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Conditions: Reportable Chemistry, Manufacturing, and Controls Changes for Approved Drug and Biologic Products; Draft Guidance for Industry; Availability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

principles in the International Conference on Harmonisation (ICH) Q9, and knowledge management as defined in ICH Q10) by the regulated industry. This will also provide the FDA pathways to better regulate postapproval changes by utilizing more flexibility and risk-based principles, as envisioned by the pharmaceutical product quality initiatives laid out in FDA's ''Pharmaceutical Current Good Manufacturing Practices (cGMPs) for the 21st Century—A Risk Based Approach'' (see *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/QuestionsandAnswersonCurrentGoodManufacturingPracticescGMPforDrugs/UCM071836*).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Established Conditions: Reportable CMC Changes for Approved Drug and Biologic Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of 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, and will be posted to the docket at *http://www.regulations.gov.*

III. Paperwork Reduction Act

This guidance refers to previously approved collections of information that 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 21 CFR parts 211, 314, and 601 have been approved under OMB control numbers 0910–0139, 0910–0001, and 0910–0338, respectively.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov.*

Dated: May 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–13104 Filed 5–29–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than July 31, 2015.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 594–4306.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Rural Outreach Benefits Counseling Program Measures OMB No. 0915–XXXX—New.

Abstract: The Rural Outreach Benefits Counseling Program (Benefits Counseling Program) is authorized by section 330A(e) of the Public Health Service (PHS) Act (42 U.S.C. 254c(e)), as amended, to ''promote rural health care services outreach by expanding the delivery of health care services to include new and enhanced services in rural areas.'' The purpose of the 3-year Benefits Counseling Program is to expand outreach, education, and enrollment efforts to eligible uninsured and newly insured individuals and families in rural communities.

The overarching goals of this grant funding are to coordinate and conduct innovative outreach activities through a strong consortium in order to: (1) Identify and enroll uninsured individuals and families who are eligible for public health insurance, such as Medicare, Medicaid, and the Children's Health Insurance Program, and qualified health plans offered through Health Insurance Marketplaces and/or private health insurance plans in rural communities and (2) educate the newly insured individuals and families in rural communities about their health insurance benefits, help connect them to primary care and preventive services to which they now have access, and help them retain their health insurance coverage.

Need and Proposed Use of the Information: For this program, performance measures were drafted to provide data to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act (GPRA) of 1993. These measures cover the principal topic areas of interest to the Federal Office of Rural Health Policy (FORHP), including: (a) Access to care; (b) population demographics; (c) staffing; (d) consortium/network; (e) sustainability; and (f) benefits counseling process and outcomes. Several measures will be used for the Benefits Counseling Program. All measures will speak to FORHP's progress toward meeting the goals set.

Likely Respondents: The respondents will be recipients of the Rural Outreach Benefits Counseling Program grant funding.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review