Dated: January 24, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0186]

Medical Devices; Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants 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 guidance entitled ''Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements.'' This guidance is final and is in effect at this time. Metallic plasma spray coatings, both porous and non-porous, 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 issuing this guidance to identify a set of testing methods that can be used to accurately evaluate the mechanical properties of the various types of coatings. CDRH will use such data to identify which coated hip devices should remain subject to postmarket surveillance requirements.

DATES: Submit written comments at any time.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological, 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 on this guidance document to David L. Daly (address below).

FOR FURTHER INFORMATION CONTACT: David L. Daly, Center for Devices and Radiological Health (HFZ–510), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3674.

SUPPLEMENTARY INFORMATION:

I. Background

On February 21, 1992, FDA sent a letter order to petitioner, Richards Medical Co., reclassifying the hip joint, metal/polymer/metal, semi-constrained, porous-coated uncemented prosthesis from class III (Premarket Approval) into class II (Special Controls). The reclassification was published 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 (ORDB) 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 consisted of prospective, long-term, followup of a population of patients who have received cementless implantation of the manufacturer's plasma sprayed porous coated hip prosthesis. The objective of the patient followup was 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, having 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 produced only porous coatings. CDRH now also recognizes that hip prostheses with non-porous metallic coatings can be 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, on February 22, 1999, reissued a draft guidance document describing testing methods that CDRH believed could measure the mechanical properties of plasma sprayed coatings. Several comments on the draft guidance document were received. CDRH has considered those comments and is now issuing this guidance as final guidance that is effective immediately.

Some comments on the draft guidance document included mechanical test data on different thermal spray coatings, both porous and non-porous. 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 inviting those manufacturers who have received postmarket surveillance orders to apply for reconsideration of those orders. CDRH will, on a case by case basis, reevaluate the need for manufacturers to conduct postmarket surveillance of their metallic thermal spray coated hip prostheses.

II. Significance of Guidance

This 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 the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants 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 guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes ''Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants 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 the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements'' will be available at http://www.fda.gov/cdrh/postsurv/plasmaspry.pdf.

IV. Comments

Interested persons may, at any time submit to the contact person above written comments regarding this guidance. FDA will consider any comments to determine whether to revise or revoke the guidance.

Dated: January 16, 2000.

Linda S. Kahan,

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

[FR Doc. 00–2242 Filed 2–1–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0854]

Determination of Regulatory Review Period for Purposes of Patent Extension; Bapten®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Bapten® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that animal drug product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Regulatory Policy Staff (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA recently approved for marketing the animal drug product Bapten® (beta-aminopropionitrile fumarate). Bapten® is indicated for the treatment of tendinitis of the superficial digital flexor tendon in the adult horse where there is sonographic evidence of fiber tearing. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Bapten® (U.S. Patent No. 4,485,088) from Alaco, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 29, 1999, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of Bapten® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Bapten® is 5,845 days. Of this time, 5,734 days occurred during the testing phase of the regulatory review period, while 111 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 512(j) of the act became effective:* June 11, 1982. The applicant claims May 27, 1982, as the date the investigational new animal drug application (INAD) became effective. However, FDA records indicate that the date of FDA's letter assigning a number to the INAD was June 11, 1982, which