to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: May 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–13063 Filed 5–29–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2005–N–0161]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Current Good Manufacturing Practices for Blood and Related Regulations for and Blood Components; and Requirements for Donor Testing, Donor Notification, and ''Lookback''

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled, ''Current Good Manufacturing Practices for Blood and Related Regulations for and Blood Components; and Requirements for Donor Testing, Donor Notification, and 'Lookback' '' 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 March 11, 2015, the Agency submitted a proposed collection of information entitled, ''Current Good Manufacturing Practices for Blood and Related Regulations for and Blood Components; and Requirements for Donor Testing, Donor Notification, and 'Lookback' '' 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 0910–0116. The approval expires on May 31, 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: May 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–13064 Filed 5–29–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–1659]

Established Conditions: Reportable Chemistry, Manufacturing, and Controls Changes for Approved Drug and Biologic Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Established Conditions: Reportable CMC Changes for Approved Drug and Biologic Products.'' The purpose of this guidance is to provide applicants of new drug applications, abbreviated new drug applications, and biologic license applications with FDA's current thinking on established conditions (*i.e.,* the chemistry, manufacturing, and controls (CMC) information in a submission that would require reporting to FDA if changed for approved drug and biologic products, per the current regulations). This guidance also describes those sections of a common technical document formatted application that typically contain information that meets the definition of established conditions, and provides considerations for managing changes to established conditions over the life cycle of an approved product.

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 July 31, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, 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 the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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.

FOR FURTHER INFORMATION CONTACT: Ashley Boam, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–2400; 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, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Established Conditions: Reportable CMC Changes for Approved Drug and Biologic Products.'' The current regulations for drugs and biologics require applicants with approved drug or biologic products to notify FDA about each change in each condition established in the approved application beyond the variations already provided for in the application (see 21 CFR 314.70) or each change in the product, production process, quality controls, equipment, facilities, responsible personnel, or labeling established in the approved license application (see 21 CFR 601.12). FDA guidance documents clarify the recommended reporting mechanism (*i.e.,* supplement, annual report) for postapproval CMC changes. This draft guidance has been developed to address the lack of clarity with respect to what CMC information in an application constitutes an established condition.

A better understanding of which elements of the CMC information constitute established conditions to FDA and where in an application these are generally expected to be described will allow for a more effective postapproval submission strategy (*e.g.,* effective use of risk management