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.


Leslie Kux,
Associate Commissioner for Policy.

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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.


Leslie Kux,
Associate Commissioner for Policy.

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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 ICH Management 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