TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
812.140 Original	600	0.5	300	10	3,000
812.140 Supplemental	600	7	4,200	1	4,200
812.140 Non-significant	600	1	600	6	3,600
Total					10,800

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

The estimate of the burden is based on the number of IDEs received in the last 3 years.

Dated: October 16, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–25539 Filed 10–22–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0486]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry, FDA, and Foreign Governments: Fiscal Year 2010 Medical Device User Fee Small Business Qualification and Certification

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 FDA Forms 3602 and FDA Form 3602A which will allow domestic and foreign applicants to certify that they qualify as a ''small business'' and pay certain medical device user fees at reduced rates.

DATES: Submit written or electronic comments on the collection of information by December 22, 2009.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.regulations.gov*. 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, Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

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 practicalutility; (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.

Guidance for Industry, FDA, and Foreign Governments: FY 2010 Medical Device User Fee Small Business Qualification and Certification FD&C Act Section 738 (OMB Control Number 0910–0508)—Extension

Section 101 of the Medical Device User Fee and Modernization Act (MDUFMA) amends the Federal Food, Drug, and Cosmetic Act (the act) to provide for user fees for certain medical device applications. FDA published a **Federal Register** notice on August 3, 2009 (74 FR 38444), announcing fees for fiscal year (FY) 2010. To avoid harming small businesses, MDUFMA provides for reduced or waived fees for applicants who qualify as a ''small business.'' This means there are two levels of fees, a standard fee, and a reduced or waived small business fee.

FDA From 3602— For Domestic Small Business Applicants

For FY 2010, you can qualify for a small business fee discount under MDUFMA if you reported gross receipts or sales of no more than $100 million on your Federal income tax return for the most recent tax year. If you have any affiliates, partners, or parent firms, you must add their gross receipts or sales to yours and the total must be no more than $100 million. If your gross receipts or sales are no more than $30 million, including all of your affiliates, partners, and parent firms, you will also qualify for a waiver of the fee for your first (ever) premarket application, (product development protocol, biologics licensing application, or Premarket Report). An applicant must pay the full standard fee unless it provides evidence demonstrating to FDA that it meets the ''small business'' criteria. The evidence required by MDUFMA is a copy of the most recent Federal income tax return of the applicant, and any affiliate, partner, or parent firm. FDA will review these

materials and decide whether an applicant is a ''small business'' within the meaning of MDUFMA.

FDA Form 3602A— For Foreign Small Business Applicants

The 2007 Amendments provide an alternative way for a foreign business to qualify as a small business eligible to pay a significantly-lower fee when a medical device user fee must be paid.

Before passage of the 2007 Amendments, the only way a business could qualify as a small business was to submit a Federal (U.S.) income tax return showing its gross receipts or sales that did not exceed a statutory threshold, currently, $100 million. If a business could not provide a Federal income tax return, it did not qualify as a small business and had to pay the standard (full) fee. Because many foreign businesses have not, and cannot, file a Federal (U.S.) income tax return, this requirement has effectively prevented those businesses from qualifying for the small business fee rates. Thus, foreign governments, including the European Union, have objected.

In lieu of a Federal income tax return, the 2007 Amendments will allow a foreign business to qualify as a small business by submitting a certification from its national taxing authority, the foreign equivalent of our Internal Revenue Service. This certification, referred to as a ''National Taxing Authority Certification,'' must:

- Be in English;
- Be from the national taxing authority of the country in which the business is headquartered;
- Provide the business' gross receipts or sales for the most recent year, in both the local currency and in U.S. dollars, and the exchange rate used in converting local currency to U.S. dollars;
- Provide the dates during which the reported receipts or sales were collected; and
- Bear the official seal of the national taxing authority.

Both FDA Forms 3602 and 3602A are available in the guidance document, ''Guidance for Industry, FDA and Foreign Governments: FY 2010 MDUFMA Small Business Qualification and Certification'' *, available on the Internet at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/UCM179257.pdf*. This guidance describes the criteria FDA will use to decide whether an entity qualifies as a MDUFMA small business and will help prospective applicants understand what they need to do to meet the small business criteria for FY 2010.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Form No.	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3602	3,000	1	3,000	1	3,000
3602A Sections I and II	340	1	340	1	340
3602A Section III	33	7	231	1	231
TOTALS					3,571

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

The FDA Form 3602 burden is based on the number of applications received in the last 3 years. FDA believes most entities that submit FDA Form 3602A will not have any affiliates, and very few will have more than three or four affiliates. Based on our experience with FDA Form 3602A, FDA believes each business will require 1 hour to complete Sections I and II. FDA does not have any data on the time that will be required to complete Section III, the National Taxing Authority Certification, since there is a different tax verification process by each country's National Taxing Authority.

The information collection for FDA Form 3602 is currently approved under OMB control number 0910–0508. The information collection for FDA Form 3602A is currently approved under OMB control number 0910–0613. With this request for approval, FDA is requesting to consolidate OMB approvals 0910–0508 and 0910–0613 into one information collection using the OMB control number 0910–0508.

Dated: October 16, 2009.

David Horowitz,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0505]

Agency Information Collection Activities; Proposed Collection; Comment Request; Recordkeeping and Reporting Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle

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 the information collection requirements of FDA's regulations that require records on FDA-regulated human food, including dietary supplements, and cosmetics that are manufactured from, processed with, or otherwise contain, material derived from cattle.

DATES: Submit written or electronic comments on the collection of information by December 22, 2009.

ADDRESSES: Submit electronic comments on the collection of