definitions were modified including foodborne illness, potentially hazardous food (with respect to garlic in oil), reduced oxygen packaging, and support animal which is now service animal.

(6) Certain food employee-related provisions are modified, such as eliminating the requirement that food employees report travel out of the country, allowances for nurse practitioners and physician assistants to provide medical documentation, and addition of certain duties of the person in charge to reflect a 1996 CFP recommendation that was overlooked in the 1997 Code.

(7) Time and temperature controls are modified specifically for the cooking temperature for hamburger at less than 1 second and for cooking pork, and labeling criteria are added relative to whole-muscle, intact beef steaks which may be cooked rare without a consumer advisory and relative to safe handling instructions for retail operations that package meat and poultry.

(8) Clarification is provided for cleaning and sanitizing utensils and equipment used in food preparation and for refilling consumer containers, used by consumers to dispense condiments, and used in refrigerated preparation areas.

(9) Date marking of ready-to-eat food is augmented to limit the amount of time new food can be added to a container of existing food.

(10) More user aids are provided, such as additional references in Annex 2 and a diagram of the date marking criteria in Annex 7.

(11) Provisions are updated to reflect consistency with the current *Code of Federal Regulations* and other Federal agencies' guidance.

The 1999 revision of the Food Code is available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Copies of the 1999 Food Code are available on the World Wide Web at ''http://vm.cfsan.fda.gov/list.html or at http://www.fedworld.com''. The 1999 Food Code also may be purchased from the National Technical Information Service, U.S. Department of Commerce, Springfield, VA 22161, in several formats: Docutek copy, spiral bound, WordPerfect 6.1 files on diskette, and enhanced electronic version on diskette or on CD-ROM including Adobe Reader. The enhanced versions include electronic features such as hypertext links that enable the reader to quickly access the text of cross-referenced Code provisions or other documents. Other documents include Federal laws and regulations and, in the CD-ROM version, reference manuals to assist with plan review and HACCP implementation.

Dated: February 10, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–4315 Filed 2–19–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 25, 1999, 8 a.m. to 5:30 p.m., and March 26, 1999, 8 a.m. to 2:30 p.m.

Location: Ramada Inn, Embassy Ballroom, 8400 Wisconsin Ave., Bethesda, MD.

Contact Person: Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3514, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 19516. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 25, 1999, in the morning, the committee will hear, discuss, and provide comments on an informational presentation on Nucleic Acid Testing of Whole Blood. In the afternoon, the committee will discuss and provide comments on Human Immunodeficiency Virus (HIV) p24 Antigen Testing and Validation of Donor History Questions. On March 26, 1999, the committee will discuss and provide comment on an informational presentation on Clinical Trial Endpoints for Immune Globulin Intravenous and will discuss and provide recommendations on algorithms to address Inadvertent Contamination (with HIV, HBsAg, and/or HCV) of Plasma Pools for Fractionation.

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 March 15, 1999. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11 a.m.; 1:30 p.m. and 2 p.m.; and 4:30 p.m. and 5 p.m. on March 25, 1999, and between 8:45 a.m. and 9:15 a.m., and 11:30 a.m. and 12 m. on March 26, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 15, 1999, 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.

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

Dated: February 11, 1999.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 99–4215 Filed 2–19–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–0235]

Premarket Notification for Food Contact Substances; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public meeting: ''FDA Implementation of the Notification Process for Food Contact Substances.'' FDA is seeking comments from industry, consumer groups, and other members of the public prior to formally announcing the availability of guidance documents for the notification program. FDA will consider the comments received as a result of this meeting as the agency develops its plan for implementing the notification process for food contact substances, as well as the guidance documents for the notification program, which will be made available for public comment, at a later date.

DATES: The meeting will be held on Friday, March 12, 1999, from 8:30 a.m. to 5 p.m. Submit written comments by March 22, 1999.

ADDRESSES: The meeting will be held on the campus of the National Institutes of Health, 9000 Rockville Pike, Bldg. 10, Masur Auditorium, Bethesda, MD, 20892.

FOR FURTHER INFORMATION CONTACT: Vivian M. Gilliam, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3167, FAX 202–418–3131, or e-mail ''vgilliam@bangate.fda.gov''.

SUPPLEMENTARY INFORMATION:

I. Background

In November 1997, Congress passed the Food and Drug Administration Modernization Act of 1997 (FDAMA) . Section 309 of FDAMA amended section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) to establish a notification process for food contact substances. A food contact substance is defined as any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have a technical effect in such food (21 U.S.C. 348(h)(6)). Congress intended the notification process to be the primary route for authorizing the use of food contact substances (21 U.S.C. 348(h)(3)(A)), once the notification program begins to operate (see 21 U.S.C. 348(h)(5)). FDA expects that the majority of new uses of food contact substances that are now the subject of food additive petitions or threshold of regulation exemption requests under § 170.39 (21 CFR 170.39) will be the subject of premarket notifications once the notification program is operating.

Under 21 U.S.C. 348(h), the notification process requires a manufacturer or supplier of a food contact substance to notify FDA at least 120 days prior to marketing a food contact substance for a new use. If FDA does not object to the notification within 120 days, the notification becomes effective (21 U.S.C. 348(h)(2)(A)), and the substance may be legally marketed (21 U.S.C. 348(a)(3)(B)).

II. Registration, Written Questions, and Requests for Oral Presentations

Persons interested in attending the March 12, 1999, meeting should send their registration information (including name, title, business affiliation, address, telephone, and fax number), any questions they wish to have considered at the meeting, and any request to make an oral presentation to the contact person (address above). In addition, any person who wishes to distribute written material at the meeting should send copies of such material to the contact person at the time of registration. To expedite processing, registration information may also be faxed to 202–418–3131. Requests to make oral presentations should include an estimate of the time desired for the presentation, which will be accommodated as time permits. Per person time limits for oral presentations may be set to allow all interested persons an opportunity to speak. If you need special accommodations due to disability, please notify the contact person at least 7 days in advance.

III. Availability of Information for Discussion at the Meeting

FDA will make available to all registrants prior to the meeting an information packet, including material on FDA's current thinking on administration of the premarket notification (PMN) process and chemistry and toxicological data recommendations for notifications. FDA also hopes to make available three draft guidance documents (administrative, chemistry, and toxicology) on the FDA website at ''http//www.fda.gov'' in the very near future.

IV. Agenda and Goals

This meeting will provide manufacturers and suppliers of food contact substances, consumer groups, and other interested members of the public with an overview of FDA's current plans for the implementation of the notification process. FDA will also present the agency's current thinking on specific issues or questions of interest to the public.

At the meeting, FDA will present highlights of its administrative plan for the PMN program, its expected chemistry and toxicology data requirements, and its plans for transition to the notification process. There will be an open question and answer period for FDA to answer questions from participants regarding these matters. The agency will also give its current thinking on any questions submitted in writing to the agency prior to February 26, 1999. Participants who, prior to the meeting have registered to make oral presentations, will be permitted to do so as time permits.

FDA is seeking the views of interested parties on all aspects of the notification process for food contact substances. However, FDA is particularly interested in comments that address the following: (1) Realistic estimates of the number and complexity of notifications that would be submitted under the notification program; (2) the application of the requirements of the National Environmental Policy Act (NEPA) to the notification process; (3) the confidentiality of third-party information submitted in support of notifications; (4) FDA's proposed requirements and recommendations on the content of notifications; and (5) the conditions, if any, under which premarket review of a food additive petition would be necessary to assure the safety of a food contact substance (see 21 U.S.C. 348(h)(3)(B)).

A. Number and Complexity of Submissions

FDA believes that full implementation of the notification process for food contact substances could largely replace the food additive petition process for such substances and could replace completely the threshold of regulation exemption process in § 170.39. FDA also believes that the predictability of the notification process and the proprietary nature of notifications will increase the number of notifications for food contact substances compared to the current number of petitions and threshold of regulation submissions for such substances. FDA has estimated that it will receive approximately 400 submissions annually, based on an analysis of the type and number of submissions the agency currently receives and the number of industry participants in different areas of chemical production. However, FDA is interested in comments from the public regarding the number and complexity of notifications for food contact substances that would likely be submitted.

B. Environmental Considerations

Currently, food additive petitions and threshold of regulation exemptions must contain either a claim for categorical exclusion or an environmental assessment. FDA's current view is that, if NEPA is applicable to the notification process, the present categorical exclusions and requirements for an environmental assessment would apply to the notification process. However, FDA seeks comments on the applicability, to the notification process, of current environmental requirements for food additive petitions and threshold of regulation exemptions.

C. Proprietary Third-Party Data

Currently, FDA receives many food additive petitions and threshold of regulation requests that reference proprietary information submitted by third parties. In some cases, the proprietary information is necessary to describe adequately either the food

contact substance or appropriate limitations on its use. FDA has tentatively concluded that a company submitting proprietary information that is necessary to identify adequately the food contact substance or the notified use implicitly agrees that such information may be publicly disclosed to the extent that it is necessary to describe the food contact substance and the notified use. However, FDA is seeking comments on how FDA should manage third-party information claimed to be confidential that is referenced in a notification where such information is necessary to provide adequate identification of the food contact substance or the proposed conditions of use.

D. Format and Content of a Notification

Under 21 U.S.C. 348(h)(1), a manufacturer or supplier of a food contact substance is required, prior to marketing a food contact substance, to notify FDA of its determination that the intended use of the substance is safe within the meaning of 21 U.S.C. 348(c)(3)(A). FDA believes that the notifier's determination of safety must be presented in such a way that the agency is able to review and verify the most important aspects of the notifier's safety determination within the 120-day notification period. FDA is requesting comments on recommendations in the material provided regarding the form and content of notifications.

E. When a Petition Shall be Required

Under 21 U.S.C. 348(h)(3)(B), FDA is authorized to issue regulations to identify the circumstances under which a petition shall be filed for the use of a food contact substance, and is to consider such factors as the probable consumption of the substance and its potential toxicity. FDA has tentatively concluded that there are substances whose intake level or potential toxicity present a level of potential risk high enough that the use of such substances should be subject to premarket review and approval and a determination of safety by the agency in order to assure their safe use. The agency is considering using a cumulative intake of 500 parts per billion or more in the diet as one criterion for requiring submission of a petition. FDA is seeking comments on this approach, and requests suggestions from the public on other potential criteria.

V. Comments

Interested persons may, on or before March 22, 1999, submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments may also be sent to the Dockets Management Branch at the following e-mail address ''FDADockets@bangate.fda.gov'' or via the FDA website ''http://www.fda.gov''. Comments should be annotated and organized to identify the the specific issues to which they refer. 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. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VI. Transcripts

Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20852, approximately 15 working days after the meeting at a cost of 10 cents per page. The transcript of the meeting will also be available for public examination after March 22, 1999, at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday, as well as on the FDA website ''http://www.fda.gov''.

Dated: February 16, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–4402 Filed 2–18–99; 11:53 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0186]

Draft Guidance for Industry on Testing Orthopedic Implants With Metallic Plasma Sprayed Coatings to Support Reconsideration of Postmarket Surveillance Requirements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance for Industry on Testing Orthopedic Implants With Metallic Plasma Sprayed Coatings to Support Reconsideration of Postmarket Surveillance Requirements.'' This draft guidance is neither final nor is it in effect at this time. Metallic plasma spray coatings, both porous and nonporous, and metallic sintered or diffusion bonded porous coatings are used to attach artificial joints to living bone. FDA's Center for Devices and Radiological Health (CDRH) is identifying a set of testing methods that will accurately compare the mechanical properties of metallic plasma spray coatings with the same properties of sintered or diffusion bonded porous coatings. This draft guidance document proposes to use a number of mechanical tests to compare the mechanical properties of the various types of coatings. CDRH needs the ability to make the above comparisons in order to identify coated hip devices that should be subject to postmarket surveillance requirements.

DATES: Written comments concerning this draft guidance document must be received by May 24, 1999.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Guidance for Industry on Testing Orthopedic Implants With Metallic Plasma Sprayed Coatings to Support Reconsideration of Postmarket Surveillance Requirements'' to the Division of Small Manufacturers Assistance (HFZ–220), CDRH, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning this draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Anita M. Rayner, Center for Devices and Radiological Health (HFZ–543), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–0006.

SUPPLEMENTARY INFORMATION:

I. Background

FDA announced the reclassification and codification of the hip joint, metal/polymer/metal, semi-constrained, porous-coated uncemented prostheses in the **Federal Register** of January 8, 1993 (58 FR 3227). The reclassification was effective February 21, 1992. On February 15, 1994, CDRH's Orthopedic and Rehabilitation Devices Branch determined that hip prostheses using plasma sprayed porous coatings for