TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR Part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Tracking information—821.25(a)	12	1	12	76	912
Record of tracking data—821.25(b)	12	46,260	555,120	1	555,120
Standard operating procedures—821.25(c) [2]	12	1	12	63	756
Manufacturer data audit—821.25(c)(3)	12	1,124	13,488	1	13,488
Multiple distributor data and distributor tracking records—821.30(c)(2) and (d)	22,000	1	22,000	1	22,000
Total					592,276

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] One-time burden.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity/21 CFR Part	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Acquisition of tracked devices and final distributor data—821.30(a) and (b)	22,000	1	22,000	1	22,000
Multiple distributor data and distributor tracking records—821.30(c)(2) and (d)	1,100	1	1,100	1	1,100
Total					23,100

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

Dated: April 21, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–09467 Filed 4–24–14; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Preparation for International Cooperation on Cosmetics Regulation; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA or we) is announcing a public meeting entitled, ''International Cooperation on Cosmetics Regulation (ICCR)—Preparation for ICCR–8 Meeting.'' The purpose of the meeting is to invite public input on various topics pertaining to the regulation of cosmetics. We may use this input to help us prepare for the ICCR–8 meeting that will be held in Canada from July 8 to 10, 2014.

Date and Time: The meeting will be held on June 4, 2014, from 2 p.m. to 4 p.m.

Location: The meeting will be held at the Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., Wiley Auditorium (first floor), College Park, MD 20740.

Contact Person: If you intend to participate in the meeting, you should register with Maria Rossana (Rosemary) Cook, Office of Cosmetics and Colors, Food and Drug Administration, 4300 River Rd., College Park, MD 20740, email: *maria.cook@fda.hhs.gov* or FAX: 301–436–2975.

Registration and Requests for Oral Presentations: Send registration information (including your name, title, firm name, address, telephone number, fax number, and email address), written material, and requests to make an oral presentation, to the contact person by May 20, 2014.

If you need special accommodations due to a disability, please contact Maria Rossana (Rosemary) Cook (see *Contact Person*) by May 28, 2014.

SUPPLEMENTARY INFORMATION: You may present proposals for future ICCR agenda items, data, information, or views orally or in writing, on issues pending at the public meeting. Time allotted for oral presentations may be limited to 10 minutes or less for each presenter. If you wish to make an oral presentation, you should notify the contact person by May 20, 2014, and submit a brief statement of the general nature of the evidence or arguments that you wish to present, your name, address, telephone number, fax number, and email address, and indicate the approximate amount of time you need to make your presentation.

Transcripts: As soon as a transcript is available, it will be accessible at *http://www.regulations.gov*. It also may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20850. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. You should send written requests for a hardcopy or CD–ROM transcript to the Division of Freedom of Information, (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

The Purpose of the Multilateral Framework on the ICCR: The purpose of the multilateral framework on the ICCR is to pave the way for the removal of regulatory obstacles to international trade while maintaining global consumer protection.

ICCR is a voluntary international group of cosmetics regulatory authorities from the United States, Japan, the European Union, and Canada. These regulatory authority members will enter into constructive dialogue with their relevant cosmetics industry trade associations and public advocacy groups. Currently, the ICCR members are: Health Canada; the European Directorate General for Health and Consumers; the Ministry of Health,

Labor and Welfare of Japan; and the U.S. Food and Drug Administration. All decisions made by consensus will be compatible with the laws, policies, rules, regulations, and directives of the respective administrations and governments. Members will implement and/or promote actions or documents within their own jurisdictions and seek convergence of regulatory policies and practices. Successful implementation will need input from stakeholders.

We will make the agenda for the public meeting available on the Internet at: *http://www.fda.gov/Cosmetics/InternationalActivities/ConferencesMeetingsWorkshops/InternationalCooperationonCosmeticsRegulationsICCR/default.htm.* Depending on the number of requests for oral presentations, we intend to have an agenda available by May 30, 2014. We may use the information that you provide to us during the public meeting to help us prepare for the July 8 to 10, 2014, ICCR–8 meeting.

Dated: April 21, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–09465 Filed 4–24–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0396]

Public Meeting on Patient-Focused Drug Development for Neurologic Manifestations of Inborn Errors of Metabolism

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a public meeting and an opportunity for public comment on Patient-Focused Drug Development for neurologic manifestations of inborn errors of metabolism. Patient-Focused Drug Development is part of FDA's performance commitments made as part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The public meeting is intended to allow FDA to obtain patient perspectives on the impact of neurologic manifestations of inborn errors of metabolism on daily life as well as patient views on treatment approaches for neurologic manifestations of inborn errors of metabolism.

DATES: The public meeting will be held on June 10, 2014, from 9 a.m. to 1 p.m. Registration to attend the meeting must be received by May 27, 2014 (see the **SUPPLEMENTARY INFORMATION** section for instructions).

ADDRESSES: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1, where routine security checks will be performed. For more information on parking and security procedures, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Submit either electronic or written comments by August 11, 2014. Submit electronic comments to *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. All comments should be identified with the docket number found in brackets in the heading of this document.

FDA will post the agenda approximately 5 days before the meeting at:*http://www.fda.gov/Drugs/NewsEvents/ucm387057.htm.*

FOR FURTHER INFORMATION CONTACT: Pujita Vaidya, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1170, Silver Spring, MD 20993, 301–796–0684, FAX: 301–796–0684, email: *Pujita.Vaidya@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on Patient-Focused Drug Development

FDA has selected neurologic manifestations of inborn errors of metabolism as the focus of a public meeting under Patient-Focused Drug Development, an initiative that involves obtaining a better understanding of patients' perspectives on the severity of the disease and the available therapies for the condition. Patient-Focused Drug Development is being conducted to fulfill FDA performance commitments that are part of the authorization of PDUFA V under Title I of the Food and Drug Safety and Innovation Act (FDASIA) (Pub. L. 112–144). The full set of performance commitments is available on the FDA Web site at *http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf.*

FDA committed to obtain the patient perspective on 20 disease areas during the course of PDUFA V. For each disease area, the Agency will conduct a public meeting to discuss the disease and its impact on patients' daily lives, the types of treatment benefit that matter most to patients, and patients' perspectives on the adequacy of the available therapies. These meetings will include participation of FDA review divisions, the relevant patient communities, and other interested stakeholders.

On April 11, 2013, FDA published a notice (78 FR 08441) in the **Federal Register** announcing the disease areas for meetings in fiscal years (FYs) 2013–15, the first 3 years of the 5-year PDUFA V timeframe. The Agency used several criteria outlined in the April 11, 2013, notice to develop the list of disease areas. FDA obtained public comment on the Agency's proposed criteria and potential disease areas through a public docket and a public meeting that was convened on October 25, 2012. In selecting the set of disease areas, FDA carefully considered the public comments received and the perspectives of review divisions at FDA. By the end of FY 2015, FDA will initiate a second public process for determining the disease areas for FY 2016–17. More information, including the list of disease areas and a general schedule of meetings, is posted on FDA's Web site at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm.*

II. Public Meeting Information

A. Purpose and Scope of the Meeting

The purpose of this Patient-Focused Drug Development meeting is to obtain input on the symptoms and other impacts of neurologic manifestations of inborn errors of metabolism that matter most to patients, as well as perspectives on current approaches to treating neurologic manifestations of inborn errors of metabolism. FDA expects that this information will come directly from patients, caregivers, and patient advocates. Inborn errors of metabolism include a range of genetic disorders in which the body has an enzyme deficiency, which causes buildup of harmful metabolites. Examples of inborn errors of metabolism include phenylketonuria, lysosomal storage disorders, Wilson disease, and many others. Symptoms vary depending on the condition and can be acute or chronic. Neurologic symptoms are common. For most inborn errors of