equivalent to paper records. Under these regulations, records and reports may be submitted to FDA electronically provided the agency has stated its ability to accept the records electronically in an agency-established public docket and that the other requirements of part 11 are met.

The recordkeeping provisions in part 11 (§§ 11.10, 11.30, 11.50, and 11.300) require standard operating procedures to assure appropriate use of, and precautions for, systems using electronic records and signatures: (1) § 11.10 specifies procedures and controls for persons who use closed systems to create, modify, maintain, or transmit electronic records; (2) § 11.30 specifies procedures and controls for persons who use open systems to create, modify, maintain, or transmit electronic records; (3) § 11.50 specifies procedures and controls for persons who use electronic signatures; and (4) § 11.300 specifies controls to ensure the security and integrity of electronic signatures based upon use of identification codes in combination with passwords. The reporting provision (§ 11.100) requires persons to certify in writing to FDA that they will regard electronic signatures used in their systems as the legally binding equivalent of traditional handwritten signatures.

The burden created by the information collection provision of this regulation is a one-time burden associated with the creation of standard operating procedures, validation, and certification. The agency anticipates the use of electronic media will substantially reduce the paperwork burden associated with maintaining FDA required records.

The respondents will be businesses and other for-profit organizations, State or local governments, Federal agencies, and nonprofit institutions.

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

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
11.100	4,500	1	4,500	1	4,500

[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 Recordkeeper	Total Hours
11.10	2,500	1	2,500	20	45,000
11.30	2,500	1	2,500	20	45,000
11.50	4,500	1	4,500	20	90,000
11.300	4,500	1	4,500	20	90,000
Total					270,000

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

Dated: March 19, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–7087 Filed 3–25–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0065]

Agency Emergency Processing Under OMB Review; Fiscal Year 2003 MDUFMA Small Business Qualification Certification (Form FDA 3602)

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 emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information will permit an applicant to certify that it qualifies as a ''small business'' within the meaning of the Medical Device User Fee and Modernization Act (MDUFMA), will help the applicant organize the information FDA needs to verify each certification, and will collect contact information to facilitate rapid resolution of any questions FDA may have concerning information the applicant has provided.

DATES: Fax written comments on the information collection provisions by April 25, 2003.

ADDRESSES: Fax written comments on the information collection provisions to the Office of Information and Regulatory Affairs, Attn: Stuart Shapiro, Desk Officer for FDA, FAX 202–395–6974, or electronically mail comments to sshapiro@omb.eop.gov. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13). This information is needed immediately so that the agency can decide whether an applicant is a ''small business'' within the meaning of MDUFMA. A small business is eligible for a reduced or waived fee for a medical device application or submission that is subject to a user fee under MDUFMA. If an applicant is not a small business, it must pay the standard (full) fee for any medical device application or submission it submits to FDA. FDA is requesting this emergency processing to implement 21 CFR 738(d)(2)(B) and (e)(2)(B) (§ 738(d)(2)(B) and (e)(2)(B)) of the Federal Food, Drug, and Cosmetic Act (the act); these provisions were added to the act by section 102 of MDUFMA. The use of normal clearance procedures would likely result in the prevention or disruption of this collection of information, thereby subjecting applicants who would

otherwise qualify as a small business to the statutory requirement to pay a standard (full) fee rather than a reduced fee.

FDA invites comments on: (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.

FY 2003 MDUFMA Small Business Qualification Certification (Form FDA 3602)

MDUFMA (Public Law 107–250) amends the Federal Food, Drug, and Cosmetic Act to provide for user fees for certain medical device applications. The initial fees (for fiscal year (FY) 2003) are set by statute. 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.

Under MDUFMA, a ''small business'' is an applicant who reported no more than $30 million ''gross receipts or sales'' on its Federal income tax return for the most recent tax year; the applicant must count the ''gross receipts or sales'' of all of its affiliates, partners, or parent firms when calculating whether it meets the $30 million threshold.

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.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of the guidance entitled ''FY 2003 MDUFMA Small Business Qualification Worksheet and Certification.'' The guidance describes the criteria FDA will use to decide whether an entity qualifies as a MDUFMA small business and helps prospective applicants understand what they need to do to meet the criteria for FY 2003.

Respondents will be businesses or other for-profit organizations.

FDA estimates the burden of this information collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Form Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3602	100	1	100	1	100

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

FDA based these estimates on conversations with industry, trade association representatives, and from internal FDA estimates. This represents FDA's estimate on the number of small businesses that will submit a premarket application, a premarket report, a panel track supplement, efficacy supplement, 180-day supplement, or a real time supplement to FDA during FY 2003.

Dated: March 10, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–7088 Filed 3–25–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01E–0030]

Determination of Regulatory Review Period for Purposes of Patent Extension; TEQUIN

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for TEQUIN and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3460.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and