ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Title Amendments	18	1	3	54
State TANF plan	18	1	30	540
Estimated Total Annual Burden Hours				594

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*.

Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2014–24329 Filed 10–10–14; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0801]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Exports: Notification and Recordkeeping Requirements

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 November 13, 2014.

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 emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0482. Also include the FDA 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, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@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.

Exports: Notification and Recordkeeping Requirements—21 CFR 1.101 (OMB Control Number 0910–0482)—Extension

Section 801 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 381) charges the Secretary of Health and Human Services, through FDA, with the responsibility of assuring exports (Exports: Notification and Recordkeeping Requirements—§ 1.101 (21 CFR 1.101)) which pertain to the exportation of unapproved new drugs, biologics, devices, animal drugs, food, cosmetics, and tobacco products that are not to be sold in the United States.

The respondents to this information collection are exporters who have notified FDA of their intent to export unapproved products that may not be sold or marketed in the United States as allowed under section 801(e) of the FD&C Act. In general, the notification identifies the product being exported (e.g. name, description, and in some cases, country of destination) and specifies where the notifications were sent. These notifications are sent only for an initial export. Subsequent exports of the same product to the same destination or in the case of certain countries identified in section 802(b) of the FD&C Act (21 U.S.C. 382) would not result in a notification to FDA.

The recordkeepers to this information collection are exporters who export human drugs, biologics, devices, animal drugs, foods, cosmetics, and tobacco products that may not be sold in the United States and maintain records demonstrating their compliance with the requirements in section 801(e)(1) of the FD&C Act.

On March 30, 2012, OMB approved ''Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Products,'' OMB control number 0910–0690, which amended, among other sections, § 1.101 to incorporate tobacco products. This amendment reflects the Agency's authority over tobacco products under the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) and added tobacco products to the list of products covered under § 1.101(a) and (b).

In the **Federal Register** of July 3, 2014 (79 FR 38036), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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
1.101(d) (Non-Tobacco products)	73	503	36,719	15	550,785

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

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
1.101(b), (c), and (e) (Non-Tobacco Products)	320	3	960	22	21,120
1.101(b) (Non-Tobacco Products for Office of International Programs only)	1	189	189	22	4,158
1.101(b) (Tobacco Products Only)	158	3	474	22	10,428
Total					35,706

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

Dated: October 7, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–24293 Filed 10–10–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1351]

Flow Cytometric Devices; Draft Guidance for Industry and Food and Drug Administration Staff; 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 ''Flow Cytometric Devices.'' This draft guidance addresses the current major review concerns regarding submissions for flow cytometric devices used as in vitro diagnostic devices for leukocyte immunophenotyping and provides suggestions on the content of submissions for these types of devices. 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 of 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 January 12, 2015.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Flow Cytometric Devices'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002, or Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

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: Kevin Maher, Office of In Vitro Diagnostics and Radiological Health, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4246, Silver Spring, MD 20993–0002, 301–796–6879, or Stephen Ripley, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance addresses certain issues that arise in premarket submissions for flow cytometric devices used as in vitro diagnostic devices for leukocyte immunophenotyping and provides suggestions on the content of submissions for these types of devices. It is intended to be used in conjunction with the other cited guidance documents referenced therein. In preparing your submission to FDA, we recommend that you contact FDA's Office of In Vitro Diagnostics and Radiological Health (see **FOR FURTHER INFORMATION CONTACT**) for additional information regarding your submission. This draft guidance focuses on issues relevant to flow cytometric devices with an expanded scope of review topics that reflect the recognition of a flow cytometric device as an analytical system, which includes processing reagents, processing instrumentation, flow cytometers, and analytical software, in addition to the monoclonal antibody (mAb) component. The information presented in this draft guidance is based on the following: (1) Current basic science, (2) clinical experience, and (3) previous submissions by manufacturers to FDA. As advances are made in science and medicine, the content of this guidance will be re-evaluated and revised as necessary to accommodate new knowledge.

This draft guidance is directed toward immunophenotyping of leukocytes using mAbs. However, the concepts may be applicable to related devices that utilize fluorochromes or fluorogenic substrates to measure ligand binding on solid particles in suspension, with or without mAbs. This draft guidance does not cover microscopy devices utilizing