

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>—Continued

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

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

## II. Reporting

Section 812.10 estimates are based on the fact that FDA has received very few, if any, waiver requests in the past, and estimates that very few will be submitted in the future. Therefore, FDA estimates a minimal burden to account for waiver requests.

Sections 812.20, 812.25, and 812.27 estimates are based on the average of IDE's submitted from fiscal years 1995 through 2002. FDA estimates the annual reporting burden for one IDE original application to be approximately 80 hours, and the annual reporting burden for one IDE supplement to be approximately 6 hours.

Sections 812.35 and 812.150 estimates are based on the average of IDE supplements submitted from fiscal years 1995 through 2002 for significant risk device studies. FDA estimates the annual reporting burden for one IDE supplement to be approximately 6 hours.

The reporting burden for nonsignificant risk device studies (§ 812.150) is negligible. Nonsignificant risk device studies are not reported to FDA unless a problem is reported such as an unanticipated adverse device reaction, failure to obtain informed consent, withdrawal of IRB approval, or a recall of a device. In the past, an average of 10 incidences or less annually have been reported to FDA.

Section 812.36(c) and (f) estimates are based on FDA's experience with the treatment use of drugs and knowledge of the types of devices that may meet the treatment use criteria. FDA estimates that an average of 6 treatment use applications will be submitted each year. FDA estimates that it will take approximately 120 hours to prepare a treatment IDE and the total annual burden for preparing applications will be 720 hours. FDA also estimates that it will take approximately 20 hours to prepare a semiannual report, resulting in a total annual burden of 240 hours for annual reports.

## III. Recordkeeping

Section 812.40 estimates are based on conversations with manufacturers, industry trade association groups, and businesses over the last 3 years. For significant risk device investigations, FDA has estimated that the recordkeeping burden for preparing an original IDE submission averages 10 hours for each original IDE submission. Similarly, through the same conversations mentioned above, FDA has estimated recordkeeping for each supplement requires 1 hour. The recordkeeping burden for nonsignificant risk device investigations is difficult to estimate because nonsignificant risk device investigations are not required to be submitted to FDA. The IDE staff estimates that the number of recordkeepers for nonsignificant risk device investigations is equal to the number for active significant risk device investigations. The recordkeeping burden, however, is reduced for nonsignificant risk device studies. It is estimated that 600 recordkeepers will spend 6 hours each in maintaining these records.

Dated: March 4, 2003.

**William K. Hubbard,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. 03-5791 Filed 3-11-03; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 01D-0195]

#### “Guidance for FDA Staff: The Leveraging Handbook, An Agency Resource for Effective Collaborations”

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled “Guidance for FDA Staff: The

Leveraging Handbook, An Agency Resource for Effective Collaborations,” dated February 2003. The guidance document is intended to provide information to assist FDA staff in creating and implementing effective collaborations consistent with relevant legal, ethical, and policy considerations. FDA and its stakeholders use collaborations to take advantage of and amplify the unique resources possessed by each to address a variety of public health issues. The guidance document enumerates factors that FDA employees should consider, and the procedures they should follow, when planning a leveraged collaboration. This guidance finalizes the draft guidance under the same title dated November 2001 that was announced in the **Federal Register** on November 13, 2001.

**DATES:** Submit written or electronic comments at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800. Submit written comments on the guidance 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/dcokets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

**FOR FURTHER INFORMATION CONTACT:** Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:**