TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

FDA Center	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Form 3500A (§§ 310.305, 314.80, 314.98, and 600.80)	600	579.9	347,940	1.1	382,734
CDRH					
Form 3500	3,433	1	3,433	0.6	2,060
Form 3500A (Part 803)	1,935	33	63,855	1.0	63,855
CFSAN					
Form 3500	847	1	847	0.6	508
Form 3500A	0	0	0	1.0	0
Form 3500					16,341
Form 3500A					446,589
Total					462,930

[1]CBER (Center for Biologics Evaluation and Research), CDER (Center for Drug Evaluation and Research), CDRH (Center for Devices and Radiological Health), and CFSAN (Center for Food Safety and Applied Nutrition). FDA Form 3500 is for voluntary reporting; FDA Form 3500A is for mandatory reporting.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

Dated: February 8, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–2821 Filed 2–14–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0073] (formerly Docket No. 2002N–0418)

Agency Information Collection Activities: Proposed Collection; Comment Request; Adverse Experience Reporting for Licensed Biological Products; and General Records

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to FDA's adverse experience reporting (AER) for licensed biological products, and general records associated with the manufacture and distribution of biological products.

DATES: Submit written or electronic comments on the collection of information by April 15, 2008.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (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.

Adverse Experience Reporting for Licensed Biological Products; and General Records —21 CFR Part 600 (OMB Control Number 0910–0308)—Extension

Under the Public Health Service Act (42 U.S.C. 262), FDA is required to ensure the marketing of only those biological products which are safe and effective. FDA must, therefore, be informed of all adverse experiences occasioned by the use of licensed biological products. FDA issued the

AER requirements in part 600 (21 CFR part 600) to enable FDA to take actions necessary for the protection of the public health in response to reports of adverse experiences related to licensed biological products. The primary purpose of FDA's AER system is to flag potentially serious safety problems with licensed biological products, focusing especially on newly licensed products. Although premarket testing discloses a general safety profile of a biological product's comparatively common adverse effects, the larger and more diverse patient populations exposed to the licensed biological product provides the opportunity to collect information on rare, latent, and long-term effects. Reports are obtained from a variety of sources, including patients, physicians, foreign regulatory agencies, and clinical investigators. Information derived from the AER system contributes directly to increased public health protection because such information enables FDA to recommend important changes to the product's labeling (such as adding a new warning), to initiate removal of a biological product from the market when necessary, and to assure the manufacturer has taken adequate corrective action if necessary.

The regulation in § 600.80(c)(1) requires licensed manufacturers to report each adverse experience that is both serious and unexpected, whether foreign or domestic, as soon as possible but in no case later than 15 calendar days of initial receipt of the information by the licensed manufacturer. These are known as postmarketing 15-day Alert reports. Section 600.80(c)(1) also requires licensed manufacturers to submit any followup reports within 15 calendar days of receipt of new information or as requested by FDA. Section 600.80(e) requires licensed manufacturers to submit a 15-day Alert report for an adverse experience obtained from a postmarketing clinical study only if there is a reasonable possibility that the product caused the adverse experience. Section 600.80(c)(2) requires licensed manufacturers to report each adverse experience not reported in a postmarketing 15-day Alert report at quarterly intervals, for 3 years from the date of issuance of the biologics license, and then at annual intervals. The majority of these periodic reports will be submitted annually because a large percentage of currently licensed biological products have been licensed longer than 3 years. Section 600.80(i) requires licensed manufacturers to maintain for a period of 10 years records of all adverse experiences known to the licensed manufacturer, including raw data and any correspondence relating to the adverse experiences. Section 600.81 requires licensed manufacturers to submit, at an interval of every 6 months, information about the quantity of the product distributed under the biologics license, including the quantity distributed to distributors. These semiannual distribution reports provide FDA with important information about products distributed under biologics licenses, including the quantity, certain lot numbers, labeled date of expiration, number of dosage units, and date of release. Under § 600.90, a licensed manufacturer may submit a waiver request for any requirements that applies to the licensed manufacturer under § 600.80 and 600.81. A waiver request submitted under § 600.90 must include supporting documentation.

Manufacturers of biological products for human use must keep records of each step in the manufacture and distribution of a product including any recalls. These recordkeeping requirements serve preventative and remedial purposes by establishing accountability and traceability in the manufacture and distribution of products. These requirements also enable FDA to perform meaningful inspections.

Section 600.12 requires, among other things, concurrently with the performance of each step that all records of each step in the manufacture and distribution of a product be made and retained for no less than 5 years after the records of manufacture have been completed or 6 months after the latest expiration date for the individual product, whichever represents a later date. In addition, manufacturers must maintain records of sterilization of equipment and supplies, animal necropsy records, and records in cases of divided manufacturing of a product. Section 600.12(b)(2) requires manufacturers to maintain complete records pertaining to the recall from distribution of any product.

Respondents to this collection of information are manufacturers of biological products. Under table 1 of this document, the number of respondents is based on the estimated number of manufacturers that submitted the required information to the Center for Biologics Evaluation and Research and Center for Drug Evaluation and Research, FDA, in fiscal year (FY) 2006. Based on information obtained from FDA's database system, there were 88 licensed biologics manufacturers. This number excludes those manufacturers who produce blood and blood components and in-vitro diagnostic licensed products, because § 600.80(k) specifically exempts manufacturers of these products from adverse experience reporting requirements. The total annual responses are based on the estimated number of submissions received annually by FDA in FY 2006. However, not all manufacturers have submissions in a given year and some may have multiple submissions. There were an estimated 23,835 15-day Alert reports, 21,872 periodic reports, and 179 lot distribution reports submitted to FDA. The number of 15-day Alert reports for postmarketing studies under § 600.80(e) is included in the total number of 15-day Alert reports. FDA received 6 requests for waiver under § 600.90, all of which were granted. The hours per response are based on FDA experience. The burden hours required to complete the MedWatch Form for § 600.80(c)(1), (e), and (f) are reported under OMB control no. 0910–0291.

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
600.80(c)(1) and 600.80(e)	88	270.85	23,835	1	23,835
600.80(c)(2)	88	248.55	21,872	28	612,416
600.81	88	2.03	179	1	179
600.90	6	1	6	1	6

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Total					636,436

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

Under table 2 of this document, the number of respondents is based on the number of manufacturers subject to those regulations. Based on information obtained from FDA's database system, there were 303 licensed manufacturers of biological products in FY 2006. However, the number of recordkeepers listed for § 600.12(a) through (e) excluding (b)(2) is estimated to be 112. This number excludes manufacturers of blood and blood components because their burden hours for recordkeeping have been reported under 21 CFR 606.160 in OMB control no. 0910–0116. The total annual records is based on the annual average of lots released (5,291), number of recalls made (1,841), and total number of adverse experience reports received (45,707) in FY 2006. The hours per record are based on FDA experience.

FDA estimates the burden of this recordkeeping as follows:

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
600.12	112	47.24	5,291	32	169,312
600.12(b)(2)	303	6.08	1,841	24	44,184
600.80(i)	88	519.40	45,707	1	45,707
Total					259,203

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

Dated: February 8, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–2890 Filed 2–14–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0095]

Draft Guidance for Industry and Food and Drug Administration Staff; Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Influenza Viruses; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Influenza Viruses.'' FDA is issuing this draft guidance to inform industry and agency staff of its recommendations for analytical and clinical performance studies to support premarket submissions for in vitro diagnostic devices intended for the detection or detection and differentiation of influenza viruses.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by May 15, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled '' Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Influenza Viruses '' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Tamara Feldblyum Center for Devices and Radiological Health (HFZ–440) Food and Drug Administration 2098 Gaither Rd., Rockville, MD 20850 240–276–0715.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance document recommends studies that may be used to establish the analytical and clinical performance of in vitro diagnostic devices (IVDs) for the detection or detection and differentiation of influenza viruses. The document addresses devices that detect either influenza viral antigens or influenza viral genome (protein or nucleic acid), including those for novel influenza viruses in either human specimens or culture isolate. The guidance does not address devices that detect serological response from the host to the viral antigen, nor does it address establishing performance of non-influenza components of multi-analyte or multiplex devices. This guidance document identifies the classification regulations and product codes for existing legally marketed influenza tests