DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1896]

Quality Metrics Site Visit Program for Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research Staff; Information Available to Industry; Extension of the Proposal Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of the proposal period.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is extending the proposal period for the ''Quality Metrics Site Visit Program for Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research Staff,'' published in the **Federal Register** of June 29, 2018. FDA is extending the proposal period to allow interested persons additional time to submit an electronic or written proposal.

DATES: FDA is extending the proposal period on the notice published June 29, 2018 (83 FR 30751). Submit either an electronic or written proposal by December 17, 2018 directly to Tara Gooen Bizjak or Stephen Ripley (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Tara Gooen Bizjak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2109, Silver Spring, MD 20993–0002, 301–796–3257, email: *Tara.Gooen@fda.hhs.gov,* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 29, 2018 (83 FR 30751), FDA announced the availability of a notice for industry entitled ''Quality Metrics Site Visit Program for Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research Staff.'' Interested persons were originally given until August 28, 2018, to submit a proposal to the Quality Metrics Site Visit Program per the notice. The Agency believes that extending the proposal period for an additional 120 days from the date of publication of this notice will allow adequate time for interested persons to submit proposals for FDA's consideration. The Site Visit Program is to provide experiential and firsthand learning opportunities to FDA staff involved in the development of the FDA Quality Metrics Program and to provide stakeholders with an opportunity to explain the advantages and challenges associated with implementing and managing a robust Quality Metrics Program. The program and information to be included in the proposal are explained more fully in the original notice.

II. Electronic Access

Persons with access to the internet may obtain the information about the FDA Quality Metrics for Drug Manufacturing Program, including this Quality Metric Site Visit Program, at *https://www.fda.gov/drugs/developmentapprovalprocess/manufacturing/ucm526869.htm.*

Dated: August 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–17783 Filed 8–16–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0279]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before October 16, 2018.

ADDRESSES: Submit your comments to *Sherette.Funn@hhs.gov* or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–New–60D and project title for reference, to *Sherrette.funn@hhs.gov,* or call the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Information Collection Request Title: 0990–0279—Extension Institutional Review Board Registration Form

Abstract: Assistant Secretary for Health, Office for Human Research Protections is requesting an extension on a currently approved information collection by the Office of Management and Budget, on the Protection of Human Subjects, on the Institutional Review Board (IRB) Form. The purpose of the IRB Registration Form is to provide a simplified procedure for institutions engaged in research conducted or supported by HHS to satisfy the (1) HHS regulations for the protection of human subjects at 45 CFR 46.103((b), 45 CFR 46.107, and 45 CFR 46, subpart E, Registration of Institutional Review Boards; and, the Food and Drug Administration (FDA) regulations for institutional review boards at 21 CFR 56.106.

Likely Respondents: Institutions or organizations operating IRBs that review human subjects research conducted or supported by HHS, or, in the case of FDA's requirements, each IRB in the United States that reviews clinical investigations regulated by FDA under sections 505(i) or 520(g) of the Federal Food, Drug and Cosmetic Act; and each IRB in the United States that reviews clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated products.