DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0115]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry and Food and Drug Administration Staff—Class II Special Controls Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry and Food and Drug Administration Staff—Class II Special Controls Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On June 29, 2015, the Agency submitted a proposed collection of information entitled ''Guidance for Industry and Food and Drug Administration Staff—Class II Special Controls Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle'' to OMB for review and clearance under 44 U.S.C. 3507. 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. OMB has now approved the information collection and has assigned OMB control number 0910–0594. The approval expires on September 30, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: October 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–27970 Filed 11–2–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–2076]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Survey on Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Survey on Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On August 18, 2015, the Agency submitted a proposed collection of information entitled ''Survey on Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types'' to OMB for review and clearance under 44 U.S.C. 3507. 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. OMB has now approved the information collection and has assigned OMB control number 0910–0744. The approval expires on September 30, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: October 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–27944 Filed 11–2–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3921]

Health Canada and United States Food and Drug Administration Joint Public Consultation on International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use; Public Webinar; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public webinar; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a regional public webinar entitled ''Health Canada and U.S. Food and Drug Administration Joint Public Consultation on International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).'' The goal of this webinar is to provide information and receive comments on the ICH, as well as the upcoming ICH meetings in Jacksonville, FL, in December 2015. The topics to be discussed are the topics for discussion at the forthcoming ICH Management Steering Meeting. The purpose of the webinar is to solicit public input prior to the next Steering Committee and Expert Working Group meetings in Jacksonville, FL, scheduled for December 5 to 10, 2015, at which the discussion of the topics underway and ICH reforms will continue.

DATES: The public webinar will be held on November 12, 2015, from 1 p.m. to 4 p.m., Eastern Standard Time. Registration to attend the webinar and requests for online presentations must be received by November 6, 2015. See the **SUPPLEMENTARY INFORMATION** section for information on how to register for the webinar. Interested persons may submit either electronic or written comments to the public docket (see **ADDRESSES**) by December 12, 2015.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your

comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov*.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–N–3921 for ''Health Canada and U.S. Food and Drug Administration Joint Public Consultation on International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use; Public Webinar.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov*. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Amanda Roache, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Strategic Programs, 10903 New Hampshire Ave., Bldg. 51, Rm. 1128, Silver Spring, MD 20993, 301–796–4548, email: *Amanda.Roache@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The ICH was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness. In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory Agencies. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. Members of the ICH Steering Committee include the European Union; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labor, and Welfare; the Japanese Pharmaceutical Manufacturers Association; FDA; the Pharmaceutical Research and Manufacturers of America; Health Canada; Swissmedic; and the World Health Organization (as an Observer). The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the ICH regions over the past two decades. The current ICH process and structure can be found at the following Web site: *http://www.ich.org*. (FDA has verified the Web site addresses as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.)

II. Webinar Attendance and Participation

A. Registration

If you wish to attend the webinar, submit a request in writing via email to *HPFB_ICH_DGPSA@hc-sc.gc.ca* by November 6, 2015. Registrations may be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, the number of participants from each organization may be limited based on space limitations. Registrants will receive confirmation once they have been accepted. If you need special accommodations because of a disability, please contact Amanda Roache (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the webinar.

B. Requests for Online Presentations

Interested persons may present data, information, or views orally or in writing on issues pending at the public webinar. Online presentations made by the public will be scheduled between approximately 3:30 p.m. and 4 p.m. Time allotted for online presentations may be limited to 5 minutes. Those desiring to make online presentations should notify Amanda Roache (see **FOR FURTHER INFORMATION CONTACT**) by November 6, 2015, and submit a brief statement of the general nature of the evidence or arguments they wish to present; the names and addresses, telephone number, fax, and email of proposed participants; and an

indication of the approximate time requested to make their presentation. The agenda for the public webinar will be made available on the Internet at *http://www.fda.gov/Drugs/NewsEvents/ucm466461.htm.*

III. Transcripts

Please be advised that as soon as a webinar transcript is available, FDA will post it at *http://www.fda.gov/Drugs/NewsEvents/ucm466461.htm.*

Dated: October 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–27953 Filed 11–2–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Science Board to the Food and Drug Administration 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: Science Board to the Food and Drug Administration (Science Board).

General Function of the Committee: The Science Board provides advice to the Commissioner of Food and Drugs and other appropriate officials on specific, complex scientific and technical issues important to the FDA and its mission, including emerging issues within the scientific community. Additionally, the Science Board provides advice to the Agency on keeping pace with technical and scientific developments including in regulatory science, input into the Agency's research agenda and on upgrading its scientific and research facilities and training opportunities. It will also provide, where requested, expert review of Agency sponsored intramural and extramural scientific research programs.

Date and Time: The meeting will be held on November 18, 2015, from 9 a.m. until 4 p.m.

Location: Food and Drug Administration, White Oak 31, Rm. 1503, Section A, 10903 New Hampshire Ave., Silver Spring, MD 20993. For those unable to attend in person, the meeting will also be webcast. The link for the webcast is available at *https://collaboration.fda.gov/scienceboard1115/.* Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

Contact Person: Rakesh Raghuwanshi, Office of the Chief Scientist, Office of the Commissioner, Food and Drug Administration, White Oak Bldg. 1 Rm. 3309, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–4769, *rakesh.raghuwanshi@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 Science Board will be provided with updates from the Center for Food Safety and Applied Nutrition, Centers for Excellence in Regulatory Science and Innovation, Evaluation Subcommittee and the ORA Food Emergency Response Network Evaluation Subcommittee. The Board will hear about the scope of FDA's involvement in precision medicine, as well as an overview of specific health informatics initiatives including precision FDA, Open FDA, and Chillax. The Board will also hear about FDA's laboratory safety initiative. A recipient of one of the FY 2014 Scientific Achievement Awards (selected by the Board) will provide an overview of the activities for which the award was given.

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 November 11, 2015. Oral presentations from the public will be scheduled between approximately 3 and 4 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 November 11, 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 November 13, 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 disabilities. If you require accommodations due to a disability, please contact Rakesh Raghuwanshi 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: October 28, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015–27957 Filed 11–2–15; 8:45 am]

BILLING CODE 4164–01–P