

heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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 Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, 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 that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Julia Beaver, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2100, Silver Spring, MD 20993-0002, 240-402-0489; 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

FDA is announcing the availability of a draft guidance for industry entitled "Hematologic Malignancy and Oncologic Disease: Considerations for Use of Placebos and Blinding in Randomized Controlled Clinical Trials for Drug Product Development." This draft guidance provides recommendations to industry regarding the use of placebos and blinding in randomized controlled clinical trials in development programs for drug or biological products for the treatment of hematologic malignancies and oncologic diseases regulated by CDER and CBER.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the use of placebos and blinding in randomized controlled clinical trials for drug product development for hematologic malignancy and oncologic disease. 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 collection of information in 21 CFR part 312 (Investigational New Drug Application) has been approved under OMB control number 0910-0014. The collections of information in 21 CFR parts 50 and 56 (Protection of Human Subjects: Informed Consent; Institutional Review Boards) have been approved under OMB control number 0910-0755.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <https://www.regulations.gov>.

Dated: August 21, 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-3030]

Site Visit Training Program for Office of Pharmaceutical Quality Staff; Information Available to Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Center for Drug Evaluation and Research (CDER) in the Food and Drug Administration (FDA) is announcing the Fiscal Year 2019 CDER Office of Pharmaceutical Quality (OPQ) Staff Experiential Learning Site Visit Program. The purpose of this document is to invite pharmaceutical companies interested in participating in this program to submit a site visit proposal to CDER's OPQ.

DATES: Submit either an electronic or written proposal to participate in this

program by November 23, 2018. See section IV of this document for information on what to include in such proposals.

FOR FURTHER INFORMATION CONTACT:

Janet Wilson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4642, Silver Spring, MD 20993-0002, 240-402-3969, email: CDEROPQSiteVisits@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A critical part of the commitment by CDER to make safe and effective high-quality drugs available to the American public is gaining an understanding of all aspects of a drug's development and commercial life cycle, including the variety of drug manufacturing operations. To support this commitment, CDER has initiated various training and development programs including the FY2019 Experiential Learning Site Visit program. This site visit program is designed to offer experiential and firsthand learning opportunities that will provide OPQ staff with a better understanding of the pharmaceutical industry and its operations, as well as the challenges that impact a drug's developmental program and commercial life cycle. The goal of these visits is to enhance OPQ staff exposure to the drug development and manufacturing processes in industry; therefore, a tour of pharmaceutical company facilities, including manufacturing and laboratory operations, is an integral part of the experience.

II. The Site Visit Program

In this site visit program, groups on average of 15 to 20 OPQ staff—who have experience in a variety of backgrounds, including science, medicine, statistics, manufacturing, engineering, testing, and project management—will observe operations of commercial manufacturing, pilot plants (if applicable), and testing over a 1- to 2-day period. To facilitate the learning process for OPQ staff, overview presentations by industry related to drug development, manufacturing and testing may be included.

OPQ encourages companies engaging in the development and manufacturing of both active pharmaceutical ingredients (small and large molecules) and drug products to respond. Please note that this site visit program is not intended to supplement or replace a regulatory inspection, e.g., a preapproval inspection, prelicense inspection, or a surveillance inspection.

OPQ staff participating in this program will benefit by gaining a better understanding of current industry practices, processes, and procedures. Participating sites will have an opportunity to showcase their technologies and their actual manufacturing and testing facilities.

Although observation of all aspects of drug development and production would be beneficial to OPQ staff, OPQ has identified a number of areas of particular interest to its staff. The following list identifies some examples of these areas but is not intended to be exhaustive, mutually exclusive, or to limit industry response:

- Drug products
 - Solutions, suspensions, emulsions, and semisolids
 - Modified- and immediate-release formulations
 - Drug-device combination products (e.g., inhalation products, transdermal systems, implants intended for drug delivery, and prefilled syringes)
- Active pharmaceutical ingredients manufactured by
 - Chemical synthesis
 - Fermentation
 - Biotechnology
- Design, development, manufacturing and controls
 - Engineering controls for aseptic processes
 - Novel delivery technologies
 - Hot melt extrusion
 - Soft-gel encapsulation
 - Lyophilization
 - Blow-Fill-Seal and isolators
 - Spray-drying
 - Process analytical technology, measurement systems, and real-time release testing
- Emerging technologies
 - Continuous manufacturing
 - 3-dimensional printing
 - Nanotechnology

III. Site Selection

Selection of potential facilities will be based on the priorities developed for OPQ 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 OPQ; therefore, selection will be based on the availability of funds and resources for the fiscal year. OPQ 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 Janet Wilson (see **DATES** and **FOR FURTHER INFORMATION CONTACT** sections of this document for more information). To aid in OPQ's site selection and planning, your proposal should include the information below:

- 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 20),
- A proposed agenda outlining the learning objectives and associated activities for the site visit,
- Maximum number of site visits (no more than 2) that your site would be willing to host by the close of the government fiscal year, September 30, 2019, and
- Proposed dates for each site visit (i.e. month and week).

Please note that the requested proposed agenda will be reviewed to determine the educational benefit to OPQ in conducting the visit, and selected sites may be asked to refine the agenda to maximize the educational benefit. After a site is selected, OPQ will communicate with the contact person for the site to determine the actual dates for the visit.

Proposals submitted without this minimum information will not be considered. Based on response rate and type of responses, OPQ may or may not consider alternative pathways to meeting our training goals.

Dated: August 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0567]

Designating Additions to the Current List of Tropical Diseases in the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes the Food and Drug Administration (FDA or Agency) to award priority review vouchers (PRVs) to tropical disease product applicants when the

applications meet certain criteria. The FD&C Act lists the diseases that are considered tropical diseases for purposes of obtaining PRVs and provides for Agency expansion of that list to include other diseases that satisfy the definition of "tropical diseases" as set forth in the FD&C Act. The Agency has determined that chikungunya virus disease, Lassa fever, rabies, and cryptococcal meningitis satisfy this definition and is therefore adding them to the list of designated tropical diseases whose product applications may result in the award of PRVs. Sponsors submitting certain drug or biological product applications for the prevention or treatment of chikungunya virus disease, Lassa fever, rabies, and cryptococcal meningitis may be eligible to receive a PRV if such applications are approved by FDA.

DATES: This order is effective August 24, 2018.

ADDRESSES: Submit electronic comments on additional diseases suggested for designation to <https://www.regulations.gov>. Submit written comments on additional diseases suggested for designation to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Katherine Schumann, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6242, Silver Spring, MD 20993-0002, 301-796-1300, Katherine.Schumann@fda.hhs.gov; or Office of Communication, Outreach and Development (OCOD), Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 1-800-835-4709 or 240-402-8010, ocod@fda.hhs.gov.

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