

of their qualifications (in particular, those that address the required qualifications, outlined above) and the current expertise needs of the Task Force. It is anticipated that 2 individuals will be invited to serve on the Task Force beginning in January, 2007. AHRQ will retain and consider for future vacancies the nominations of those not selected during this cycle.

**ADDRESSES:** Submit your response to: Helen Burstin, MD MPH, ATTN: USPSTF Nominations, Center for Primary Care, Prevention, and Clinical Partnerships, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland 20850.

#### Nomination Submissions

Nominations may be submitted in writing or electronically, but must include (1) the applicant's current curriculum vitae, and (2) a letter explaining how this individual meets the qualification requirements and how he/she would contribute to the Task Force. The letter should also attest to the nominee's willingness to serve as a member of the Task Force.

AHRQ will later ask persons under serious consideration for membership to provide detailed information that will permit evaluation of possible significant conflicts of interest. Such information will concern matters such as financial holdings, consultancies, and research grants or contracts.

#### Nomination Selection

Nominations for the Task Force will be selected on the basis of qualifications as outlined above (see qualification requirements) and the current expertise needs of the Task Force.

#### Arrangement for Public Inspection

Nominations and applications are kept on file at the Center for Primary Care, Prevention and Clinical Partnerships, and are available for review during business hours. AHRQ does not reply to individual responses, but considers all nominations in selecting members. Information regarded as private and personal, such as a nominee's social security number, home and internet addresses, home telephone and fax numbers, or names of family members will not be disclosed to the public. This is in accord with agency confidentiality policies and Department regulations (45 CFR 5.67).

**FOR FURTHER INFORMATION CONTACT:** Therese Miller at [therese.miller@ahrq.hhs.gov](mailto:therese.miller@ahrq.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

#### Background

Under Title IX of the Public Health Service Act, AHRQ is charged with enhancing the quality, appropriateness, and effectiveness of health care services and access to such services. AHRQ accomplishes these goals through scientific research and promotion of improvements in clinical practice, including prevention of diseases and other health conditions, and improvements in the organization, financing, and delivery of health care services (42 U.S.C. 299-299c-7 as amended).

The Task Force is an independent expert panel, first established in 1984 under the auspices of the U.S. Public Health Service. Currently, the USPSTF, under AHRQ's authorizing legislation (see in particular, 42 U.S.C. 299b-4(a)), is convened at the call of the Director of AHRQ. The Task Force is charged with rigorously evaluating the effectiveness, cost-effectiveness and appropriateness of clinical preventive services and formulating or updating recommendations for primary care clinicians regarding the appropriate provision of preventive services. The USPSTF transitioned to a standing Task Force in 2001. Current Task Force recommendations and associated evidence reviews are available on the Internet (<http://www.preventiveservices.ahrq.gov>).

Dated: June 22, 2006.

**Carolyn M. Clancy,**  
Director.

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Centers for Disease Control and Prevention

##### Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 6772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 71 FR 32349-32350, dated June 5, 2006) is amended to reflect the reorganization of the Office of the Chief Science Officer, Office of the Director, Centers for Disease Control and Prevention.

Section C-B, Organization and Functions, is hereby amended as follows:

Revise the functional statement for the *Office of the Chief Science Officer (CAS)*, as follows:

After item (12), insert the following item: (13) provides oversight, training, monitoring, and quality assurance in the use of animals in research.

Delete item (10) of the functional statement for the *Scientific Resources Program (CVCE)*, *National Center for Infectious Diseases (CVC)*, and renumber the remaining items accordingly.

Dated: June 22, 2006.

**William H. Gimson,**

*Chief Operating Officer, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 06-5785 Filed 6-28-06; 8:45 am]

**BILLING CODE 4160-18-M**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. 2006N-0021]

##### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Request for Samples and Protocols

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. **DATES:** Fax written comments on the collection of information by July 31, 2006.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezuto, Office of Management Programs (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.

**Request for Samples and Protocols — (OMB Control Number 0910-0206) — Extension**

Under section 351 of the Public Health Service Act (42 U.S.C. 262), FDA has the responsibility to issue regulations that prescribe standards designed to ensure that the biologics licenses for such products are only issued when a product meets the prescribed standards. Under § 610.2 (21 CFR 610.2), FDA may at any time require manufacturers of licensed biological products to submit to FDA samples of any lot along with the protocols showing the results of applicable tests prior to marketing the lot of the product. In addition to § 610.2, there are other regulations that require the submission of samples and protocols for specific licensed biological products: § 660.6 (21 CFR 660.6) (Antibody to Hepatitis B Surface Antigen), 660.36 (21 CFR 660.36) (Reagent Red Blood Cells), and 660.46 (21 CFR 660.46) (Hepatitis B Surface Antigen).

Section 660.6(a) provides requirements for the frequency of submission of samples from each lot of Antibody to Hepatitis B Surface Antigen product, and § 660.6(b) provides the requirements for the submission of a protocol containing specific information along with each required sample. For § 660.6 products subject to official release by FDA, one sample from each filling of each lot is required to be submitted along with a protocol consisting of a summary of the history of manufacture of the product, including all results of each test for which test results are requested by the Center for Biologics Evaluation and Research (CBER). After official release is no longer required, one sample along with a protocol is required to be submitted at an interval of 90 days. In addition, samples, which must be accompanied by a protocol, may at any time be required to be submitted to FDA if continued evaluation is deemed necessary.

Section 660.36(a) requires, after each routine establishment inspection by FDA, the submission of samples from a lot of final Reagent Red Blood Cell product along with a protocol containing specific information. Section

660.36(a)(2) requires that a protocol contain information including, but not limited to, manufacturing records, test records, and test results. Section 660.36(b) requires a copy of the antigenic constitution matrix specifying the antigens present or absent to be submitted to FDA at the time of initial distribution of each lot.

Section 660.46(a) provides requirements for the frequency of submission of samples from each lot of Hepatitis B Surface Antigen product, and § 660.46(b) provides the requirements for the submission of a protocol containing specific information along with each required sample. For § 660.46 products subject to official release by FDA, one sample from each filling of each lot is required to be submitted along with a protocol consisting of a summary of the history of manufacture of the product, including all results of each test for which test results are requested by CBER. After notification of official release is received, one sample along with a protocol is required to be submitted at an interval of 90 days. In addition, samples, which must be accompanied by a protocol, may at any time be required to be submitted to FDA if continued evaluation is deemed necessary.

Samples and protocols are required by FDA to help ensure the product meets the criteria for lot release that have been determined to be necessary by FDA. In cases of certain biological products (e.g., Albumin, Plasma Protein Fraction, and specified biotechnology and specified synthetic biological products) that are known to have lot-to-lot consistency, official lot release is not normally required. However, submissions of samples and protocols of these products may still be required for surveillance, licensing, and export purposes, or in the event that FDA obtains information that the manufacturing process may not result in consistent quality of the product.

The following burden estimate is for the protocols that are required to be submitted with each sample. The collection of samples is not a collection of information under 5 CFR 1320.3(h)(2). Respondents to the

collection of information under § 610.2 are manufacturers of licensed biological products. Respondents to the collection of information under § 660.6(b), 660.36(a)(2) and (b), and 660.46(b) are manufacturers of the specific products referenced previously in this document. The estimated number of respondents for each regulation is based on the annual number of manufacturers that submitted samples and protocols for biological products including submissions for lot release, surveillance, licensing, or export. Based on information obtained from FDA's database system, approximately 70 manufacturer's submitted samples and protocols in fiscal year (FY) 2005, under the regulations cited previously in this document. FDA estimates that 65 manufacturers submitted protocols under § 610.2, and 4 manufacturers submitted protocols under the regulations (§§ 660.6 and 660.46) for the other specific products. FDA received no submissions under § 660.36, however FDA is using the estimate of one protocol submission in the event one is submitted in the future.

The estimated total annual responses are based on FDA's final actions completed in FY 2005, which totaled 4,930, for the various submission requirements of samples and protocols for the licensed biological products. The rate of final actions is not expected to change significantly in the next few years. The hours per response are based on information provided by industry. The burden estimates provided by industry ranged from 1 to 5.5 hours. Under § 610.2, the hours per response are based on the average of these estimates and rounded to 3 hours. Under the remaining regulations, the hours per response are based on the higher end of the estimate (rounded to 5 or 6 hours) since more information is generally required to be submitted in the protocol than under § 610.2.

In the **Federal Register** of January 24, 2006 (71 FR 3856), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours
610.2	65	74.1	4,816	3	14,448
660.6(b)	3	26	78	5	390

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>—Continued

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours
660.36(a)(2) and (b)	1	1	1	6	6
660.46(b)	1	35	35	5	175
Total	70				15,019

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: June 23, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006N-0247]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device User Fee Cover Sheet

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on Form FDA 3601 entitled "Medical Device User Fee Cover Sheet" which must be submitted along with certain medical device product applications, supplements, and fee payment of those applications.

**DATES:** Submit written or electronic comments on the collection of information by August 28, 2006.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the

docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Denver Presley, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### Medical Device User Fee Cover Sheet; Form FDA 3601 (OMB Control Number 0910-0511)—Extension

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. Under this authority, companies pay a fee for certain new medical device applications or supplements submitted to the agency for review. Because the submission of user fees concurrently with applications and supplements is required, the review of an application cannot begin until the fee is submitted. Form FDA 3601, the "Medical Device User Fee Cover Sheet", is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference of the fees submitted for an application with the actual application by using a unique number tracking system. The information collected is used by FDA's Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of new medical device applications and supplemental applications.

According to FDA's database system, there are an estimated 4,600 manufacturers of products subject to MDUFMA. However, not all manufacturers will have any cover sheet submissions in a given year and some may have multiple cover sheet submissions. The total number of annual responses is based on the number of cover sheet submissions received by FDA in fiscal year 2005. CDRH received 4,436 annual responses that included the following submissions: 43 premarket approval applications (PMAs), 4,071 premarket notifications, 22 modular premarket applications, 1 product development protocol, 1 premarket report, 15 panel track supplements, 174 real-time supplements, and 109 180-day