ergonomic topics of study include management, supervisory, and employment practices; worker demographics and special populations; job, tool, and environmental design; design of health and safety services; and the interaction of these conditions. The scope of research includes (a) etiologic and health effects studies to serve as the basis for intervention strategies; (b) design and testing of prototype interventions in laboratory and controlled environments, and collaboration with external partners and organizations to field test and validate, and disseminate intervention techniques; (c) methodological research to better characterize exposures, outcomes, and their relationships; (2) provides technical assistance to other NIOSH and governmental units and to private organizations in the investigation of organizational and ergonomic stressors in the workplace and in the design and testing of prevention measures; (3) develops and disseminates scientific and technical reports on organizational and physical risk factors at work, and intervention strategies.

Human Factors and Ergonomics Research Section (CC962). (1) Plans and conducts integrated laboratory and field studies to develop and evaluate ergonomic interventions for preventing musculoskeletal injuries, neurobehavioral illnesses, fatigue, and social, economic and other losses resulting from exposure to physical, environmental and organizational stressors at work; (2) plans and conducts etiologic studies to provide the foundation for the development of ergonomic interventions, including laboratory and worksite research to assess the individual and interactive effects of physical stressors (excessive force, posture, etc.) and organizational stressors (e.g., long work hours, time pressure) on occupational injury and illness risk: (3) plans and conducts research leading to improved methods for exposure assessment to physical stressors and characterizing dose-response relationships; (4) provides assistance to other organizational units of NIOSH and to other Federal agencies in the assessment and prevention of risk for occupational injury and illness.

Health Services Research Section (CC963). (1) Plans and conducts research to evaluate and improve the effectiveness of occupational health care services, including access to and utilization of health care services, availability of trained health professionals and providers, and efficacy and efficiency of care; (2) conducts intervention research (intervention development, demonstration, and effectiveness research) to evaluate occupational health services and occupational health delivery systems and programs, including the social, economic, and organizational benefits of these services and programs; (3) provides technical assistance and collaborates with external organizations, including academia, industry, labor, and health care provider organizations in the implementation, evaluation and promotion of innovative occupational health services and occupational safety and health programs; (4) conducts research to evaluate the economic and social outcomes of occupational illnesses and injuries, and the benefits of interventions.

Work Organization and Stress Research Section (CC964). (1) Plans and conducts laboratory and field studies to characterize organizational stressors in the workplace and worker demographic factors such as race, ethnicity, gender, culture, age, etc., to study the effects and interactive effects of these variables on stress, illness, injury, and disability, and on social, economic and family outcomes, and to develop and test intervention strategies; (2) conducts survey studies to identify emerging work organization risk factors and related developments (new organizational structures and process changing employment relationships such as contingent labor arrangements, increasing workforce diversity and changing worker demographics) and investigate their effects on worker health, injury and other outcomes; (3) collaborates with external organizations to develop field-test and disseminate work organization, workforce development, and related interventions that promote worker health, safety, and other desirable outcomes; (4) provides technical assistance inside and outside of NIOSH in the conduct of etiologic and intervention studies addressing work organization and related factors.

Dated: January 18, 2000.

Jeffrey P. Koplan,

Director.

[FR Doc. 00–2212 Filed 2–1–00; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–4202]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use—Form FDA 356h

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by March 3, 2000.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use; Form FDA 356h (OMB Control Number 0910–0338)—Extension

FDA is the Federal agency charged with the responsibility for determining that drugs, including antibiotic drugs, and biologics are safe and effective. Manufacturers of a drug, or biologic for human use must file applications for FDA approval of the product prior to introducing it into interstate commerce. Statutory authority for the collection of this information is provided by section 505(a), (b), and (j) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(a), (b), and (j)) and section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262). Manufacturers of new drugs for human use regulated under the act must submit

a new drug application (NDA) for review and approval to the Center for Biologics Evaluation and Research (CBER) or the Center for Drug Evaluation and Research (CDER) prior to marketing a drug in interstate commerce (§ 314.50 (21 CFR 314.50)). Manufacturers of generic drugs regulated under the act must submit an abbreviated new drug application (ANDA) for review and approval to CDER prior to marketing a generic drug in interstate commerce (§ 314.94 (21 CFR 314.94)). Manufacturers of biological products regulated under the PHS Act must submit an establishment license application (ELA) and a product license application (PLA) or biologics license application (BLA) for review and approval to CBER prior to marketing a biological product in interstate commerce (§ 601.2 (21 CFR 601.2)). Blood and blood components fall within the category of biological products. All establishments collecting and/or preparing blood and blood components for sale or distribution in interstate commerce are subject to the licensing application provisions of section 351 of the PHS Act. Applicants are required to report to FDA any transfer of ownership of an NDA (21 CFR 314.72). Applicants are required to report a change in ownership of an ANDA (21 CFR 314.99(a)). Manufacturers of a drug or biologic for human use are required to file supplemental applications for certain changes to applications previously approved (§§ 314.70, 314.71, 314.97, and 601.12 (21 CFR 314.70, 314.71, 314.97, and 601.12)). The form is also submitted with an amendment to an unapproved original application or supplemental application, and a presubmission or resubmission of information pertaining to an application. The information provided by manufacturers with the application form is necessary for FDA to carry out its mission of protecting the public health and helping to ensure that drugs and biologics for human use have been shown to be safe and effective. Form FDA 356h was developed initially as a checklist to assist manufacturers in filling out a drug application and has been previously used only by manufacturers of products regulated under the act. In the **Federal Register** of July 8, 1997 (62 FR 36558), FDA announced the availability of the revised Form FDA 356h. The form was revised as a ''Reinventing Government'' initiative to harmonize application procedures between CBER and CDER. The application form serves primarily as a checklist for firms to gather and submit to the agency studies and data that have been completed. The checklist helps to ensure that the application is complete and contains all the necessary information, so that delays due to lack of information may be eliminated. The form provides key information to the agency for efficient handling and distribution to the appropriate staff for review. For biologics manufacturers, the form will replace a number of different ELA and PLA forms that were formerly used for these products. The information collection burden for various ELA and PLA forms is covered under OMB Control No. 0910–0124. There are an estimated 343 licensed biologics manufacturers. However, not all manufacturers will have any submissions in a given year and some may have multiple submissions. The annual responses are based on submissions received by FDA in 1998. The time estimated to prepare an ELA, PLA, or BLA under § 601.2 for CBER approval to market a new product is based on information provided by industry. The time required for preparing an ELA, PLA, or BLA includes the estimate for filling out the form. The estimated average burden hours for the other submissions using Form 356h to CBER is based on past FDA experience and includes the time to fill out the form and collate the documentation. The average burden hours also include the time to prepare an amendment submitted to CBER. The estimated burden hours to prepare a supplement to CBER (§ 601.12) are reported under OMB Control No. 0910–0315.

In the **Federal Register** of October 21, 1999 (64 FR 56797), the agency requested comments on the proposed collections of information. No significant comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICS [1]

21 CFR Section/FDA form	No. of respondents	Total annual responses	Hours per response	Total hours
601.2	343	84	1,600	134,400
Form FDA 356h	343	4,947	16	79,152
Total				213,552

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

There are 483 drug applicants that submitted the form. The annual responses are based on submissions received by FDA in 1997 and 1998. The estimated average burden hours for the submissions using Form 356h to CDER is based on past FDA experience and includes the time to fill out the form and collate the documentation. The estimated burden hours to prepare an NDA (§ 314.50); an ANDA (§ 314.94); supplements (§§ 314.70, 314.71, and 314.97); and amendments (21 CFR 314.60 and 314.96) are approved under OMB Control No. 0910–0001.

FDA estimates the burden of this collection of information as follows:

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS [1]

FDA form	No. of respondents	Total Annual responses	Hours per response	Total hours
Form FDA 356h	483	16,221	24	389,304
Total				389,304

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: January 24, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–2150 Filed 2–1–00; 8:45 am]

BILLING CODE 4160–01–F

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.