Dated: June 25, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) in the Food and Drug Administration (FDA or Agency) are announcing a 2018 CDER and CBER staff experiential learning site visit program specific to FDA's Quality Metrics Program. FDA is proposing this program, in part, in response to input from a variety of stakeholders over the past couple of years. The purpose of this 2018 Quality Metrics 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. This notice invites pharmaceutical companies interested in participating in this program to submit a Quality Metrics Site Visit proposal.

DATES: Submit either an electronic or written proposal to participate in this program by August 28, 2018. See section IV of this notice for information on what to include in such proposals.

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. 7268, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

More than a decade ago, FDA launched an initiative to encourage the implementation of a modern, risk-based pharmaceutical quality assessment system. As part of this initiative, and in recognition of the increasing complexity of pharmaceutical manufacturing, FDA developed a 21st century vision for manufacturing and quality with input from academia and industry. The desired state was described as follows: ''A maximally efficient, agile, flexible pharmaceutical manufacturing sector that reliably produces high-quality drug products without extensive regulatory oversight.'' [1]

There has been significant progress toward this vision in the intervening years as evidenced by programs and guidances from FDA around major initiatives such as pharmaceutical development and quality by design, quality risk management and pharmaceutical quality systems, process validation, and emerging technology, among others. These programs and guidances are intended to promote effective use of the modern pharmaceutical science and engineering principles and knowledge throughout the life cycle of a product.

FDA sought input from industry on the establishment of an FDA Quality Metrics Program as another mechanism to promote continual improvement in manufacturing quality. FDA has also consulted with other stakeholders to identify mutually useful and objective quality metrics. The Agency heard that it should perform further studies of existing quality metrics programs and conduct additional discussions with stakeholders. Based on this input, CDER and CBER are initiating this 2018 Quality Metrics Site Visit Program to assist the Agency in understanding existing programs. This voluntary site visit program is designed to offer experiential and firsthand learning opportunities to CDER and CBER staff involved in the development of FDA's 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. One goal of these visits is to provide CDER and CBER staff exposure to existing quality metrics programs through onsite visits, tour of operations, and discussions with establishments to assist staff in further developing FDA's Quality Metrics Program. Another goal is to provide a forum for industry to engage in the process and provide additional feedback into improving the FDA Quality Metrics Program.

[1] See ''FDA Pharmaceutical Quality Oversight: One Quality Voice'' at *https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM442666.pdf.*

II. The Site Visit Program

During a quality metrics site visit, CDER and CBER staff will observe how quality metrics data are gathered, collected, and reported to management. We anticipate 5 to 10 FDA representatives (involved in the development of FDA's Quality Metrics Program) would participate in a site visit taking place over a 1- to 2-day period. To facilitate the learning process, the host establishment may present overviews of the development and management of their quality metrics program. The presentation(s) will allow the participating establishments an opportunity to showcase technologies that support their program.

CDER and CBER encourage covered establishments, including establishments that do not perform physical manipulation of drugs, engaging in the development and manufacturing of both active pharmaceutical ingredients (small and large molecules) and drug products to submit quality metrics site visit proposals. A covered establishment is an owner or operator of an establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a covered drug product, or an active pharmaceutical ingredient (API) used in the manufacture of a covered drug product. CDER and CBER staff participating in this program will benefit by gaining a better understanding of current industry practices, processes, and procedures for quality metrics programs.

CDER and CBER identified a number of establishment types that are of particular interest to their staff. The following list identifies some examples of these establishments but is not intended to be exhaustive, mutually exclusive, or to limit industry response to the notice:

- Manufacturer of brand, generic, biotechnology, APIs, and non-application product(s) marketed under the over-the-counter (OTC) monograph system, and any combination of these products;
- contract development and manufacturing organizations;
- establishments with small and large portfolios; and
- establishments with past or current product availability issues (*e.g.,* history of a drug supply issue, recall).

The Quality Metrics Site Visit Program does not supplement or replace a regulatory inspection (*e.g.,* a preapproval inspection, pre-license inspection, or a surveillance inspection).

III. Site Selection

Selection of potential facilities will be based on the priorities developed for CDER and CBER staff training, the facility's current compliance status with FDA, and in consultation with the appropriate FDA district office. All travel expenses associated with this program will be the responsibility of FDA; therefore, selection will be based on the availability of funds and resources for the fiscal year. FDA will not provide financial compensation to the pharmaceutical site as part of this program.

IV. Proposals for Participation

Companies interested in offering a site visit or learning more about this site visit program should respond by submitting a proposal directly to Tara Gooen Bizjak or Stephen Ripley (see **FOR FURTHER INFORMATION CONTACT**). To aid in FDA's site selection and planning, your proposal should include the following information:

- A contact person;
- site visit location(s);
- Facility Establishment Identifier and Data Universal Numbering System numbers, as applicable;
- maximum number of FDA staff that can be accommodated during a site visit (maximum of 10),
- a description of the development, history, and ongoing management of the quality metrics program;
- a sample agenda outlining the proposed learning objectives and associated activities for the site visit; and
- preferred dates for a quality metrics site visit.

Proposals submitted without this minimum information will not be considered.

Dated: June 25, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1772]

Oncology Therapeutic Radiopharmaceuticals: Nonclinical Studies and Labeling Recommendations; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Oncology Therapeutic Radiopharmaceuticals: Nonclinical Studies and Labeling Recommendations.'' The purpose of this draft guidance is to assist sponsors in designing appropriate nonclinical studies before initiation of first-in-human (FIH) trials and through product approval. In addition, this draft guidance provides recommendations for product labeling, such as duration of contraception to minimize potential risk to a developing embryo/fetus and recommendations for lactating women to minimize potential risk to a nursing infant. This draft guidance intends to provide recommendations for nonclinical programs in a unique and challenging area of product development, provide a more consistent approach in nonclinical studies and product labeling, and reduce the conduct of nonclinical studies that are not informative for product use.

DATES: Submit either electronic or written comments on the draft guidance by August 28, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2018–D–1772 for ''Oncology Therapeutic Radiopharmaceuticals: Nonclinical Studies and Labeling Recommendations; Draft Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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