TABLE 1—ESTIMATED ONE-TIME REPORTING BURDEN [1]

Product reporting for compounding outsourcing facilities	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of Initial Product Report	50	1	50	2	100
Waiver Request from Electronic Submission of Initial Product Report	1	1	1	1	1
Total					101

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Product reporting for compounding outsourcing facilities	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of December Product Report	50	1	50	2	100
Submission of June Product Report	50	1	50	2	100
Waiver Request from Electronic Submission of Product Reports	1	1	1	1	1
Total					201

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

III. Comments

Interested persons can 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 can be viewed at 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.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: November 18, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–27691 Filed 11–21–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1429]

Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act; Final Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry entitled ''Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act.'' The guidance addresses new provisions in the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Drug Quality and Security Act (DQSA). The guidance is intended to assist human drug compounders that elect to register as outsourcing facilities in registering, re-registering, or de-registering with FDA. The guidance provides information on how an outsourcing facility should submit facility registration information electronically in structured product labeling (SPL) format using FDA's electronic submission system. This guidance reflects the Agency's current thinking on the issues addressed by the guidance.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the final 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the final guidance document. Submit electronic comments on the final 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.

FOR FURTHER INFORMATION CONTACT: Soo Jin Park, Drug Registration and Listing Team, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–3100.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act.'' This guidance is being issued consistent with the new authority conferred to FDA in the DQSA (Pub. L. 113–54). In that legislation, Congress created a new category for certain facilities that

compound human drugs called ''outsourcing facilities.'' Section 503B(d)(4) of the FD&C Act (21 U.S.C. 353B(d)(4)) defines an outsourcing facility, in part, as a facility that complies with all of the requirements of section 503B, including registering with FDA as an outsourcing facility and paying associated fees. If the conditions outlined in section 503B(a) of the FD&C Act are satisfied, a drug compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from certain sections of the FD&C Act, including section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use) and section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)). Drugs compounded in outsourcing facilities are not exempt from the requirements of section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice for drugs). This guidance is intended to assist compounding facilities that wish to register as outsourcing facilities to register with FDA and discusses the process for registering, re-registering, and de-registering.

In the **Federal Register** of December 4, 2013 (78 FR 72899), FDA issued a notice announcing the availability of the draft version of this guidance. That draft guidance set forth an interim and electronic submission method for human drug compounders that elect to register as outsourcing facilities. The comment period on the draft guidance ended on February 3, 2014. FDA received nine comments on the draft guidance. Some of the received comments raised issues that were not directly pertinent to the topics addressed in this guidance. FDA intends to consider those comments as they relate to issues being addressed in other policy documents being developed by the Agency.

In response to received comments or on its own initiative, FDA made the following changes as it finalized this guidance: (1) We included a phone number for a point of contact; (2) we deleted reference to an alternative interim registration method; (3) we added information on how a registered outsourcing facility can de-register; (4) we clarified what registration information will be made public; (5) we clarified the standard to be used to grant a waiver of the electronic submission requirements; and (6) we made grammatical and other minor editorial changes to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on this topic. 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 statutes and regulations.

II. Paperwork Reduction Act

This guidance contains collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information have been approved under OMB control number 0910–0777.

III. Comments

Interested persons can 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 can 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.*

IV. Electronic Access

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Dated: November 18, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–27693 Filed 11–21–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2011–D–0360 and FDA–2011–D–0357]

Framework for Regulatory Oversight of Laboratory Developed Tests; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs).'' The purpose of this workshop is to discuss FDA's proposal for a risk-based framework for addressing the regulatory oversight of a subset of *in vitro* diagnostic devices (IVDs) referred to as laboratory developed tests (LDTs), which are intended for clinical use and designed, manufactured and used within a single laboratory, and provide an additional opportunity for public comment

Dates and Times: The 2-day public workshop will be held on January 8, 2015, from 8:30 a.m. to 5:30 p.m. and on January 9, 2015 from 8:30 a.m. to 5:30 p.m.

Location: The public workshop will be held at the Natcher Center at the National Institutes of Health Campus, 9000 Rockville Pike, Bldg. 45, Auditorium, Bethesda, MD 20814. For parking and security information, please refer to *http://www.nih.gov/about/visitor/.*

Contact Person: Allen Webb, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, Rm 5675, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–4217, *LDTframework@fda.hhs.gov.*

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by December 12, 2014, at 4 p.m. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, (email: *Susan.Monahan@fda.hhs.gov* or phone: 301–796–5661) no later than December 19, 2014.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this meeting/public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number. If you are unable to register online, please contact Susan Monahan (see *Registration.*) Registrants will receive confirmation after they have been accepted and will be notified if they are on a waiting list.