Dated: April 1, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0231]

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 proposed extension of the collection of information concerning requirements relating to FDA's Adverse Experience Reporting System (AERS) for licensed biological products, and general records associated with the manufacture and distribution of biological products.

DATES: Submit either electronic or written comments on the collection of information by June 6, 2014.

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

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 may only approve a biologics license application for a biological product that is safe, pure, and potent. When a biological product is approved and enters the market, the product is introduced to a larger patient population in settings different from clinical trials. New information generated during the postmarketing period offers further insight into the benefits and risks of the product, and evaluation of this information is important to insure its safe use. FDA issued the Adverse Experience Reporting (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 identify potentially serious safety problems with licensed biological 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. In addition, production and/or distribution problems have contaminated biological products in the past. AER reports are obtained from a variety of sources, including manufacturers, patients, physicians, foreign regulatory agencies, and clinical investigators. Identification of new and unexpected safety issues through the analysis of the data in AERS contributes directly to increased public health protection. For example, evaluation of these safety issues enables FDA to take focused regulatory action. Such action may include, but is not limited to, important changes to the product's labeling (such as adding a new warning), coordination with manufacturers to ensure adequate corrective action is taken, and removal of a biological product from the market when necessary.

Section 600.80(c)(1) requires licensed manufacturers or any person whose name appears on the label of a licensed biological product 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 reports are known as postmarketing 15-day Alert reports. This section also requires licensed manufacturers to submit any followup reports within 15 calendar days of receipt of new information or as requested by FDA, and if additional information is not obtainable, to maintain records of the unsuccessful steps taken to seek additional information. In addition, this section requires a person who submits an adverse action report to the licensed manufacturer, rather than FDA, to maintain a record of this action. 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 the licensed manufacturer concludes that 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 are submitted annually since 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 distribution reports provide FDA with important information about products distributed under biologics licenses, including the quantity, certain lot numbers, labeled date of expiration, the fill lot numbers for the total number of dosage units of each strength or potency distributed (e.g., 50,000 per 10-milliliter vials), and date of release. FDA may require the licensed manufacturer to submit distribution reports under this section at times other than every 6 months. Under § 600.90, a licensed manufacturer may submit a waiver request for any requirements that apply 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, that records must be made concurrently with the performance of each step in the manufacture and distribution of products. These records must be 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, under § 600.12, manufacturers must maintain records relating to the sterilization of equipment and supplies, animal necropsy records, and records in cases of divided manufacturing responsibility with respect to a product. Under § 600.12(b)(2), manufacturers are also required to maintain complete records pertaining to the recall from distribution of any product. Furthermore, § 610.18(b) requires, in part, that the results of all periodic tests for verification of cultures and determination of freedom from extraneous organisms be recorded and maintained. The recordkeeping requirements for §§ 610.12(g), 610.13(a)(2), 610.18(d), 680.2(f) and 680.3(f) are approved under OMB control number 0910–0139.

Respondents to this collection of information include manufacturers of biological products and any person whose name appears on the label of a licensed biological product. In table 1, the number of respondents is based on the estimated number of manufacturers that are subject to those regulations or that submitted the required information to the Center for Biologics Evaluation and Research and Center for Drugs Evaluation and Research, FDA, in fiscal year (FY) 2013. Based on information obtained from FDA's database system, there were 131 licensed biologics manufacturers. This number excludes those manufacturers who produce Whole Blood or components of Whole Blood and in vitro diagnostic licensed products, because of the exemption under § 600.80(k). The total annual responses are based on the number of submissions received by FDA in FY 2013. There were an estimated 92,470 15-day Alert reports, 132,667 periodic reports, and 334 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 64 requests from 35 manufacturers for waivers under § 600.90, of which 63 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 number 0910–0291.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
600.80(c)(1) and 600.80(e)	131	705.88	92,470	1	92,470
600.80(c)(2)	131	1,012.73	132,667	28	3,714,676
600.81	131	2.55	334	1	334
600.90	35	1.83	64	1	64
Total					3,807,544

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

In table 2, 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 334 licensed manufacturers of biological products in FY 2013. However, the number of recordkeepers listed for § 600.12(a) through (e) excluding (b)(2) is estimated to be 164. This number excludes manufacturers of blood and blood components because their burden hours for recordkeeping have been reported under § 606.160 in OMB control number 0910–0116. The total annual records is based on the annual average of lots released in FY 2013 (6,887), number of recalls made (1,679), and total number of adverse experience reports received (225,137) in FY 2013. 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	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
600.12[2]	164	41.99	6,887	32	220,384
600.12(b)(2)	334	5.03	1,679	24	40,296
600.80(c)(1) and 600.80(i)	131	1,718.60	225,137	1	225,137
Total					485,817

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]The recordkeeping requirements in § 610.18(b) are included in the estimate for § 600.12.

Dated: April 1, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0341]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices

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 FDA's ''Guidance for Industry on Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices.'' The guidance describes procedures and responsibilities for updating information on susceptibility test interpretive criteria, susceptibility test methods, and quality control parameters in the labeling for systemic antibacterial drug products for human use, and also describes procedures for making corresponding changes to susceptibility test interpretive criteria for antimicrobial susceptibility testing devices.

DATES: Submit either electronic or written comments on the collection of information by June 6, 2014.

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov*.

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.

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Guidance for Industry on Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices—(OMB Control Number 0910–0638)—Extension

The Food and Drug Administration Amendments Act of 2007 (FDAAA) includes a requirement that FDA identify and periodically update susceptibility test interpretive criteria for antibacterial drug products and make those findings publicly available. As a result of this provision, the guidance explains the importance of making available to health care providers the most current information regarding susceptibility test interpretive criteria for antibacterial drug products. To address concerns about antibacterial drug product labeling with out-of-date information on susceptibility test interpretive criteria, quality control parameters, and susceptibility test methods, the guidance describes procedures for FDA, applications holders, and antimicrobial susceptibility testing device manufacturers to ensure that updated susceptibility test information is available to health care providers. Where appropriate, FDA will identify susceptibility test interpretive criteria, quality control parameters, and susceptibility test methods by recognizing annually, in a **Federal Register** notice, standards developed by one or more nationally or internationally recognized standard development organizations. FDA recognized standards will be available to application holders of approved