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Flow Cytometric Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Flow Cytometric Devices.'' This draft guidance addresses the current major review concerns regarding submissions for flow cytometric devices used as in vitro diagnostic devices for leukocyte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 This draft guidance is not final nor is it in effect at this time.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by January 12, 2015.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 Submit written requests for a single hard copy of the draft guidance document entitled ''Flow Cytometric Devices'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological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

fluorescent or chromogenic enzyme-substrate detection methods (e.g., immunohistochemical stains) nor does it cover the use of flow cytometry for cell enrichment and cell sorting/purification when used in cell therapy product manufacturing.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on flow cytometric devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov* or from CBER at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* Persons unable to download an electronic copy of ''Flow Cytometric Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1787 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801 and 21 CFR 809.10 have been approved under OMB control number 0910–0485.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: October 7, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–24308 Filed 10–10–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Society of Clinical Research Associates—Food and Drug Administration: Food and Drug Administration Clinical Trial Requirements, Regulations, Compliance, and Good Clinical Practice; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing an educational conference co-sponsored with the Society of Clinical Research Associates (SoCRA). The public workshop regarding FDA's clinical trial requirements is designed to aid the clinical research professional's understanding of the mission, responsibilities, and authority of FDA and to facilitate interaction with FDA representatives. The program will focus on the relationships among FDA and clinical trial staff, investigators, and institutional review boards (IRB). Individual FDA representatives will discuss the informed consent process and informed consent documents; regulations relating to drugs, devices, and biologics; as well as inspections of clinical investigators, IRB, and research sponsors.

Date and Time: The public workshop will be held on November 5 and 6, 2014, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Wyndham Lake Buena Vista Hotel, 1850 Hotel Plaza Blvd., Lake Buena Vista, FL 32830, 407–828–4444.

Attendees are responsible for their own accommodations. Please mention SoCRA to receive the hotel room rate of $95.00 plus applicable taxes (available until October 6, 2014, or until the SoCRA room block is filled).

Contact: C. Stewart Watson, Food and Drug Administration, 555 Winderley Pl., Suite 200, Maitland, FL 32751, 407–475–4756, FAX: 407–475–4768, or Society of Clinical Research Associates (SoCRA), 530 West Butler Ave., Suite 109, Chalfont, PA 18914, 800–762–7292 or 215–822–8644, FAX: 215–822–8633, email *SoCRAmail@aol.com,* Web site: *www.socra.org.*

Registration: The registration fee will cover actual expenses including refreshments, lunch, materials and speaker expenses. Seats are limited; please submit your registration as soon as possible. Workshop space will be filled in order of receipt of registration. Those accepted into the workshop will receive confirmation. The cost of the registration is as follows: SoCRA member—$575; SoCRA nonmember (includes membership)—$650; Federal Government member—$450.00; Federal Government SoCRA nonmember—$525.00; FDA Employee—Fee Waived.

If you need special accommodations due to a disability, please contact SoCRA (see *Contact*) at least 21 days in advance.

Extended periods of question and answer and discussion have been included in the program schedule. SoCRA designates this education activity for a maximum of 13.3 continuing education (CE) credits for SoCRA CE and continuing nursing education (CNE). SoCRA designates this live activity for a maximum of 13.3 American Medical Association Physicians Recognition Award Category 1 Credit(s).™ Physicians should claim only the credit commensurate with the extent of their participation. *Continuing Medical Education for physicians:* SoCRA is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. *CNE for nurses:* SoCRA is an approved provider of continuing nursing education by the Pennsylvania State Nurses Association (PSNA), an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation (ANCC). ANCC/PSNA Provider Reference Number: 205–3–A–09.

Registration Instructions: To register, please submit a registration form with your name, affiliation, mailing address, telephone, fax number, and email, along with a check or money order payable to ''SoCRA''. Mail to: SoCRA (see *Contact* for address). To register via the Internet, go to *http://www.socra.org/html/FDA_Conference.htm.* (FDA has verified the Web site addresses throughout this document, but we are not responsible for any subsequent changes to the Web