express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–6758, FAX: 301–827–6776, or e-mail: *PerezT@cder.fda.gov*. Please call the FDA Advisory Information Line at 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512538, for up-to-date information on this meeting.

Agenda: The committee will discuss the efficacy and safety of new drug application (NDA) #21–200, ZELNORM (tegaserod maleate), for the proposed indication of the treatment of patients with chronic constipation and relief of associated symptoms of straining, hard or lumpy stools, and infrequent defecation.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 6, 2004. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 6, 2004, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please notify Thomas H. Perez at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 7, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04–13430 Filed 6–14–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0258]

Produce Safety From Production to Consumption: An Action Plan to Minimize Foodborne Illness Associated With Fresh Produce; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to elicit information from stakeholders concerning key elements of FDA's new produce safety action plan entitled ''Produce Safety From Production to Consumption: An Action Plan to Minimize Foodborne Illness Associated With Fresh Produce.'' The new produce safety action plan will be forthcoming and posted at *http://www.foodsafety.gov/~dms/fs-toc.html* prior to the public meeting. We request that those who speak at the meeting or otherwise provide FDA with their comments focus on the questions set out in section II of this document concerning the draft of the produce safety action plan.

DATES: The public meeting will be held in College Park, MD, on Tuesday, June 29, 2004, from 1 p.m. to 4 p.m. We request that all those planning to attend the meeting register prior to the meeting. For security reasons and due to space limitations, we recommend that you register at least 5 days prior to the meeting. You may register via the Internet and also by fax until close of business 5 days before the meeting, provided that space is available (see **FOR FURTHER INFORMATION CONTACT**). In addition to participating at the public meeting, you may submit written or electronic comments until July 24, 2004.

ADDRESSES: The public meeting on Tuesday, June 29, 2004, will be held at the Harvey W. Wiley Federal Bldg., FDA, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740–3835.

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*.

FOR FURTHER INFORMATION CONTACT: Amy L. Green, Center for Food Safety and Applied Nutrition (HFS–306), FDA, 5100 Paint Branch Pkwy., College Park, MD, 301–436–2025, FAX: 301–436–2651, or e-mail: *amy.green@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In 1997, the Produce and Imported Food Safety Initiative (PIFSI) was released, which brought increased attention and resources to produce and microbial food safety. In 1998, as a part of this initiative, FDA issued guidance on good agricultural practices (GAPs) and the good manufacturing practice regulations (GMPs) for fresh produce. This guidance entitled ''Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables,'' (1998 guidance or 1998 GAPs/GMPs guidance), is broad in scope and covers all fresh produce consumed in the United States that is produced domestically and abroad and practices commonly involved in the production and packing of fresh produce. The 1998 GAPs/GMPs guidance has been well received and widely adopted; however, foodborne illness outbreaks associated with fresh produce continue to occur.

The draft 2004 produce safety action plan continues the 1997 initiative, building on experience from earlier efforts such as the development and implementation of the 1998 GAPs/GMPs guidance, inspections of farms and produce packing facilities, and investigations of foodborne illness outbreaks. The draft of the 2004 produce action plan addresses all principal points between the farm and table where contamination of produce could occur. It covers fresh fruit and vegetables in their native form and raw, minimally processed products, i.e., raw, pre-cut, or fresh-cut fruits and vegetables that have received some processing to alter their form (such as peeling, slicing, chopping, shredding, coring, trimming, or mashing), but have not been subject to a thermal process that would reduce, control, or eliminate microbial hazards. The draft action plan is not intended to cover processed products such as juice, or agricultural products other than fruits and vegetables, such as tree nuts.

In the 7 years since PIFSI began, many changes have occurred in the industry and much new knowledge and information are available. FDA believes that a good first step in moving the produce safety action plan forward is to engage and solicit the views of other Government agencies at Federal, State, and local levels, from industry groups, and from the public generally. The public meeting and comment period are intended to provide that opportunity.

FDA has drafted the set of questions below to help focus comments presented at the public meeting or otherwise communicated to the agency.

II. Questions

1. What concepts or underlying principles should guide the 2004 Produce Safety Action Plan? Are the seven objectives in the working draft appropriate for achieving the overarching goal to minimize foodborne illness associated with the consumption of fresh produce?

2. What major practices contribute to the contamination of fresh produce by harmful pathogens? What intervention strategies will prevent, reduce, or control this contamination?

3. The produce action plan covers fresh fruits and vegetables that have not been heat treated to reduce, control, or eliminate pathogens, or otherwise significantly processed. The draft action plan is not intended to 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. Should the produce action plan cover additional foods? If so, which foods?

4. What measurements should be used to measure progress toward the overarching goal (to minimize foodborne illness associated with fresh produce consumption)? What measures should be used to measure progress toward the individual objectives?

5. Does FDA's current GAPs/GMPs guidance (*http://www.foodsafety.gov/~dms/prodguid.html*) need to be expanded or otherwise revised? If yes, please describe generally the areas that need expansion or other revision.

6. In today's production and food preparation environments (farms, packing houses, retail establishments, and consumers), what conditions, practices, or other factors are the principal contributors to contamination of produce with a pathogen? What interventions would reduce, control, or eliminate this contamination?

7. There is broad variation within food operations including variations in size of establishments, the nature of the commodity produced, the practices used in production, and the vulnerability of a particular commodity to microbial hazards. How, if at all, should the produce action plan be structured to take into account such variation? For example, should there be different sets of interventions for identifiable segments of the fresh produce industry?

8. What roles can and should Federal, State, and local agencies and the food industry play in developing and implementing action items to help achieve the objectives in this action plan?

9. Are there existing food safety systems or standards (such as international standards) that FDA should consider as part of the agency's development and implementation of a produce safety action plan? Please identify these systems or standards and explain what their consideration might contribute to this effort.

III. Registration

You may register through FDA's Web site *http://www.cfsan.fda.gov/* and choose ''Public 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. Registration will be accepted on a first-come-first-serve basis. You may register until close of business June 22, 2004. 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**). There is no registration fee for this public meeting, but early registration is encouraged because space is limited, and it will expedite entry into the building and its parking area. If you require parking, please include the vehicle make and tag number, if known, on your registration form. Because the meeting will be held in a Federal building, you should also bring a photo identification (ID) and plan for adequate time to pass through security screening systems. If you would like to make oral comments at the meeting, please specify your interest in speaking when you register. The amount of time for each oral presentation may be limited based upon the number of requests to speak. FDA encourages individuals or firms with relevant data or information to present such information at the meeting or in written comments to the record.

IV. Transcripts

A transcript will be made of the proceedings of the meeting. You may request a copy of the meeting transcript 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 meeting at a cost of 10 cents a page. The transcript of the 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 the public meeting, interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the subject of this meeting. 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: June 9, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–13544 Filed 6–10–04; 1:35 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.