

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 BURDEN¹

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.

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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