (HUS, a condition occurring mainly in children that can result in kidney failure), more than 100 hospitalizations, and 3 deaths (Ref. 4). In addition to working to identify the food involved in the outbreak, we worked with others to trace the source of the implicated

product to packing, cooling and processing facilities involved and to the farm to identify practices or conditions that may have contributed to the contamination of the produce.

One challenge faced by public health officials during an outbreak is to quickly identify through traceback the sources of contamination. FDA's regulations require the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States (21 CFR 1.326–1.368). Such records allow for the identification of the immediate previous sources and immediate subsequent recipients of food, and thereby help FDA and other authorities determine the source and cause of the event. Farms and restaurants are excluded from these requirements. Traceback can be particularly problematic when fresh produce is involved.

Eating fruits and vegetables is an important part of a healthy diet (Ref. 5). We place a high priority on identifying and implementing measures that can reduce the incidence of foodborne illness associated with fresh produce.

B. Guidance Documents and Letters Issued by FDA to Enhance the Safety of Fresh Produce

In 1998, FDA issued guidance to industry entitled ''Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables'' (GAPs/GMPs Guide) (Ref. 6). This guide recommends good agricultural practices (GAPs) and good manufacturing practices (GMPs) that growers, packers, and shippers can undertake to address common risk factors in their operations and thereby minimize food safety hazards potentially associated with fresh produce. Implementation of risk reduction measures is critical; as the GAPs/GMPs Guide notes, current technologies cannot eliminate all potential food safety hazards associated with fresh produce that will be eaten raw.

On February 5, 2004, FDA issued a letter to firms that grow, pack, or ship fresh lettuce and fresh tomatoes, expressing concern regarding outbreaks of foodborne illness associated with the consumption of fresh lettuce and fresh tomatoes, and recommending actions to enhance the safety of these products (Ref. 7). On November 4, 2005, FDA issued a second letter to firms that grow, pack, process or ship fresh and fresh-cut lettuce, reiterating concerns about continuing outbreaks (Ref. 8). In the November 2005 letter, FDA strongly encouraged applicable firms to review their current operations in light of the GAPs\GMPs Guide, as well as other available information regarding the reduction or elimination of pathogens on fresh produce. FDA encouraged firms to consider modifying their operations to ensure that they were taking the appropriate measures to provide a safe product to the consumer. FDA recommended that firms from the farm level through the distribution level undertake these steps.

On March 1, 2006, FDA issued a draft entitled ''Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables'' (the Fresh-cut Guide) (Ref. 9). The draft Fresh-cut Guide is intended to be used in conjunction with the GAPs/GMPs Guide, which covers stages prior to fresh-cut processing, with the current GMPs in part 110 (21 CFR part 110), which contain food safety practices applicable to processors who manufacture, process, pack, or hold processed food, and with the FDA Food Code (Ref. 10), which focuses on activities at subsequent stages, such as retail. The FDA Food Code gives State and local governments a scientifically sound technical and legal basis for regulating the retail and food service segment of the industry (restaurants and grocery stores and institutions such as nursing homes). State, local, tribal, and Federal regulators use the FDA Food Code as a model to develop or update their own food safety rules and to be consistent with national food regulatory policy. (For more information on the FDA Food Code, see *http://www.cfsan.fda.gov/~dms/foodcode.html*.) FDA is currently working to finalize the Fresh-cut Guide.

C. Produce Safety Action Plan

In October 2004, FDA issued the ''Produce Safety from Production to Consumption: 2004 Action Plan to Minimize Foodborne Illness Associated with Fresh Produce Consumption'' or Produce Safety Action Plan (PSAP) (Ref. 11). The PSAP expands on the areas covered by the GAPs/GMPs Guide for farms and packing, to extend to all parts of the food supply chain from farm through retail or consumer preparation and consumption. The PSAP does not cover frozen fruits and vegetables, fruit and vegetable juices, or other commodities, such as tree nuts, that are neither fruits nor vegetables and not typically regarded as produce. The PSAP has four main objectives which are to: (1) Prevent contamination of fresh produce with pathogens; (2) minimize the public health impact when contamination of fresh produce occurs; (3) improve communication with producers, packers, processors, transporters, distributors, preparers, consumers, and other government entities about the safety of fresh produce; and (4) facilitate and support research relevant to the contamination of fresh produce. For each objective, the PSAP identifies steps or actions that could contribute to the achievement of that objective. The PSAP has measurable goals and outcomes, and several steps outlined in the PSAP are already in progress or have been completed. For example, we issued the draft Fresh-cut Guide as part of the PSAP objective regarding prevention of contamination.

D. Partnerships and Collaborations

Because following the GAPs/GMPs Guide is voluntary, FDA and food safety partners in the public and private sectors have stressed education and outreach to industry to promote adoption of the guidance. Buyer requirements that producers and other suppliers provide self- or third-party audit verification that they are following the GAPs/GMPs Guide have further promoted adoption of the guidance. We have worked with the fresh produce industry since the release of the GAPs/GMPs Guide to promote its recommendations and to advance the scientific knowledge applicable to enhancing the safety of fresh produce. For example, in conjunction with the PSAP, we have provided technical assistance to industry in developing several commodity specific guidelines that cover the entire supply chain. Commodity-specific industry guidelines exist for three foods: Melons, lettuce and leafy greens, and tomatoes (see Refs. 12, 13, and 14). An additional industry guideline on green onions and herbs is in progress. Between 1996 and 2006, these commodities together accounted for approximately 80 percent of the foodborne outbreaks associated with produce (Ref. 2).

In August 2006 we launched the ''Lettuce and Leafy Greens Initiative,'' which involved assessments of practices and conditions at select farms and facilities in California. The initiative, conducted in collaboration with the California Department of Health Services and the California Department of Food and Agriculture, is intended to be a multi-year effort and may be a model for other initiatives in the future.

E. Other Food Safety Measures

The provisions in part 110 (Current Good Manufacturing Practice In Manufacturing, Packing, Or Holding Human Food) establish requirements and recommendations as follows that apply in determining whether a food is adulterated: (1) Within the meaning of

section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 341(a)(3)), in that the food has been manufactured under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the act, in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. Under § 110.19(a), establishments engaged solely in the harvesting, storage, or distribution of one or more raw agricultural commodities (as defined in section 201(r) of the act (21 U.S.C. 321)), are not subject to the requirements of part 110. However, under § 110.19(b), we may issue special regulations if it is necessary to cover these excluded operations. In addition, the GAPs/GMPs Guide recommends that operations excluded from the provisions of part 110 consider implementing the current GMPs required or recommended in part 110 as appropriate.

For foods other than fresh produce, we have issued regulations designed to enhance food safety, including safety related to microbial pathogens (see, e.g., 21 CFR part 113, concerning thermally processed low-acid foods packaged in hermetically sealed containers; 21 CFR part 114, concerning acidified foods; 21 CFR 15.51, concerning refrigeration of shell eggs held for retail distribution; 21 CFR part 120, concerning hazard analysis and critical control point (HACCP) systems for juice; and 21 CFR part 123, concerning HACCP requirements for fish and fishery products). Some FDA regulations to enhance the safety of particular food products (e.g., the HACCP requirements in 21 CFR part 120 for juice and in 21 CFR part 123 for fish and fishery products) contain training and other requirements for performing particular functions. For some food products, we have augmented our regulations with nonbinding guidance to assist industry in complying with the regulations (e.g., FDA's Juice HACCP Hazards and Controls Guidance (available at *http://www.cfsan.fda.gov/~dms/guidance.html*) and Fish And Fisheries Products Hazards And Controls Guidance (available at *http://www.cfsan.fda.gov/~dms/guidance.html*)).

F. Next Steps

We believe that the measures outlined in the PSAP, the GAPs/GMPs Guide, and other public and private sector actions, when implemented, have or can be effective in reducing the risk of microbial contamination of fresh produce. In particular, the GAPs/GMPs Guide has been used as a basis for a number of food safety programs, both in the United States and internationally. However, the fact that outbreaks of foodborne illness associated with fresh produce continue to occur supports a close examination of the extent to which these measures have been implemented; whether they have been effective, if implemented properly; and what additional or different interventions might be appropriate to reduce the risk of future outbreaks. As a next step, we intend to hold two public hearings regarding the safety of fresh produce. The purpose and scope of the hearings, each of which will be governed by part 15 (21 CFR part 15) of FDA's regulations, are described in section II of this document.

II. Purpose and Scope of the Hearings

We want to share information about recent outbreaks of foodborne illness associated with microbial contamination of fresh produce, and to invite comments, data, and other scientific information about: Current agricultural and manufacturing practices used to produce, harvest, pack, cool, process, and transport fresh produce; risk factors for contamination of fresh produce associated with these practices; and possible measures by FDA to enhance the safety of fresh produce.

This notice describes the scope of the hearings. We invite information and comment on the issues and questions in section III of this document. If you are interested in these hearings or this subject, you may address as many of the following questions as you wish. We do not expect you to address all questions. When possible, please provide scientific information and data in support of your comments. In addition, to the extent possible, please provide as specific information as is feasible about the estimated costs and benefits associated with your responses (e.g., the costs and benefits of current practices and/or the cost and benefits of any recommendations you may make).

III. Issues and Questions for Discussion

Issue 1: In the supply chain for fresh produce (e.g., farms, packing houses, cooling facilities, and fresh-cut processing facilities), various factors can contribute to the risk of microbial contamination of fresh produce. We request information to enable us to identify and understand such factors more fully.

Question 1. For each stage in the supply chain, and for each industry sector, what are the risks or practices that could lead to microbial contamination of fresh produce?

Question 2. How can or should current practices be changed to reduce the risk of contamination?

Question 3. For each stage in the supply chain, and for each industry sector, what current practices (including, for example, following the GAPs/GMPs Guide) reduce the risk of microbial contamination of fresh produce? What data are available to support a conclusion that the risk of such contamination is lower than it would be without the practice in place?

Question 4. Is fresh produce, or inputs such as agricultural water, sampled and tested for pathogens or indicator organisms at any stage of the supply chain? If yes, please describe the sampling and testing done.

Issue 2: As described more fully in sections I.B through I.E of this document, we already have implemented several measures to enhance the safety of fresh produce and other foods within FDA's jurisdiction.

Question 5. Beyond the Federal actions described in sections I.B. through I.E, what new Federal actions, if any, are needed to enhance the safety of fresh produce? On what aspects of the produce supply chain should the measures focus?

Question 6. In identifying possible Federal interventions or actions, to what extent can or should we take into account the wide variation within the fresh produce industry with respect to, e.g., the size and type of establishments, the nature of the commodity produced, the practices used in production, and the vulnerability of particular commodities to contamination? To what extent should such measures apply to specific products, sectors of the industry, regions, or businesses? For example, is there a need for special treatment for different commodity groups?

Issue 3: Traceback can be problematic when unpackaged fresh produce is involved in an outbreak, especially for products which may undergo several packing and repacking steps in the supply chain with multiple opportunities for commingling. Even with respect to packaged and labeled products, traceback is difficult if there are insufficient records to identify the specific farm, field, or block of origin; if the records lack sufficient specificity about where the fresh produce went after leaving the packing or processing facility; or if there are discrepancies between records of incoming and outgoing product.

Question 7. What types of records and other information, from what types of

facilities, are or would be most useful in facilitating traceback efforts?

Issue 4: Written food safety plans, sanitation standard operating procedures (SSOPs), and monitoring records can serve as useful tools for both industry and regulators. Such records can assist operators in conducting operations in a manner that could enhance the safety of fresh produce. For growers, an assessment of factors such as the field environment and agricultural inputs could contribute to the development of written food safety plans and SSOPs, and also could help to determine which factors should be monitored and the frequency of monitoring. (In the following questions we use the term ''assessment'' when referring to an evaluation conducted by, or on behalf of, a grower or operator to identify measures to enhance food safety.)

Written food safety plans, SSOPs, and monitoring records also can assist regulators in verifying that certain practices are being followed consistently and properly over time. Onsite inspections, either alone, or in conjunction with records review, are another approach to such verification. (We use the term ''inspection'' when referring to an evaluation conducted by, or on behalf of, a regulator to evaluate compliance and the term ''audit'' to refer to a self- or third-party evaluation of whether operations adhere to, for example, voluntary guidelines or written food safety plans or SSOPs developed by the grower, operator, or buyer.)

Question 8. Are written food safety plans, written SSOPs, periodic assessments, training, and/or the establishment and maintenance of records useful for risk identification and risk mitigation or management purposes? If yes, to what extent are these practices in place, and in what sectors of the industry?

Issue 5: As noted in section II.D of this document, some buyers require that producers and other suppliers provide self- or third-party audit verification that they are following the GAPs/GMPs Guide. However, the extent to which these verifications reflect adherence to the guidance is not well-established.

Question 9. How should adherence to the GAPs/GMPs Guide or new produce safety guidance(s) be measured and verified by the grower or operator, government regulators, or third-party auditors, in the event of any new recommended Federal action or in the event you are not recommending any new Federal action?

Question 10. If you are recommending any new Federal measures, please describe how they might affect certain small businesses, such as roadside stands, farm gate operations, farmers' markets, or other small businesses involved in direct sales.

IV. Notice of Hearings Under 21 CFR Part 15

By delegation from the Commissioner of Food and Drugs (the Commissioner) (Staff Manual Guide 1420.21, section 1(b)), the Associate Commissioner for Policy and Planning finds that it is in the public interest to permit persons to present information and views at a public hearing regarding the safety of fresh produce and is announcing that the public hearings will be held in accordance with part 15. The presiding officer will be the Commissioner or his designee. The presiding officer will be accompanied by a panel of FDA employees with relevant expertise.

Persons who wish to participate in either hearing (either by making a presentation or as a member of the audience) must file a notice of participation (see **ADDRESSES**, **DATES**, **FOR FURTHER INFORMATION CONTACT**, and ''How to Participate in the Hearings'' in section V of this document). By delegation from the Commissioner (Staff Manual Guide 1420.21, section 1(b)), the Associate Commissioner for Policy and Planning has determined under § 15.20(c) that advance submissions of oral presentations are necessary for the panel to formulate useful questions to be posed at the hearings under § 15.30(e), and that the submission of a comprehensive outline or summary is an acceptable alternative to the submission of the full text of the oral presentation. Because we anticipate attendance at the hearings to be high, we request that individuals and organizations with common interests consolidate their requests for oral presentation and request time for a joint presentation through a single representative. After reviewing the notices of participation and accompanying information, we will schedule each oral presentation and notify each participant of the time allotted to the presenter and the approximate time that the presentation is scheduled to begin. If time permits, we may allow interested persons who attend one or both hearings but did not submit a notice of participation in advance to make an oral presentation at the conclusion of one or both hearings. The hearing schedules will be available at the hearings.

After the hearings, the schedules will be placed on file in the Division of Dockets Management (see **ADDRESSES**) under the docket number listed in brackets in the heading of this notice.

To ensure timely handling of any mailed notices of participation, presentations, or comments, any outer envelope should be clearly marked with the docket number listed in brackets in the heading of this notice along with the statement ''Safety of Fresh Produce; Public Hearing.''

Under § 15.30(f), the hearings are informal, and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation.

Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10 (21 CFR part 10, subpart C)). Under § 10.205, representatives of the electronic media may be permitted, subject to the procedures and limitations in § 10.206, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearings will be transcribed as stipulated in § 15.30(b). The transcript will be available on the Internet at *http://www.fda.gov/ohrms/dockets/default.htm*, and orders for copies of the transcript can be placed at the hearing or through the Division of Dockets Management (see **ADDRESSES**).

Any handicapped persons requiring special accommodations to attend the hearings should direct those needs to the contact person (see **FOR FURTHER INFORMATION CONTACT**).

To the extent that the conditions for the hearings, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of these provisions as specified in §§ 10.19 and 15.30(h). In particular, § 15.21(a) states that the notice of hearing will provide persons an opportunity to file a written notice of participation with the Division of Dockets Management within a specified period of time. If the public interest requires, e.g., if a hearing is to be conducted within a short period of time, the notice may name a specific FDA employee and telephone number to whom an oral notice of participation may be given. If the public interest requires, the notice may also provide for submitting notices of participation at the time of the hearing. In this document, the conditions for the hearings specify that notices of participation be submitted electronically to an agency Internet site, to a contact person (outside of FDA) who will accept notices of participation

by mail, telephone, fax, or e-mail, or in person on the day of the hearing (as space permits). We are using these procedures for submitting notices of participation, rather than provide for the submission of notices of participation to the Division of Dockets Management, because the hearing is to be conducted within a short period of time and these procedures are more efficient. In addition, these procedures provide more flexibility to persons who wish to participate in the hearings than would be provided if participants were required to submit the notice of participation in writing to the Division of Dockets Management. By delegation from the Commissioner (Staff Manual Guide 1420.21, section 1(f)(2)(i)), the Associate Commissioner for Policy and Planning finds under § 10.19 that no participant will be prejudiced, the ends of justice will thereby be served, and the action is in accordance with law if notices of participation are submitted by the procedures listed in this notice rather than to the Division of Dockets Management.

V. How to Participate in the Hearings

Registration by submission of a notice of participation is necessary to ensure participation and will be accepted on a first-come, first-served basis. The notice of participation may be submitted electronically (see **ADDRESSES**). The notice of participation also may be submitted orally, by fax, or by e-mail (see **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT**). We encourage you to submit your notice of participation electronically. A single copy of any notice of participation is sufficient, except that any person who wishes to participate in both hearings must submit a separate notice of participation for each hearing.

The notice of participation must include your name, title, business affiliation (if applicable), address, telephone number, fax number (if available), and e-mail address (if available). If you wish to request an opportunity to make an oral presentation during the open public comment period of the hearing, your notice of participation also must include the title of your presentation, the sponsor of the oral presentation (e.g., the organization paying travel expenses or fees), if any; and the approximate amount of time requested for the presentation. Presentations will be limited to the questions and subject matter identified in section III of this document, and, depending on the number of requests received, we may be obliged to limit the time allotted for each presentation.

Persons who wish to request an opportunity to make an oral presentation at the March 20, 2007, public hearing must submit a notice of participation (register) by March 2, 2007. All other persons wishing to register to attend the March 20, 2007, public hearing must submit a notice of participation by March 12, 2007. Persons who request an opportunity to make an oral presentation at the March 20, 2007, public hearing also must submit either the full text of the oral presentation, or a comprehensive outline or summary of the oral presentation, by March 12, 2007. Persons requiring special accommodations due to a disability must register by March 6, 2007.

Persons who wish to request an opportunity to make an oral presentation at the April 13, 2007, public hearing must submit a notice of participation by March 23, 2007. All other persons wishing to register to attend the April 13, 2007, public hearing must submit a notice of participation by April 6, 2007. Persons who request an opportunity to make an oral presentation at the second public hearing also must submit either the full text of the oral presentation, or a comprehensive outline or summary of the oral presentation, by April 6, 2007.

Under § 15.20(c), if you request an opportunity to make an oral presentation you must submit your presentation (either as the full text of the presentation, or as a comprehensive outline or summary) by e-mail or by fax. See **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** for information on where to send your presentation.

Individuals who request an opportunity to make an oral presentation will be notified of the scheduled time for their presentation prior to the hearing. Depending on the number of oral presentations, we may need to limit the time allotted for each oral presentation (e.g., 5 minutes each). As stated earlier, we request that interested persons and groups having similar interests consolidate their requests for oral presentation and present them through a single representative. If you need special accommodations due to a disability, please inform us (see **FOR FURTHER INFORMATION CONTACT**).

We will also accept registration onsite; however, space is limited and will be closed when the maximum seating capacity is reached. If space is available, on-site registration will be accepted on a first-come, first-served basis. Requests for an opportunity to make a presentation from individuals or organizations that did not register to make an oral presentation may be granted if time permits.

Persons who registered for the hearing should check in at the on-site registration desk between 8:30 and 9 a.m. Persons who wish to register onsite on the day of the hearing should do so at the registration desk between 8:30 and 9 a.m. We encourage all participants to attend the entire day. Because the hearings will be held in Federal buildings, hearing participants must present photo identification and plan adequate time to pass through the security system.

VI. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments in response to this document and notice of hearings for consideration at or after the hearings in addition to, or in place of, a request for an opportunity to make an oral presentation (see section V of this document). Submit two paper copies of any written comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in 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.

FDA is inviting public comment in writing and at the public hearings. These comments are sought to inform FDA decisionmaking about possible regulatory action with respect to the safety of fresh produce. Written or electronic comments (i.e., submissions other than notices of participation and the text, comprehensive outline, or summary of an oral presentation) may be submitted until June 13, 2007. The administrative record of the hearing will remain open until June 13, 2007.

VII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.

1. Sivapalasingam, S., et al. ''Fresh Produce: A Growing Cause of Outbreaks of Foodborne Illness in the United States, 1973 through 1997,'' *Journal of Food Protection* 67(10): 2342–53, 2004.

2. U.S. Food and Drug Administration, 1996–2006 Produce Outbreaks (unpublished compilation).

3. U.S. Food and Drug Administration, FDA News Release, ''FDA Warning on Serious Foodborne *E. coli* O157:H7

Outbreak,'' P06–131, September 14, 2006, available at *http://www.fda.gov/po/indexes/2006news.html*.

4. U.S. Centers for Disease Control and Prevention, ''Update on Multi-State Outbreak of *E. coli* O157:H7 Infections From Fresh Spinach, October 6, 2006, available at *http://www.cdc.gov/ecoli/2006/september/updates/100606.htm*.

5. U.S. Department of Health and Human Services and U.S. Department of Agriculture, ''Dietary Guidelines for Americans 2005,'' January 2005, available at *http://www.healthierus.gov/dietaryguidelines/*.

6. U.S. Food and Drug Administration, ''Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables,'' October 26, 1998, available at *http://www.cfsan.fda.gov/~dms/prodguid.html*.

7. U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Plant and Dairy Foods, ''Letter to Firms that Grow, Pack, or Ship Fresh Lettuce and Fresh Tomatoes,'' February 5, 2004, available at *http://www.cfsan.fda.gov/~dms/prodltr.html*.

8. U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Plant and Dairy Foods, ''Letter to California Firms that Grow, Pack, Process, or Ship Fresh and Fresh-cut Lettuce,'' November 4, 2005, available at *http://www.cfsan.fda.gov/~dms/prodltr2.html*.

9. U.S. Food and Drug Administration, ''Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables,'' March 2006, available at *http://www.cfsan.fda.gov/~dms/prodgui2.html*.

10. U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, FDA Food Code, 2005, available at *http://www.cfsan.fda.gov/~dms/foodcode.html*.

11. U.S. Food and Drug Administration, ''Produce Safety from Production to Consumption: 2004 Action Plan to Minimize Foodborne Illness Associated With Fresh Produce Consumption,'' October 2004, available at *http://www.cfsan.fda.gov/~dms/prodpla2.html*.

12. Produce Marketing Association and United Fresh Fruit and Vegetable Association, ''Commodity Specific Food Safety Guidelines for the Melon Supply Chain,'' November 7, 2005, available at *http://www.cfsan.fda.gov/~dms/melonsup.html* or *http://www.cfsan.fda.gov/~acrobat/melonsup.pdf*.

13. International Fresh-Cut Produce Association, Produce Marketing Association, United Fresh Fruit and Vegetable Association, Western Growers Association; Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain; April 25, 2006, available at *http://www.cfsan.fda.gov/~dms/lettsup.html* or *http://www.cfsan.fda.gov/~acrobat/lettsup.pdf*.

14. North American Tomato Trade Work Group, ''Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain, May 2006, available at *http://www.cfsan.fda.gov/~dms/tomatsup.html* or *http://www.cfsan.fda.gov/~acrobat/tomatsup.pdf*.

Dated: February 21, 2007.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. 07–891 Filed 2–23–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0480]

Draft Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration.'' In recent years, the practice of complementary and alternative medicine (CAM) has increased in the United States, and we have seen increased confusion as to whether certain products used in CAM are subject to regulation under the Federal Food, Drug, and Cosmetic Act (the act) or Public Health Service Act (PHS Act). We have also seen an increase in the number of CAM products imported into the United States. Therefore, the draft guidance discusses when a CAM product is subject to the act or the PHS Act.

DATES: Submit written or electronic comments on the draft guidance by April 30, 2007. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy and Planning (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0587.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration.'' The term ''complementary and alternative medicine'' (CAM) encompasses a wide array of health care practices, products, and therapies that are distinct from practices, products, and therapies used in ''conventional'' or ''allopathic'' medicine.

In the United States, the practice of CAM has risen dramatically in recent years. In 1992, Congress established the Office of Unconventional Therapies, which later became the Office of Alternative Medicine (OAM), to explore ''unconventional medical practices.'' In 1998, OAM became the National Center for Complementary and Alternative Medicine (NCCAM). NCCAM is a center within the National Institutes of Health. The Institute of Medicine, in its book entitled, *Complementary and Alternative Medicine in the United States*, stated that more than one-third of American adults reported using some form of CAM and that visits to CAM providers each year exceed those to primary care physicians (see Institute of Medicine, *Complementary and Alternative Medicine in the United States*, pages 34 through 35 (2005)).

As the practice of CAM has increased in the United States, we have seen increased confusion as to whether certain products used in CAM (which, for convenience, we will refer to as ''CAM products'') are subject to regulation under the act or the PHS Act. We have also seen an increase in the number of CAM products imported into the United States. Therefore, the draft guidance discusses when a CAM product is subject to the act or the PHS Act. (When the draft guidance mentions a particular CAM therapy, practice, or product, it does so in order to provide background information or to serve as an example or illustration; any mention of a particular CAM therapy, practice, or product should not be construed as expressing FDA's support for or endorsement of that particular CAM therapy, practice, or product or, unless specified otherwise, as an agency determination that a particular product