TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
58.35(b)(1) to (b)(6) and (c)	300	270.76	81,228	3.36	272,926
58.63(b) and (c)	300	60	18,000	0.09	1,620
58.81(a) to (c)	300	301.8	90,540	0.14	12,676
58.90(c) and (g)	300	62.7	18,810	0.13	2,445
58.105(a) and (b)	300	5	1,500	11.8	17,700
58.107(d)	300	1	300	4.25	1,275
58.113(a)	300	15.33	4,599	6.8	31,273
58.120	300	15.38	4,614	32.7	150,878
58.195	300	251.5	75,450	3.9	294,255
Total					786,308

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

Dated: July 11, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–17736 Filed 7–13–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0231]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 15, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0308. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *juanmanuel.vilela@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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 the AER system 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) (21 CFR 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.

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. Under table 1 of this document, 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) 2010. Based on information obtained from the FDA's database system, there were 108 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 2010. There were an estimated 86,583 15-day Alert reports, 57,300 periodic reports, and 349 lot distribution reports submitted to FDA. The number of 15-day alert reports for post marketing studies under § 600.80(e) is included in the total number of 15-day alert reports. FDA received 21 requests for waivers under § 600.90, of which 19 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.

In the **Federal Register** of April 21, 2011 (77 FR 22401), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received from the public.

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)	108	801.69	86,583	1	86,583
600.80(c)(2)	108	530.55	57,300	28	1,604,400
600.81	108	3.23	349	1	349
600.90	21	1	21	1	21
Total					1,691,353

[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 304 licensed manufacturers of biological products in FY 2010. However, the number of recordkeepers listed for § 600.12(a) through (e) excluding (b)(2) is estimated to be 131. 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 2010 (6,752), number of recalls made (1,881), and total number of adverse experience reports received (143,883) in FY 2010. 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]	131	51.54	6,752	32	216,064
600.12 (b)(2)	304	6.19	1,881	24	45,144
600.80(c)(1) and 600.80(i)	108	1,332.25	143,883	1	143,883
Total					405,091

[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: July 8, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–17675 Filed 7–13–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0215]

Draft Guidance for Industry and FDA Staff on In Vitro Companion Diagnostic Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''In Vitro Companion Diagnostic Devices.'' This guidance is intended to assist sponsors planning to develop a therapeutic product that depends on the use of an in vitro companion diagnostic device for its safe and effective use or an in vitro diagnostic device that is intended for use with a corresponding therapeutic product and included in the instructions for use in the labeling of those products. This guidance defines in vitro companion diagnostic devices; explains the need for FDA oversight of companion diagnostic devices; clarifies that, in most circumstances, if use of a companion diagnostic device is essential for the safe and effective use of a therapeutic product, the diagnostic device and therapeutic product should be approved or cleared contemporaneously by FDA for the use indicated in the therapeutic product labeling; provides guidance for industry and FDA staff on possible premarket regulatory pathways and FDA's regulatory enforcement policy; and describes certain statutory and regulatory approval requirements relevant to therapeutic product labeling that stipulate concomitant use of a companion diagnostic device to ensure safety and effectiveness of the therapeutic product. This draft guidance is not final, nor is it in effect at this time.

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 either electronic or written comments on the draft guidance by September 12, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''In Vitro Companion Diagnostic Devices'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send a fax request to 301–827–8149 to receive a hard copy. Alternatively, you may submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002, or Office of Communication, Outreach and Development (HFM–40), 1401 Rockville Pike, suite 200N, Rockville, MD 20852. Send one self-addressed adhesive label to the office that you are ordering from to assist in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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

FOR FURTHER INFORMATION CONTACT: Elizabeth Mansfield, Center for Devices and Radiologic Health, Food and Drug Administration, Bldg. 66, rm. 5676, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–4664; or Christopher Leptak, Office of Translational Sciences, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 22, rm. 5102, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–0017; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and FDA staff entitled ''In Vitro Companion Diagnostic Devices.'' This guidance is intended to provide assistance both to sponsors developing therapeutic products, which for purposes of this guidance includes therapeutic, preventive, or prophylactic drugs and biological products that depend on the use of and are labeled for use with an in vitro diagnostic device, and to sponsors of the companion diagnostics. This guidance defines ''companion diagnostic device'' and clarifies that in most circumstances, if use of a companion diagnostic device is essential for the safe and effective use of a therapeutic product, the diagnostic device and therapeutic product should be approved or cleared contemporaneously by FDA for the use indicated in the therapeutic product labeling.

Diagnostic tests have been employed for many years to enhance the use of therapeutic products. Recently, therapeutic products that depend on the use of a diagnostic test to meet their labeled safety and effectiveness claims have become more common. For example, a test could identify or limit appropriate populations for treatment or identify populations who should not receive a particular treatment because of