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

biological fixation can be substantially equivalent to the reclassified porous coated hip prosthesis. As part of the decision CDRH, using the then existing authority of section 522(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act, required manufacturers of plasma spray porous coated hip prostheses to conduct postmarket surveillance of their devices. Postmarket surveillance was required because of CDRH's concern that reported differences between the mechanical properties, particularly abrasion resistance, of plasma sprayed coatings and sintered and diffusion bonded porous coatings could have an adverse effect on the long-term revision rate of the plasma sprayed devices. While CDRH has clinical data describing the long-term revision rate of sintered and diffusion bonded porous coated hip prostheses, CDRH does not have this type of data on the cementless use of plasma sprayed hip prostheses. The postmarket surveillance will consist of prospective, long-term, followup of a population of patients who have received a cementless implantation of the manufacturer's plasma sprayed porous coated hip prosthesis. The objective of the patient followup is to determine the long-term revision rate for each plasma sprayed porous coated hip prosthesis.

At the time postmarket surveillance was required, CDRH believed that the term ''plasma spray'' was a single manufacturing technique that produced a single form of coating with a single set of metallurgical and mechanical properties. CDRH now recognizes that plasma spray manufacturing methods are a subset of the larger, thermal spray group of metallic coating production methods. CDRH has come to recognize that thermal spray coating methods can produce coatings with a wide range of metallurgical and mechanical properties. As an example, CDRH originally believed that, when used to apply metallic coatings to hip prostheses, plasma spray manufacturing techniques were used to produce only porous coatings. CDRH now also recognizes that hip prostheses with nonporous metallic coatings are also manufactured by plasma spray and other thermal spray methods.

Several manufacturers, using a variety of thermal spray coating methods, have received substantial equivalence decisions for their coated hips. A number of these manufacturers have sought reconsideration of CDRH's decision to require postmarket surveillance of their products. Several of the requests for reconsideration are, in part, based on claims that manufacturing technology permits the production of plasma sprayed coatings with mechanical properties, particularly abrasion resistance, equal to or better than those of the sintered or diffusion bonded porous coatings upon which the reclassification was based. In response to the requests for reconsideration, CDRH released a draft guidance document describing testing methods that CDRH believed could compare the mechanical properties of plasma sprayed coatings with those of sintered and diffusion bonded porous coatings. Several comments on that draft guidance document were received. Some comments on that draft guidance document included mechanical test data on different thermal spray coatings, both porous and nonporous. These data indicate that thermal spray coatings can have mechanical properties greater than, less than, or almost equal to those of sintered or diffusion bonded porous coatings.

CDRH does not believe that postmarket surveillance is necessary for hip prostheses whose coatings have mechanical properties, particularly abrasion resistance, equal to or better than sintered or diffusion bonded porous coatings. As a result, CDRH is now proposing to use the mechanical test methods described in this draft guidance document to reevaluate, on a case-by-case basis, the need for manufacturers to conduct postmarket surveillance of their metallic thermal spray coated hip prostheses.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on what data are necessary to support reconsideration of the thermal spray coated hip prosthesis postmarket surveillance requirements. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''Guidance for Industry on Testing Orthopedic Implants With Metallic Plasma Sprayed Coatings to Support Reconsideration of Postmarket Surveillance Requirements'' via your fax machine, call the CDRH Facts–On–Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number 946 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes ''Guidance for Industry on Testing Orthopedic Implants With Metallic Plasma Sprayed Coatings to Support Reconsideration of Postmarket Surveillance Requirements,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''. ''Guidance for Industry on Testing Orthopedic Implants With Metallic Plasma Sprayed Coatings to Support Reconsideration of Postmarket Surveillance Requirements'' will be available at ''http://www.fda.gov/cdrh/postsurv''.

IV. Comments

Interested persons may, on or before May 24, 1999, submit to Dockets Management Branch (address above) written comments regarding this draft guidance. 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 guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 8, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99–4213 Filed 2–19–99; 8:45 am]

BILLING CODE 4160–01–F