

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3397 .....	155	1.6903	262	0.5 (30 minutes) .....	131

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall decrease of 1,724 hours and a corresponding decrease of 3,448 responses. We attribute this program change to the restructuring of the Prescription Drug Use Fee Program fees. The FD&C Act, as amended by the Prescription Drug User Fee Amendments of 2017 (PDUFA VI), authorizes FDA to collect application fees for certain applications for the review of human drug and biological products and discontinued the supplement fee. This resulted in the removal of supplements from the Prescription Drug User Fee Cover Sheet, therefore reducing the burden for this collection of information.

Dated: August 20, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-18307 Filed 8-23-18; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2018-D-3092]

**Hematologic Malignancy and Oncologic Disease: Considerations for Use of Placebos and Blinding in Randomized Controlled Clinical Trials for Drug Product Development; Draft Guidance for Industry; Availability**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**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Hematologic Malignancy and Oncologic Disease: Considerations for Use of Placebos and Blinding in Randomized Controlled Clinical Trials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 This draft guidance provides recommendations to industry regarding the use of placebos and blinding in randomized controlled clinical trials in development programs for drug or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 the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).

**DATES:** Submit either electronic or written comments on the draft guidance by October 23, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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-3092 for Hematologic Malignancy and Oncologic Disease: Considerations for Use of Placebos and Blinding in Randomized Controlled Clinical Trials for Drug Product Development. 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 in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the

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](mailto: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.