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Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet.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 the CBER Internet at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.*

Persons unable to download an electronic copy of ''Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1739 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This draft guidance refers to previously approved collections of information found in FDA regulations.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; the collections of information in 21 CFR part 807 Subpart B and C have been approved under OMB control number 0910–0625; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR part 814, subparts B and E, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H, have been approved under OMB control number 0910–0332; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 806 have been approved under OMB control number 0910–0359; the collections of information in 21 CFR 801 and 21 CFR 809.10 have been approved under OMB control number 0910–0485; and the collections of information in 21 CFR part 803 have been approved under OMB control numbers 0910–0291 and 0910–0437.

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.*

Comments will also be accepted at a public meeting, which will be held prior to finalizing this draft guidance. A 2-day meeting is tentatively scheduled for early January, 2015 and will be announced separately in the **Federal Register**.

Dated: September 30, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–23596 Filed 9–30–14; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0357]

Food and Drug Administration Notification and Medical Device Reporting for Laboratory Developed Tests; Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories; 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 ''FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs).'' This draft guidance document is intended to describe the process for clinical laboratories to notify FDA of the laboratory developed tests (LDTs) they manufacture as well as to describe the Medical Device Reporting (MDR) requirements for clinical laboratories manufacturing LDTs. LDTs are those in vitro diagnostic devices that are intended for clinical use and designed, manufactured, and used within a single laboratory. 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 February 2, 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 single hard copies of the draft guidance document entitled ''FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), 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. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800.

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: *LDT framework@fda.hhs.gov;* or Katherine Serrano, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5646, Silver Spring, MD 20993–0002, 240–402–4217; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

In 1976, Congress enacted the Medical Device Amendments (MDA) (Public Law 94–295), which amended the

Federal Food, Drug, and Cosmetic Act (the FD&C Act) to create a comprehensive system for the regulation of medical devices intended for use in humans. At that time, the definition of a device was amended to make explicit that it encompasses in vitro diagnostic devices (IVDs): ''The term 'device' . . . means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article. . . .'' (section 201(h) of the FD&C Act (21 U.S.C. 321(h)). The definition of device applies equally to IVDs manufactured by conventional device manufacturers and those manufactured by laboratories. An IVD, therefore, meets the device definition irrespective of where and by whom it is manufactured.

However, since the implementation of the MDA of 1976, FDA has generally exercised enforcement discretion so that the Agency has generally not enforced applicable provisions under the FD&C Act and FDA regulations with respect to LDTs, a subset of IVDs that are intended for clinical use and designed, manufactured, and used within a single laboratory. Given a changing landscape in terms of the volume, technology, and business model of IVDs offered as LDTs since 1976, in combination with the increasingly important role of diagnostic devices, including LDTs, in critical clinical treatment decisions, the FDA does not believe that generally exercising enforcement discretion with respect to the regulatory requirements for these devices remains appropriate.

Consistent with the draft guidance entitled ''Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)'' that is being distributed for comment contemporaneously with this document, FDA intends to enforce certain medical device regulatory requirements for LDTs and device-manufacturer requirements for laboratories that manufacture, prepare, propagate, compound, assemble, or process LDTs. FDA intends to collect information regarding LDTs currently being used by laboratories through a notification process. In addition, FDA intends to enforce the requirements under part 803 (21 CFR part 803) for reporting safety issues related to LDTs, to provide a mechanism for collecting information on any known or suspected adverse events related to the use of an LDT. FDA believes that this is the appropriate regulatory oversight approach to adopt initially in achieving the desired public health goal of assuring that these IVDs used in the provision of health care, regardless of the manufacturer, provide reasonable assurance of safety and effectiveness.

FDA welcomes comments on all aspects of this guidance, as well as on the following specific issue: FDA notes that some laboratory networks (i.e., more than one laboratory under the control of the same parent entity) offer the same test in multiple laboratories throughout their network. Although devices in this scenario do not meet FDA's definition of an LDT (i.e., they are not designed, manufactured and used within a single laboratory), FDA would like feedback on whether a single notification from the laboratory network for that test is sufficient, provided that the laboratory network indicates in the notification to FDA that the test is offered at multiple sites. Elsewhere in this issue of the **Federal Register**, FDA is issuing a notice announcing the availability of the draft guidance entitled ''Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)'' that also identifies specific issues for comment.

Additionally, FDA intends to hold a public webinar in late October 2014 to summarize the proposed oversight framework and answer clarification questions from stakeholders. The webinar will not require registration and will be announced at least 1 week in advance on FDA's Web site. It will be recorded and made available on FDA's Web site shortly thereafter.

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 FDA notification and medical device reporting requirements for LDTs. 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 on the CBER Internet at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.*

Persons unable to download an electronic copy of ''FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1738 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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 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 the following 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.

Title: Notification for Laboratory Developed Tests (LDTs).

FDA intends to collect information from laboratories regarding their current LDTs and new LDTs through a notification process. This information collection is needed to classify LDTs and to prioritize enforcement of premarket review requirements for categories of LDTs based on risk using a public process. Specifically, FDA plans to use advisory panels to provide recommendations to the Agency on LDT risks, classification and prioritization of enforcement of applicable regulatory requirements on certain categories of LDTs, as appropriate. Additionally, the notification information will be made

available in part to the laboratory community and interested stakeholders to act as a resource for accessing information on the LDTs currently being used by laboratories. If these data are not collected, FDA and interested stakeholders will not have reliable data on the types of LDTs currently used. Further, because notification data will be used to classify LDTs and prioritize enforcement of premarket review requirements based on risk, it will benefit laboratories to provide the most accurate information possible to ensure that appropriate classification is made.

To facilitate future FDA regulatory activity for LDTs, clinical laboratories should notify FDA of all of the LDTs manufactured, prepared, propagated, compounded, assembled, or processed by their laboratories. To appropriately notify FDA of all LDTs manufactured at an establishment, the owner/operator should provide information on the data elements identified in the following paragraph for each LDT manufactured at their establishment. Laboratory owner/operators with LDTs currently being used in their laboratories should begin to report this information no later than 6 months after publication, in final form, of the ''Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)'' guidance document referred to in section I. Background. Starting 6 months after publication of the final version of the ''Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)'' guidance, laboratories that intend to offer new LDTs should provide notification prior to offering the LDT for clinical use. It should be noted that when laboratories make a significant change to the marketed intended use of an LDT for which they have previously provided notification, the LDT will be considered by the FDA to be a new LDT and, therefore, a new notification should be provided prior to offering that LDT for clinical use.

Data Elements to be Reported [1]

- Laboratory Name
- Laboratory Contact Email Address
- Test Name
- Monthly Test Volume
- Intended Use
- Clinical Use of Test
- What is measured or detected (i.e. analyte, measurand, etc.)
- Disease/Condition for which the diagnostic device is indicated
- Patient Population
- Does the patient population include pediatric patients? (<21 years old)
- Sample Type
- Test Method
- Is the test a modification of an FDA cleared/approved test?
- If the test is a modification of an FDA cleared/approved test, what modifications were made?

Respondents to this collection of information are manufacturers of LDTs. FDA estimates the burden of this collection as follows.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN FIRST YEAR[1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
LDT Notification—Initial notification	650	1	650	1	650
LDT Notification—Subsequent first year notifications	650	16	10,400	0.5	5,200
Total					5,850

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN SUBSEQUENT YEARS [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
LDT Notification—Subsequent years	650	1	650	0.5	325

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

Upon publication of a final guidance based on this draft guidance, FDA expects approximately 650 manufacturers to provide notification information regarding approximately 17 LDTs each. The number of respondents and total number of responses are based on information provided by New York State. Specifically, in July 2014, New York State indicated that it has reviewed 9,800 submissions from 565 labs. While these numbers represent the best estimates available for the number of LDTs currently on the market, FDA acknowledges that additional LDTs may be offered to patients in the United States that are not currently offered in New York State, and therefore, have not undergone review. To take into account the possibility that the number of LDTs and number of labs in New York State understate the totals for the United States, FDA assumes that the nationwide totals are 10 percent higher and, therefore, estimates that there are approximately 11,000 LDTs manufactured in 650 labs. To corroborate our estimate of the total number of responses, i.e., the total number of LDTs currently being offered, we looked at National Institutes of Health Genetic Test Registry data. In June 2014, the registry included approximately 7,600 genetic tests that are not FDA-approved or cleared, but are currently offered. If we assume that genetic tests represent roughly 70 to 80 percent of all LDTs, this supports our estimate of 11,050 LDTs (total annual responses in the first year).

FDA estimates an average of 17 LDTs offered per laboratory based upon the ratio of labs offering LDTs to the number of LDT submissions received by New York State. We therefore estimate that there will be 650 respondents (manufacturers of LDTs) and 17 responses per respondent (LDT notifications) in the first year. This results in 11,050 total annual responses in the first year.

[1] Please refer to Appendix A of the draft guidance document for a more detailed discussion of data elements.

FDA acknowledges that according to the CLIA (Clinical Laboratory Improvement Amendments) program at CMS (August 2014), there are approximately 11,000 CLIA-certified high complexity labs that have the appropriate certifications to manufacture LDTs. However, FDA is not aware of information describing the exact number of certified high complexity laboratories currently offering LDTs. Therefore, FDA has relied upon the information provided by New York State when creating these estimates. FDA acknowledges that, without firm data on the number of labs offering LDTs or the number of tests offered per lab, the estimate of the number of respondents is necessarily uncertain.

After the initial notification, respondents will only notify FDA of new tests or modifications that affect performance or intended use. We estimate the number of tests in subsequent years to be approximately 5 percent of the estimated number of initial notifications.

FDA bases its estimate of the average burden per response on Agency creation of a mock notification. We would expect labs to take up to an hour for their first notification and only 30 minutes for subsequent notifications, due to familiarity with the system.

Therefore, we estimate the total reporting burden to respondents to be 5,850 hours for the first year and 325 hours for subsequent years.

This draft guidance also 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 803 (medical device reporting) have been approved under OMB control numbers 0910–0291 and 0910–0437; the collections of information in 21 CFR part 806 (reports of corrections and removals) have been approved under OMB control number 0910–0359; and the collections of information in 21 CFR part 807, subparts B and C (registration and listing) have been approved under OMB control number 0910–0625.

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.*

Comments will also be accepted at a public meeting, which will be held prior to finalizing this draft guidance. A 2-day meeting is tentatively scheduled for early January 2015 and will be announced separately in the **Federal Register**.

Dated: September 29, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–23586 Filed 9–30–14; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Pulmonary-Allergy Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pulmonary-Allergy Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 21, 2014, from 8 a.m. to 4 p.m.

Location: FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center (Rm. 1503), 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Cindy Hong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *PADAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss supplemental new drug application (sNDA) 203188, ivacaftor oral tablets, submitted by Vertex Pharmaceuticals Inc., for the treatment of cystic fibrosis in patients with an R117H mutation in the cystic fibrosis transmembrane conductance regulator gene.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 14, 2014. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 6, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will