review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 498–1210. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

Longitudinal Surveillance for Beryllium Disease Prevention OMB No. 0920–0463 (formerly titled Gene-Environment Interactions in Beryllium Sensitization and Disease Among Current and Former Beryllium Industry Workers)—Extension—National Institute for Occupational Safety and Health (NIOSH)—Centers for Disease Control and Prevention (CDC).

Background

Beryllium is a light weight metal with wide application in modern technology. The size of the USA workforce at risk of beryllium exposure is estimated at approximately one million, with exposed workers in primary production, nuclear power and weapons, aerospace, scrap metal reclaiming, specialty ceramics, and electronics industries. Demand for beryllium is growing worldwide, which means that increasing numbers of workers are likely to be exposed. An acute pneumonitis due to occupational exposure to beryllium was common in the 1940s and 1950s, but has virtually disappeared with improvements in work-site control measures. However, even with improved controls as many as 5% of currently-exposed workers will develop chronic beryllium disease (CBD).

CBD is a chronic granulomatous lung disease mediated through a poorly understood immunologic mechanism in workers who become sensitized. Sensitization can be detected using a blood test, that is used by the industry as a surveillance tool. The blood test for sensitization was first reported in 1989, but many questions remain about the natural history of sensitization and disease, as well as exposure risk factors. Sensitized workers, identified through workplace surveillance programs, undergo clinical diagnostic tests to determine whether they have CBD. The proportion of sensitized workers who have beryllium disease at initial clinical evaluation has varied from 41–100% in different workplaces. Sensitized workers often develop CBD with follow-up, but whether all sensitized workers will eventually develop beryllium disease is unknown. Early diagnosis at the subclinical stage and careful follow-up seems prudent in that CBD usually responds to corticosteroid treatment. However, the efficacy of screening in preventing adverse outcomes of the disease has not yet been evaluated. Research has indicated certain genetic determinants in the risk of CBD; follow-up studies will be invaluable for further characterizing the genetic contribution to sensitization and disease.

The National Institute for Occupational Safety and Health (NIOSH) wants to determine how beryllium workers and former workers develop beryllium disease and how to prevent it. Through the proposed study, NIOSH has the opportunity to contribute to the scientific understanding of this disease in the context of environmental and genetic etiologic factors. The goals of this investigation are to: (1) Determine the occurrence of beryllium sensitization or disease; (2) seek an association with exposure measurements; (3) explore genetic determinants of susceptibility to CBD; and (4) characterize genetic determinants to ascertain if they are associated with clinical impairment or progression of disease. Through a greater understanding of the environmental and genetic risk factors associated with the onset and progression of CBD, NIOSH will be able to develop strategies for both primary and secondary prevention applicable to beryllium-exposed workers. The total annualized burden for this data collection is 263 hours.

Respondents	Number of respondents	Number of responses/respondent	Avg. burden/response (in hours)
Former Workers	525	1	30/60

Dated: November 13, 2002.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 02–29669 Filed 11–20–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Termination of Two Food and Drug Administration Advisory Committees: Medical Imaging Drugs Advisory Committee and the Pharmacy Compounding Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the termination of two FDA advisory committees: The Medical Imaging Drugs Advisory Committee, a nonstatutory advisory committee to FDA's Center for Drug Evaluation and Research (CDER), and the Pharmacy Compounding Advisory Committee, a statutory committee to the FDA's Center for Drug Evaluation and Research.

DATES: November 21, 2002.

FOR FURTHER INFORMATION CONTACT: Linda Ann Sherman, Director Advisory Committee Oversight and Management Staff (HF–4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1220.

SUPPLEMENTARY INFORMATION: Under its current charter, the Medical Imaging Drugs Advisory Committee will expire on February 28, 2004. The Medical Imaging Drugs Advisory Committee is responsible for: (1) Reviewing and evaluating data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and for use as contrast media in diagnostic radiology and (2) making appropriate recommendations to the Commissioner of Food and Drugs. The Commissioner has determined that a separate advisory committee for these products is not necessary as these products can be more effectively reviewed by an existing advisory committee or a by a subcommittee of an existing committee with responsibility for providing advice and recommendations regarding the specific systemic product area at issue with a given product.

The charter for the Pharmacy Compounding Advisory Committee was renewed February 3, 2002, for a 2-year

term. This Committee was created by section 503A(d)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 353a(d)(1)). Section 503a(d)(1) specifically directed the Secretary of Health and Human Resources to convene and consult an advisory committee on compounding.

On April 29, 2002, the *United States Supreme Court in Thompson, et al.* v. *Western States Medical Center Pharmacy, et al.*, 122 S.Ct. 1497 (2002), affirmed a decision of the U.S. Court of Appeals for the Ninth Circuit invalidating section 503A of act. Section 503A of the act, enacted as part of the Food and Drug Administration Modernization Act of 1997, exempted drugs compounded by pharmacies from the act's new drug approval, adequate directions for use, and good manufacturing practice requirements if specified conditions, including two restrictions on commercial speech, were met. The Supreme Court held that these two speech related restrictions violate the first amendment to the U.S. Constitution. The Ninth Circuit had also concluded that these unconstitutional speech restrictions may not be severed from the rest of the provisions in section 503A of the act, and that section 503A is invalid in its entirety. Because neither the Government nor the compounding pharmacy plaintiffs sought review of this aspect of the Ninth Circuit's decision, the Supreme Court did not reach the issue. As a result, the Ninth Circuit's invalidation of section 503A of the act in its entirety stands. Because the entire section 503A of the act is invalid, the statutory authorization for an advisory committee on compounding no longer exists.

For the reasons stated previously, the Medical Imaging Drugs Advisory Committee and the Pharmacy Compounding Advisory Committee are terminated.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2)).

Dated: November 14, 2002.

Linda Arey Skladany,

Senior Associate Commissioner for External Relations.

[FR Doc. 02–29573 Filed 11–20–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Establishment of Medical Device User Fee Rates for Fiscal Year 2003 and Interim Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates and interim procedures for medical device user fees for fiscal year (FY) 2003. The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250), authorizes FDA to collect user fees for certain medical device applications. This notice establishes fee rates for FY 2003. These fees are effective for applications submitted on October 1, 2002, and will remain in effect through September 30, 2003. However, FDA may not begin to collect these fees until enabling appropriations are enacted. FDA will issue invoices for all fees payable for applications submitted between October 1, 2002, and 30 days after the date of the **Federal Register** notice the agency will issue after enactment of enabling appropriations. Those invoices will be due and payable within 30 days of issuance. Subsequently, fees must be submitted to FDA at the time that applications are submitted.

ADDRESSES: Visit the FDA Web site that provides further information on MDUFMA at http://www.fda.gov/cdrh/mdufma/index.html.

FOR FURTHER INFORMATION CONTACT: Frank Claunts, Office of Management and Systems (HFA–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4427.

SUPPLEMENTARY INFORMATION:

I. Background

The act establishes fees in sections 737 and 738 (21 U.S.C. 379i and j) for different kinds of medical device applications. Fees are assessed on certain types of medical device applications and supplements. When certain conditions are met, FDA may waive or reduce fees (21 U.S.C. 379j(d) and (e)).

For FY 2003 through FY 2007, MDUFMA establishes revenue amounts for the aggregate of all application fee revenues. Revenue amounts established for years after FY 2003 are subject to adjustment for inflation, workload, and revenue shortfalls from previous years. Fees for applications are to be established each year by FDA so that revenues will approximate the levels established in the statute, after those amounts have first been adjusted for inflation, workload, and, if required, revenue shortfalls from previous years.

This notice establishes fee rates for FY 2003. These fees are effective on October 1, 2002, and will remain in effect through September 30, 2003.

II. Inflation, Workload, and Compensating Adjustment Process

MDUFMA provides that fee revenue amounts for each FY after 2003 shall be adjusted for inflation. The adjustment must reflect the greater of: (1) The total percentage change that occurred in the Consumer Price Index (all items, U.S. city average) during the 12-month period ending on June 30 preceding the FY for which fees are being set, or (2) the total percentage pay change for the previous FY for Federal employees stationed in the Washington, DC metropolitan area. MDUFMA provides for this annual adjustment to be cumulative and compounded annually after 2003 (21 U.S.C. 379j(c)(1)). No inflation adjustment is to be made with respect to fee revenue amounts established in the statute for FY 2003.

For each FY beginning in FY 2004, MDUFMA provides that fee revenue amounts, after they have been adjusted for inflation, shall be further adjusted to reflect changes in workload for the process for the review of medical device applications (21 U.S.C. 379j(c)(2)). No workload adjustment is to made be with respect to fee revenue amounts established in the statute for FY 2003.

For each FY beginning in FY 2004, MDUFMA provides that fee revenue amounts, after they have been adjusted for inflation and workload, shall be further adjusted, if necessary, to compensate for any shortfall in fee revenue from previous years (21 U.S.C. 379j(c)(3)). No compensating adjustment is to be made with respect to fee revenue amounts established in the statute for FY 2003.

Inflation, workload, and compensating adjustments do not apply to the revenue amounts established in MDUFMA for FY 2003.

III. Fee Calculations for FY 2003

MDUFMA establishes the fee for a premarket application (PMA) at $154,000 in FY 2003. All other fees are set as a percent of this fee. At these rates, the medical device user fees are expected to generate $25,125,000 in FY 2003. The applications subject to fees, the rate of each fee as a percent of a premarket application, and the FY 2003