three categories may affect implementation: (1) Drug manufacturing and packaging, and printing labels and other labeling; (2) supply chain issues; and, (3) other issues. FDA may use the information received to develop draft guidance for industry regarding timeframes for revising product labeling following the approval of safety labeling changes, and may apply these timeframes to particular safety labeling changes.

III. Questions Posed by FDA

With this notice, FDA is soliciting comments from application holders, manufacturers, distributors, and other stakeholders on the following questions:

A. Considerations Related to Drug Manufacturing and Packaging, and to Printing Labeling

1. What are the considerations related to drug manufacturing and packaging, of which FDA should be aware, as they relate to implementation of revised product labeling?

2. What are the considerations related to printing labels and other types of labeling of which FDA should be aware, as they relate to implementation of different types of revised product labeling?

B. Supply Chain Issues

3. What are the supply chain factors (including storage, shipping, and distribution factors) of which FDA should be aware that limit or otherwise affect how quickly a labeling change can be implemented?

C. Other Considerations

4. What alternative labeling mechanisms (*e.g.,* having labeling available on a product Web site) could be used to disseminate new safety information quickly to patients and health care providers?

5. How should the relative seriousness of the new safety information, or whether the new safety information describes a newly identified risk, or strengthens a risk already identified in current labeling, affect timelines for implementing revised product labeling?

6. What are the implementation considerations when the safety labeling change is to prescriber versus patient labeling (or both)?

7. What would be a reasonable timeframe following approval of revised safety related labeling changes for applicants to implement the revised labeling? Please relate this timeframe to the optimal point in the supply chain (*e.g.,* newly manufactured product, newly shipped product) and the type of labeling change.

8. Are there other considerations or options related to implementing safety labeling changes of which FDA should be aware?

IV. Comments

Interested persons may submit either electronic or written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, as well as at *http://www.regulations.gov*.

Dated: December 14, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–32438 Filed 12–19–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0476]

Guidance for Industry and Food and Drug Administration Staff; Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic and Radiology Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic and Radiology Devices.'' This document describes FDA's intent with regard to enforcement of premarket notification (510(k)) requirements for certain in vitro diagnostic and radiology devices under the regulations.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic and Radiology Devices'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to (301) 847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the 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: Scott McFarland, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5543, Silver Spring, MD 20993–0002, (301) 796–6217.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has identified certain Class I and Class II in vitro diagnostic and radiology devices that have established safety and effectiveness profiles and for which it believes 510(k) review is not necessary to assure safety and effectiveness. While FDA intends to exempt these devices from the 510(k) requirement through rulemaking that would reclassify the Class II devices and amend the classification regulations of the Class I devices, FDA no longer believes it is necessary to review premarket notification (510(k)) submissions for these devices before they enter the market. FDA is issuing a guidance concerning a policy of exercising enforcement discretion with regard to the 510(k) requirement for such devices. The guidance lists the devices for which FDA intends to exercise enforcement discretion with regard to premarket notification requirements, subject to the limitations to the exemption criteria found in 21 CFR 862.9, 21 CFR 864.9, 21 CFR 866.9, and 21 CFR 892.9. FDA intends to continue to enforce all other applicable requirements under the FD&C Act, including, but not limited to: Registration and listing (part 807 (21 CFR part 807)); labeling (part 801 (21 CFR part 801) and § 809.10 (21 CFR 809.10)); good manufacturing practice requirements as set forth in the Quality System regulation (part 820 (21 CFR part 820)); and Medical Device Reporting requirements (part 803 (21

CFR part 803)). The draft guidance published in the **Federal Register** on July 12, 2011 (76 FR 40921), and the comment period closed on October 11, 2011. There were 5 comments received.

II. Significance of Guidance

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 ''Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic and Radiology 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 guidance may do so by using 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.* To receive ''Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic and Radiology Devices,'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to (301) 847–8149 to receive a hard copy. Please use the document number 1752 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations and guidance documents. 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 part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in part 807, subparts B and C have been approved under OMB control number 0910–0387; the collections of information in part 820 have been approved under OMB control number 0910–0073; the collections of information in part 801 and § 809.10 have been approved under OMB control number 0910–0485; and the collections of information in part 803 have been approved under OMB control number 0910–0437.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: December 14, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–32437 Filed 12–19–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0885]

Food and Drug Administration Rare Disease Patient Advocacy Day; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration's (FDA) Office of Orphan Products Development is announcing the following meeting: FDA Rare Disease Patient Advocacy Day. This meeting is intended to enhance the awareness of the rare disease community as to FDA's roles and responsibilities in the development of products (drugs, biological products, and devices) intended for the diagnosis, prevention, and/or treatment of rare diseases or conditions. The goal of this meeting is to engage and educate the rare disease community on the FDA regulatory processes.

This educational meeting will consist of a live and interactive simultaneous Web cast of presentations provided by FDA experts from various Centers and Offices, as well as from outside experts. The interactive meeting will include two general panel discussion sessions, as well as afternoon breakout sessions for more indepth information on the roles of FDA. In addition, onsite attendees will have an opportunity during lunch to engage with FDA and outside experts in a small group setting.

Date and Time: The meeting will be held on March 1, 2012, from 8:30 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. For participants who cannot attend the live meeting, a live interactive Web cast will be made available. Participants may access this live Web cast by visiting the following site: *http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/OOPDNewsArchive/ucm277194.htm.*

Contact: Soumya Patel, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm.5279, Silver Spring, MD 20993–0002, (301) 796–8660, FAX: (301) 847–8621, email: *FDAadvocacy@fda.hhs.gov.*

Registration: Interested participants may register for this meeting at the following Web site: *https://www.teamshare.net/FDA_Rare_Disease_Patient_Advocacy_Day_Registration.*

If you need sign language interpretation during this meeting, please contact Megan McNamee at *mmcnamee@icfi.com* by February 15, 2012.

The FDA Rare Disease Patient Advocacy Day is supported by FDA, the National Institutes of Health (NIH), the National Organization for Rare Disorders, and the Genetic Alliance.

FDA encourages all attendees to also plan on attending the NIH Rare Disease Day day-long celebration on February 29, 2011. Please refer to the following Web site for more information regarding the NIH Rare Disease Day event: *http://rarediseases.info.nih.gov/RareDiseaseDay.aspx.* (FDA has verified the Web site addresses throughout this document, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Dated: December 14, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–32436 Filed 12–19–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Advisory Committees; Tentative Schedule of Meetings for 2012

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a