provisions. In response to this notice, FDA received two general comments on the information collection requirements which are described in this document along with FDA's responses.

(Comment 1) The commenter recommended that once a firm has qualified for small business status, this should be good enough for 3 to 5 years. Further, that it would be quite unlikely that a small business firm would move from a small business to a huge business in 3 years, particularly for the starting business or very small business. The commenter concluded that the extra paperwork will cost time and money for the industry and FDA as well.

(Response) FDA cannot accept this recommendation, because current provisions of the 2007 Amendments do not permit the recommended approach. Section 738(d)(2)(B) and (e)(2)(B) of the act (21 U.S.C. 379j(d)(2)(B) and (e)(2)(B)) defines the ''Evidence of Qualification'' that must be provided to qualify as a small business. The provisions specifically require the applicant to support its claim that it qualifies as a small business by submitting, among other things, the following:

- ''a copy of the most recent Federal income tax return for a taxable year'' and
- A signed certification of gross receipts or sales for the most recent year.

Because both requirements specify that the information must be for the ''most recent'' year, FDA cannot determine whether an applicant's status as a small business will persist for a period of more than 1 year.

(Comment 2) The commenter expressed concern there could be some problems in collecting the tax certification information required of Form FDA 3602A, Section III, from the national taxing authority of each country where an applicant has business entities. The commenter cited that in some countries, the national taxing authority may not agree to fill out this form for various reasons including: (1) The fact that it may not be its own official form, (2) the form is in English, and (3) authorities do not agree to determine the exchange rate for the U.S. dollar.

As an alternative to Form FDA 3602A, Section III, the commenter recommends the following information be provided:

- A tax report or an income statement from each country of business entities,
- Translation to English could be organized by the applicant, and a
- Determination of exchange rate could be done by the applicant.

(Response) FDA cannot accept this recommendation because the agency does not have authority to modify the statutory requirement for a signed certification form, and bearing the seal of the national taxing authority of the country in which the applicant, or if applicable, affiliate, is headquartered (see section 738(d)(2)(B)(iii) and 738(e)(2)(B)(iii)).

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form FDA 3602A	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Sections I and II (completed by the business seeking small business status)	229	1	229	1	229
Section III (completed by the foreign national taxing authority)	33	7	231	1	231
Total					460

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

This burden estimate is based on an examination of 510(k) premarket notifications received during FY 2006 and FDA's estimation of the time to collect the required information to complete Form FDA 3602A. The evidence supporting each Form FDA 3602A must be reviewed by a foreign national taxing authority to complete Section III, the National Taxing Authority Certification, of each Form FDA 3602A. Because this is a new activity, and neither FDA nor any foreign national taxing authority has any data that would provide an objective measure of the effort required to complete Section III, FDA is estimating that the burden will be the same as FDA experiences in reviewing Form FDA 3602, ''FY 2008 MDUFMA Small Business Qualification Certification For a Business Headquartered in the United States,'' approved under OMB control number 0910–0508.

FDA believes most entities that submit Form FDA 3602A will not have any affiliates, and very few will have more than three or four affiliates. Based on our experience with FDA Form 3602, FDA believes each business will require 1 hour to complete Sections I and II. Because this is a new requirement, FDA does not have any data on the time that will be required to complete Section III, the National Taxing Authority Certification.

Dated: April 7, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–7637 Filed 4–9–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0213] (formerly Docket No. 2007N–0460)

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reports of Corrections and Removals

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 May 12, 2008.

ADDRESSES: 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, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0359. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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.

Reports of Corrections and Removals—21 CFR Part 806; (OMB Control Number 0910–0359)—Extension

The collection of information required under the reports of corrections and removals, part 806 (21 CFR part 806), implements section 519(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i(f)), as amended by the Food and Drug Modernization Act of 1997 (FDAMA) (21 U.S.C. 301) (Public Law 105–115). Each device manufacturer or importer under § 806.10 shall submit a written report to FDA of any action initiated to correct or remove a device to reduce a risk to health posed by the device, or to remedy a violation of the act caused by the device which may present a risk to health, within 10 working days of initiating such correction or removal. Each device manufacturer or importer of a device who initiates a correction or removal of a device that is not required to be reported to FDA under § 806.20 shall keep a record of such correction or removal.

The information collected in the reports of corrections and removals will be used by FDA to identify marketed devices that have serious problems and to ensure that defective devices are removed from the market. This will assure that FDA has current and complete information regarding these corrections and removals and to determine whether recall action is adequate.

In the **Federal Register** of December 11, 2007 (72 FR 70327), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
806.10	488	1	488	10	4,880
Total					4,880

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
806.20	132	1	132	10	1,320
Total					1,320

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

In preparing the previous clearances for approval of the information collection requirements under §§ 806.10 and 806.20, FDA reviewed the reports of corrections and removals submitted for the previous 3 years under part 7 (21 CFR part 7), the agency's recall provisions. FDA has determined that estimates of the reporting burden in § 806.10 should be revised to reflect a 1.2 percent increase for reports and records submitted under part 7 due to a decrease in class I and class II recall actions. FDA also estimates the reporting burden in § 806.20 should be revised to reflect a reduction of 8 percent for reports and records submitted under part 7 due to a decrease in class III recall actions. The time needed to collect information has not been changed.

Dated: April 4, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–7638 Filed 4–9–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0202] (formerly Docket No. 2008N–0009)

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Customer/Partner Service Surveys

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 May 12, 2008.

ADDRESSES: 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, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0360. Also include the FDA docket number found