

contact person before April 20, 1998, 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.

Closed Committee Deliberations: On April 27, 1998, from 11:30 a.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). This portion of the meeting will be closed to permit discussion of this material.

FDA regrets that it was unable to publish this notice 15 days prior to the April 27, 1998, Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: April 8, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98-9704 Filed 4-9-98; 12:38 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0451]

Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a proposed guide entitled "Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (the proposed guide)." The document provides guidance on good agricultural practices (GAP's) and good manufacturing practices (GMP's). The GAP's and GMP's are designed to

minimize microbial food safety hazards common to the growing, harvesting, packing, and transport of most fruits and vegetables sold to consumers in an unprocessed or minimally processed (i.e., raw) form. This action is in response to the Presidential initiative to ensure the safety of imported and domestic fruits and vegetables. The proposed guide is intended to assist growers, packers, and other operators in continuing to improve the safety of domestic and imported produce.

DATES: Written comments by June 29, 1998.

ADDRESSES: Submit written comments on the proposed guide to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Submit written requests for single copies of the proposed guide entitled "Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" to Lou Carson, Center for Food Safety and Applied Nutrition, 200 C St. SW., rm. 3812, Washington, DC 20204, 202-260-8920. Send one self-adhesive address label to assist that office in processing your request. Comments and requests for copies should be identified with the docket number found in brackets in the heading of this document. A copy of the proposed guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

Joyce J. Saltsman, Center for Food Safety and Applied Nutrition (HFS-165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5916, FAX 202-260-9653, e-mail: jsaltsma@bangate.fda.gov, or Michelle A. Smith, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-2975, FAX 202-205-4422, e-mail: msmith1@bangate.fda.gov.

SUPPLEMENTARY INFORMATION:

On October 2, 1997, the President announced the "Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables" (fresh produce safety initiative). As part of the fresh produce safety initiative, the President directed the Secretary of Health and Human Services (DHHS) and the Secretary of the U.S. Department of Agriculture (USDA), in cooperation with the agricultural community, to issue, within 1 year, guidance on GAP's and GMP's

for fresh fruits and vegetables. FDA is coordinating the effort for DHHS.

As part of this effort, FDA and USDA held a series of public meetings between November 17, 1997, and December 12, 1997, to provide the details on a broad approach on how to minimize microbial contamination through the control of water, manure, worker health and hygiene, field and facility sanitation, and transportation. A draft guide entitled "Working Draft: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruit and Vegetables" (the working draft) was made available on FDA's World Wide Web (WWW) home page (<http://www.fda.gov>) and at each public meeting. The Fresh Produce Subcommittee of the National Advisory Committee for Microbiological Criteria for Food also reviewed and commented on sections of a working draft at the November 1997, meeting. Transcripts of these meetings and all comments received on the working draft of the proposed guide are on file in the Dockets Management Branch (address above) under the docket number appearing in brackets in the heading of this document and are accessible via the FDA home page on the WWW (<http://www.fda.gov/dockets/dockets.htm>).

With this notice, FDA is announcing the availability of the proposed guide. The proposed guide responds to comments received on the draft guidance document and represents the agencies' current thinking on strategies to minimize microbial hazards for fresh fruits and vegetables. The proposed guide does not create or confer any rights for or on any person and does not operate to bind FDA, USDA, or the public. An alternative approach may be used if such approach would effectively serve to reduce the microbial contaminants that could result in foodborne illnesses and if such approach satisfies applicable statutes and regulations. The proposed guide is being distributed for comment purposes, in accordance with the FDA's policy for Level 1 Good Guidance Practices documents as set out in the **Federal Register** of February 27, 1997 (62 FR 8961).

Because the guide is voluntary guidance, and not a regulation imposing binding requirements, FDA is not required to perform an economic impact analysis of the recommendations contained therein. However, the agency recognizes that, to reduce microbial hazards, the industry will want to select good agricultural and manufacturing practices that are most cost-effective, appropriate to their individual operations.

The guide represents the best effort of FDA, USDA, and other technical experts to identify practices that are feasible and that are likely to reduce microbial hazards. However, because of the broad-scope nature of the guide (such as covering all fresh fruits and vegetables grown in all regions of the US and overseas) and the current state of science (such as the need for additional research on pathogen survival under varying field conditions and the impact of various treatments to eliminate or reduce pathogens on the surface of crops with different physical characteristics), FDA has not attempted to rank the risk factors in order of significance or rank the intervention strategies in order of importance. It may, however, be possible to provide such information as science progresses and as additional, more focused documents (such as education and outreach materials on specific commodities or practices) are developed. To this end, FDA is requesting comment on the following:

(1) Current industry practices to reduce microbial hazards and how the recommendations in the guide might be most effectively applied to farms of various sizes. The agency specifically requests comments from small farmers and other industry groups currently employing these or other practices to reduce microbial hazards from fresh produce;

(2) Mechanisms used by growers and packers as part of good agricultural and good management practices programs and cost of application of such mechanisms;

(3) Most appropriate ways to analyze benefits and costs, such as by crop group (e.g., berries, tree fruit, vegetable row crops), by region, or by practice (e.g., manure management, water use in packing houses); and

(4) How to best draw on existing resources and expertise to assemble existing data and analyze costs and benefits (such as industry partnerships or pilot programs) to assess cost effective measures.

Interested persons may, on or before June 29, 1998, submit written comments to the Dockets Management Branch (address above) on the proposed guide. Two copies of any comments are to be submitted, 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. The proposed guide may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. An electronic version of this draft guidance is available on the Internet using the WWW (<http://www.fda.gov/dockets/dockets.htm>) or (<http://vm.cfsan.fda.gov/~dms/fs-toc.html>).

Dated: April 3, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98-9636 Filed 4-10-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council and Its Subcommittees

Pursuant to Pub. L. 92-463, notice is hereby given of a meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council and its subcommittees, National Institute of Diabetes and Digestive and Kidney Diseases, on May 27-28, 1998. The meeting of the full Council will be open to the public on May 27th; from 8:30 a.m. to 12:00 p.m. in Conference Room 10, Building 31C, National Institutes of Health, Bethesda, Maryland, to discuss administrative issues relating to Council business and special reports. The following subcommittee meetings will be open to the public May 27th from 1:00 p.m. to 2:00 p.m.: Diabetes, Endocrine and Metabolic Diseases Subcommittee meeting will be held in Conference Room 10, Building 31C; Digestive Diseases and Nutrition Subcommittee meeting will be held in Conference Room 7, Building 31C; and Kidney, Urologic and Hematologic Diseases Subcommittee meeting will be held in Conference Room 9, Building 31C. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and sec. 10(d) of Pub. L. 92-463, the meetings of the subcommittees and full Council will be closed to the public for the review, discussion and evaluation of individual grant applications. The following subcommittees will be closed to the public on May 27th, from 2:00 p.m. to 5:00 p.m. and again on May 28th, from 8:30 a.m. to 10:00 a.m.: Diabetes, Endocrine and Metabolic Diseases Subcommittee, Digestive Diseases and Nutrition Subcommittee; and Kidney, Urologic and Hematologic Diseases Subcommittee. The full Council will meet in closed session on May 28th from 10:00 a.m. to 10:30 a.m. in Conference Room 10, Building 31C. These deliberations, whether held in a subcommittee or in the full council,

could reveal confidential trade secrets on commercial property, such as patentable materials, and personal information concerning individuals associated with the applications, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

A final open session of the full Council will be held on May 28th from 10:30 a.m. to 12:00 p.m. to hear reports from the Division Directors and conduct other administrative business.

For any further information, and for individuals who plan to attend and need special assistance such as sign language interpretation or other reasonable accommodations, please contact Dr. Walter Stolz, Executive Secretary, National Diabetes and Digestive and Kidney Diseases Advisory Council, NIDDK, Natcher Building, Room 6AS-25C, Bethesda, Maryland 20892, (301) 594-8334, in advance of the meeting.

In addition, upon request, a summary of the meeting and roster of the members may be obtained from the Committee Management Office NIDDK, Building 45, Room 6AS-37J, National Institutes of Health, Bethesda, Maryland 20892, (301) 594-8892.

(Catalog of Federal Domestic Assistance Program No. 93.847-849, Diabetes, Endocrine and Metabolic Diseases; Digestive Diseases and Nutrition; and Kidney Diseases, Urology and Hematology Research, National Institutes of Health)

Dated: April 6, 1998.

Laverne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98-9570 Filed 4-10-98; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health (NIH)

National Institute on Aging; Notice of Meeting of the Board of Scientific Counselors, National Institute on Aging

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Board of Scientific Counselors, National Institute on Aging, May 12-14, 1998 to be held at the Gerontology Research Center, Baltimore, Maryland. On Wednesday, May 13, the meeting will be open to the public for the review of the Intramural Research Program from 8:30 until 11:45 a.m.; and again from 1:00 to 3:30 p.m. On Thursday, May 14, the meeting will be open to the public from 8:30 until 11:30 a.m. and from 12:30 to