Supporting Statement For

Medical Devices; Inspection by Accredited Persons Program

Under the Medical Device User Fee and Modernization Act Of 2002 (MDUFMA)

A. JUSTIFICATION

1. Circumstances Necessitating Information Collection

The Federal Food, Drug and Cosmetic Act was amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250) on October 26, 2002. Section 201 of MDUFMA requires that not later than 180 days of enactment of MDUFMA, FDA publish in the Federal Register, criteria to accredit or deny accreditation to persons who wish to conduct inspections of eligible manufacturers of class II and class III medical devices. In addition, FDA must accredit persons pursuant to the published criteria not later than one year after enactment of MDUFMA.

FDA is publishing a notice announcing the criteria it will use to accredit persons to inspect eligible device manufacturers and the availability of a guidance entitled "Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria: Guidance for Industry, FDA Staff, and Third Parties." The guidance further describes the criteria FDA will use to accredit persons that wish to conduct inspections of eligible manufacturers of class II and class III medical devices. The guidance also addresses the format and

content of accreditation applications and the evaluation process FDA will use in qualifying firms to participate in this program.

Purpose and use of Information

Information from this collection will be used by FDA to implement an Inspection by Accredited Persons program that will train and accredit persons that wish to conduct inspections of eligible manufacturers of class II and class III medical devices.

Manufacturers may continue to have FDA perform inspections or, if eligible, they may utilize an Accredited Person. FDA will serve as the accreditation body. FDA will begin accepting applications immediately following approval by OMB of the proposed collection of information. Because the statute requires the agency to make accreditation decisions by no later than one year after MDUFMA's enactment (October 26, 2003), FDA intends to stop accepting applications on August 25, 2003.

2. Use of Information Technology and Burden Reduction

Accredited persons must have the capability to interface with FDA's electronic data systems, including the FDA Internet websites, and the

CDRH Facts-On-Demand system. At a minimum, this would require a computer system with a modem and an independent facsimile machine. FDA will rely extensively on the use of our electronic systems for timely dissemination of guidance documents to Accredited Persons and other interested parties. FDA will accept alternative technology if the technology is compatible with FDA's technology.

3. Efforts to Identify Duplication and Use of Similar Information

FDA is the only Federal Agency responsible for the collection of this information. Therefore, duplication with other data sources is nonexistent.

5. Impact on Small Businesses or Other Small Entities

Participation in the Inspection by Accredited Persons program is entirely voluntary. FDA will provide information on its procedures and criteria, through guidance documents and training programs.

6. Consequences of Collecting the Information Less Frequently

Accredited persons conduct inspections in the same manner as those conducted by FDA.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This proposed collection is consistent with 5 CFR 1320.5, except for 5 CFR 1320(d)(2)(ii). FDA is requesting 10 hard copies for each Accredited Person application to provide a copy to each of the 10 members (reviewers) of the Third Party Recognition Board. This will be a group review requiring consensus of the Board.

8. Consultation Outside the Agency

FDA will solicit comments through the emergency Federal Register Notice.

9. Explanation of Any Payment or Gift to Respondents

No Payments or gifts shall be provided to respondents under this regulation.

10. Assurance of confidentiality Provided to Respondents

FDA will post on its internet site, a list of persons who are accredited. Information submitted by accredited persons will be available for disclosure by FDA in accordance with the Freedom of Information Act (FOIA).

11. Justification for Sensitive Questions

This information collection does not concern questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs or other matters considered private.

12. <u>Estimate of Hour Burden Including Annualized Hourly Costs</u>

FDA estimates the burden of this information collection as follows:

TABLE 1. ESTIMATED ANNUAL REPORTING BURDEN[1]

Item	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Request for Accreditation (1st Year)	15	1	25	80	2000
Request for Accreditation (2nd Year)	10	1	10	15	150
Request for Accreditation (3rd Year)	5	1	5	80	400
Total Hours					2,550

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

Explanation of Reporting Burden Estimate

FDA based these estimates on conversations with industry, trade association representatives, and internal FDA estimates. There are only 75 bodies worldwide that would be qualified to serve as Accredited Persons for inspections. The expectation is that 25 bodies will apply and meet the minimum standard the first year. Under MDUFMA we can only accredit 15 persons during the first year. All of these bodies should have the requested information readily available. We estimate it will take no more than 80 hours to assemble this information per respondent (25 x 80 = 2000).

Under MDUFMA only 15 may be accredited the first year. We expect the 10 lowest ranking (the ones not accredited the first year), will reapply the following year with an updated application. Thus the time required to prepare their application will be significantly less than preparing an entire application (10 x 15 = 150 hours).

The preparation time is increased again for the third year because new applicants may apply the third year (5 x 80 = 400 hours). Once an organization is accredited, it will not be required to reapply. Thus applying for accreditation is a one time expenditure of time and resources.

13. <u>Estimate of Other Total Annual Cost to Respondents or Recordkeepers</u>

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

14. Annualized Cost to the Federal Government

FDA estimates that approximately 2.5 staff-years will be devoted to this activity during **the first year** of this program at a cost of $300,000.00. During the **second year**, approximately 1 staff-year will be used at a cost of $100,000.00. The **third year** approximately 0.5 staff-years will be used at a cost of $50,000.00. The **total cost** over the three year period is estimated at $450,000.00 involving the total use of 4 staff-years. These expenses include both the application reviews and the training of accepted applicants.

15. Explanation for Program Changes of Adjustments

This is a new collection.

16. Plans for Tabulation and Publication and Project Time Schedule

No publication of information for statistical use is planned.

17. Reason(s) Display of OMB Expiration Date Is Inappropriate

N/A

18. <u>Exceptions to Certification for Paperwork Reduction Act Submissions</u>

FDA is not requesting any exemption from the certification statement identified in Item 19 of OMB Form 83-I