Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: September 20, 2000.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 00–24622 Filed 9–22–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1502]

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 November 24, 2000.

ADDRESSES: Submit electronic comments on the collection of information via the Internet at: http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All documents 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 Information Resources Management (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 request 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: (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 600.12 and Part 600 Subpart D (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 adverse experience reporting requirements 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 adverse experience reporting 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 new drug'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 adverse experience reporting 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.

Section 600.80(c)(1) (21 CFR 600.80(c)(1)), requires the licensed manufacturer to report each adverse experience that is both serious and unexpected, regardless of source, as soon as possible but in any case within 15 working days of initial receipt of the information. Section 600.80(e) requires licensed manufacturers to submit a 15-day alert report 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 the licensed manufacturer to report each adverse experience not reported under paragraph (c)(1) at quarterly intervals, for 3 years from the date of issuance of the product license, and then at annual intervals. The majority of the periodic reports will be submitted annually since a large percentage of the current licensed biological products have been licensed longer than 3 years. Section 600.80(i) requires the licensed manufacturer 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 (21 CFR 600.81) requires the licensed manufacturer to submit information about the quantity of the product distributed under the product license, including the quantity distributed to distributors at an interval of every 6 months. The semiannual distribution report informs FDA of the quantity, the lot number, and the dosage of different products. Section 600.90 (21 CFR

600.90) requires a licensed manufacturer to submit a waiver request with supporting documentation when asking for waiving the requirement that applies to them under §§ 600.80 and 600.81.

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

Section 600.12 (21 CFR 600.12) requires 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, records of sterilization of equipment and supplies, animal necropsy records, and records in cases of divided manufacturing of a product are required to be maintained. Section 600.12(b)(2) requires complete records to be maintained pertaining to the recall from distribution of any product.

Respondents to this information collection are manufacturers of biological products. In fiscal year (FY) 99 there were approximately 79 licensed manufacturers. This number excludes those manufacturers who produce blood and blood components and in-vitro diagnostic licensed products because they are specifically exempt from the regulations. However, not all manufacturers may have any submissions in a given year and some may have multiple submissions. FDA received four waiver requests under § 600.90, of which one was approved for exemption of the AER requirements. In FY 99, there were an estimated 3,662 15-day alert reports, 13,238 periodic reports, and 502 distribution reports submitted to FDA. The number of 15-day alert reports for postmarketing studies as stated in § 600.80(e) was minimal and is included in the total number of 15-day alert reports. 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 information collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
600.80(c)(1) and (e)	78	46.95	3,662	1	3,662
600.80(c)(2)	78	169.72	13,238	1	13,238
600.81	78	6.44	502	1	502
600.90	4	1	4	1	4
Total					17,407

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

There are approximately 343 licensed manufacturers of biological products. However, the number of recordkeepers listed for § 600.12(a) through (e) excluding paragraph (b)(2) is estimated to be 111. This number excludes manufacturers of blood and blood components, because their burden hours for recordkeeping have been reported under § 606.160 in OMB Control No. 0910–0116. The recordkeeping burden is based on the number of lots released (6,446), the number of recalls made (1,176) and the total number of AER reports received (16,900) for FY 99. 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	Number of recordkeepers	Annual frequency of recordkeeping	Total annual records	Hours per record	Total hours
600.12	111	58.1	6,446	32	206,272
600.12(b)(2)	343	3.4	1,176	24	28,224
600.80(i)	79	213.92	16,900	1	16,900
Total					251,396

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

Dated: September 19, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–24477 Filed 9–22–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0472]

Agency Information Collection Activities; Proposed Collection; Comment Request; Petition for Administrative Stay of Action

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 requirements for filing a petition for administrative stay of action.

DATES: Submit written or electronic comments on the collection of information by November 24, 2000.

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (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 Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501093520), 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: (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.

Petition for Administrative Stay of Action—21 CFR 10.35 (OMB Control Number 0910–0194)—Reinstatement)—Extension

The regulations in 21 CFR 10.35, issued under the authority of section 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(a)), set forth the format and procedures by which an interested person may file a petition for an administrative stay of action.

Respondents to this information collection are interested persons who choose to file a petition for an administrative stay of action. Such a petition must: (1) Identify the decision involved; (2) state the action requested, including the length of time for which a stay is requested; and (3) include a statement of the factual and legal grounds on which the interested person relies in seeking the stay. The information provided in the petition is used by the agency to determine whether the requested stay should be granted.

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
10.35	13	1	13	10	130

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