DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1837]

Transfer of a Premarket Notification (510(k)) Clearance—Questions and Answers; Draft Guidance for Industry and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Transfer of a Premarket Notification (510(k)) Clearance—Questions and Answers.'' The purpose of the draft guidance is to provide information on how to notify FDA of the transfer of a premarket notification clearance from one holder to another, and the procedures FDA and industry should use to ensure public information in FDA's databases about the current 510(k) holder for a specific device(s) is accurate and up-to-date. This draft guidance is not final nor is it in effect at this time.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 23, 2015. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by February 20, 2015, (see the ''Paperwork Reduction Act of 1995'' section of this document).

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 Submit written requests for a single hard copy of the draft guidance document entitled ''Transfer of a Premarket Notification (510(k)) Clearance—Questions and Answers'' to the Office of the Center Director, Guidance and Policy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 to the Office of Communication, Outreach and Development, 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.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*.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: Marjorie Shulman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1536, Silver Spring, MD 20993–0002, 301–796–6572 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.

I. Background

FDA is announcing the availability of the draft guidance entitled ''Transfer of a Premarket Notification (510(k)) Clearance—Questions and Answers.'' This draft guidance provides information on how to notify FDA of the transfer of a 510(k) clearance from one holder to another, and the procedures FDA and industry should use to ensure public information in FDA's databases about the current 510(k) holder for a specific device(s) is accurate and up-to-date.

Previously, FDA's databases did not reflect changes in the 510(k) holder that occurred after FDA's clearance of the 510(k). This was in part because 510(k) holders were not required to list their devices by 510(k) number, which made it difficult for FDA to tie a particular 510(k) to its current holder. Lack of updated, accurate 510(k) holder information created a number of challenges for FDA, for current 510(k) holders, future 510(k) submitters, and other stakeholders.

The Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110–85) amended section 510 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) by requiring domestic and foreign device establishments to begin submitting their registration and device listing information to FDA by electronic means rather than on paper forms,[1] and also specified the timeframes within which establishments are required to submit such information.[2] In accordance with FDAAA, the Agency launched FDA's Unified Registration and Listing System (FURLS), an Internet-based registration and listing system.[3]

Notification to FDA of a sale or other transfer of a 510(k) clearance, whether or not the device is already on the market, is accomplished by compliance with device listing requirements. As a result of the launch of the FURLS Device Registration and Listing Module (DRLM) and the changes to the registration and listing regulations that became effective on October 1, 2012,[4] the medical device listing information provided to FDA changed. Owners and operators of medical device establishments that market 510(k)-cleared devices must now supply the FDA-assigned premarket submission number of the cleared 510(k) when they list their devices in FURLS.[5] This listing allows FDA to easily identify the holder of each 510(k) based on the records created by manufacturers, specification developers, repackers/relabelers, single-use device reprocessors, or remanufacturers in FURLS DRLM. Listing information is required to be updated at least annually[6] and there may only be one 510(k) holder for a device at a time;[7] therefore, this updated listing provides FDA with current 510(k) holder information by 510(k) number.

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 how to notify FDA of the transfer of a 510(k) clearance and the procedures FDA and industry should use to ensure public information in FDA's databases about the current 510(k) holder for a specific device(s) is accurate and up-to-date. 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

[1] See FD&C Act section 510(p) (21 U.S.C. 360(p)).

[2] See FD&C Act sections 510(b)(2), (i), and (j) (21 U.S.C. 360(b)(2), (i), and (j)).

[3] See 77 FR 45927 (August 2, 2012).

[4] See id.

[5] See 21 CFR 807.25(g)(4).

[6] See FD&C Act section 510(j) (21 U.S.C. 360(j)) and 21 CFR 807.22.

[7] See FD&C Act section 510(k) (21 U.S.C. 360(k)) and 21 CFR 807.81(a).

downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health 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 http://www.fda.gov/BiologicsBloodVaccines/Guidance ComplianceRegulatoryInformation/default.htm.* Persons unable to download an electronic copy of ''Transfer of a Premarket Notification (510(k)) Clearance—Questions and Answers,'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1808 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 these 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: Transfer of a Premarket Notification (510(k)) Clearance—Questions and Answers

This draft guidance is intended to provide information on how to notify FDA of the transfer of a 510(k) clearance from one person to another, and the procedures FDA and industry should use to ensure public information in FDA's databases about the current 510(k) holder for a specific device(s) is accurate and up-to-date. The proposed information collection seeks to provide information in order to notify FDA of the transfer of a premarket notification (510(k)) clearance.

Description of respondents: The respondents to this collection of information are 510(k) holders and parties claiming to be 510(k) holders. The Agency estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Guidance title: transfer of a premarket notification (510(k)) clearance—questions and answers	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Voluntary reporting of transfer of 510(k) Clearance on FDA's Unified Registration and Listing System (Outside of Annual Listing Reporting Requirement)	4,080	1	4,080	.25	1,020
Submission of 510(k) transfer documentation when more than one party lists the same 510(k)	2,033	1	2,033	4	8,132
Total					9,152

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

Currently, FDA estimates 78% of 510(k)s are listed outside of the annual registration cycle based on numbers in the FURLS database from fiscal year 2009 through fiscal year 2014. Fiscal year 2008 was left out of this cohort as it was the first year that registrants were required to report the 510(k) number on their listings and, therefore, an unusually high number of listings were created. An average of 5,231 510(k)s have been listed in each year since 2008. Because listing outside of the annual requirement is voluntary, FDA estimates that annually 78% of 510(k)s will continue to be listed outside of the annual requirement. FDA estimates that 4,080 510(k)s may be listed outside of the annual registration cycle. FDA estimates that it will take approximately 15 minutes for each listing, for a total reporting burden of 1,020 hours.

FDA estimates it will have 2,033 instances of more than one party claiming to be a 510(k) holder for a specific device as part of annual registration and listing. The Agency reached this estimate by identifying the number of unique 510(k) device listings entered in FURLS between fiscal years 2009 and 2014 that conflict with a listing already entered by another party (5,304), dividing that number by the number of years (six), and multiplying by the average number of parties claiming to be the 510(k) holder when there is a conflict in the current FURLS database (2.3). The draft guidance identifies potential documentation a party could submit to FDA to establish the transfer of a 510(k) clearance. FDA estimates it will take a party approximately 4 hours to locate and submit information to establish the transfer of the 510(k) clearance, resulting in 8,132 burden hours for those 2,033 parties claiming to be 510(k) holders. FDA reached this estimate based on its expectation of the amount of time it will take a party to locate the information, to copy, and to submit a copy to FDA.

The burden estimate does not include the maintenance of records used to document transferring a premarket notification (510(k)) clearance. Based on available information, FDA believes that the maintenance of these records is a usual and customary part of normal business activities. For example, in the ordinary course of business, supporting documents should be kept to verify asset information for calculating the annual depreciation or calculating gain or loss on sale of an asset on a businesses' tax return. Therefore, this

recordkeeping requirement creates no additional paperwork burden.

Before the proposed information collection provisions contained in this draft guidance become effective, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 807 (registration and listing) are approved under OMB control number 0910–0625; collections of information in 21 CFR part 807 subpart E (premarket notification submission) have been approved under OMB control number 0910–0120 and collections of information in 42 CFR 493.17 have been approved under OMB control number 0910–0607.

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: December 16, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–29832 Filed 12–19–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Vaccines and Related Biological Products 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: Vaccines and Related Biological Products 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 March 4, 2015, from 8:30 a.m. to 3 p.m.

Location: DoubleTree Hotel by Hilton, 8727 Colesville Rd., Silver Spring, MD 20910. The hotel's phone number is 301–589–5200.

Contact Person: Sujata Vijh or Denise Royster, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6128, Silver Spring, MD 20993–0002, 240–402–7107 or 240–402–8158, 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: On March 4, 2015, from 8:30 a.m. to 3 p.m., the committee will meet in open session to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2015–2016 influenza season.

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 February 18, 2015. Oral presentations from the public will be scheduled between approximately 12:40 p.m. and 1:40 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 February 9, 2015. 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 notify interested persons regarding their request to speak by February 10, 2015.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Sujata Vijh at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 17, 2014.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2014–29860 Filed 12–19–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1504]

Independent Assessment of the Process for the Review of Device Submissions; Final Implementation Plan

AGENCY: Food and Drug Administration, HHS.