4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-0787]

Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank; Guidance for Responsible Parties, Submitters of Certain Applications and Submissions to the Food and Drug Administration, and Food and Drug Administration Staff; 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 final guidance for industry and other responsible parties entitled "Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank; Guidance for Responsible Parties, Submitters of Certain Applications and Submissions to FDA, and FDA Staff." The guidance provides the current thinking of FDA's medical product Centers--the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health--regarding civil money penalties that may be assessed under the Federal Food, Drug, and Cosmetic Act (FD&C Act) for violations of the requirements to submit clinical trial registration and results information to the ClinicalTrials.gov data bank and certain certifications to FDA.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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-0787 for "Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank; Guidance for Responsible Parties, Submitters of Certain Applications and Submissions to FDA, and FDA Staff." 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.govinfo.gov/content/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 guidance to the Office of Good Clinical Practice (OGCP), Office of Clinical Policy and Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Patrick McNeilly, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5172, Silver Spring, MD 20993-0002, 301-796-2941.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and other responsible parties entitled "Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank; Guidance for Responsible Parties, Submitters of Certain Applications and Submissions to FDA, and FDA Staff." The guidance provides the current thinking of FDA's Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, and Center for Devices and Radiological Health (Center, or collectively Centers), regarding civil money penalties for responsible parties and/or submitters of certain applications and submissions to FDA regarding

drug products, biological products, and device products (submitters) who violate applicable FD&C Act (21 U.S.C. 301 *et seq*.) prohibitions relating to requirements under section 402(j) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)), including its implementing regulations in 42 CFR part 11, to submit clinical trial registration and results information to the ClinicalTrials.gov data bank and certain certifications to FDA.

The guidance is intended to address several questions. First, the guidance addresses how the Centers may identify whether responsible parties have failed to submit required clinical trial registration and/or results information to the ClinicalTrials.gov data bank or submitted false or misleading information to the data bank, and whether submitters have failed to submit the certification required by section 402(j)(5)(B) of the PHS Act to FDA or knowingly submitted a false certification to FDA. Second, the guidance addresses the circumstances under which a Center may decide to seek civil money penalties against a responsible party or submitter. Third, the guidance addresses the procedures that apply when a Center seeks civil money penalties; and fourth, the guidance addresses the civil money penalty amounts that may be assessed for: (1) failing to submit required clinical trial registration and/or results information to the ClinicalTrials.gov data bank, (2) knowingly submitting false or misleading clinical trial information to the data bank, (3) failing to submit the required certification to FDA, or (4) knowingly submitting a false certification to FDA.

In the *Federal Register* of September 21, 2018 (83 FR 47926), FDA announced the availability of the draft guidance. FDA received comments on the draft guidance and considered all comments in finalizing this guidance. FDA revised the guidance to clarify that FDA does not intend to include on its Lists of Inspectional Observations, Forms FDA 483, any inspectional observations regarding potential violations relating to the ClinicalTrials.gov data bank; however,

information that is collected by an investigator regarding potential violations of such requirements will be included in an Establishment Inspection Report and provided to the relevant Center for further evaluation. The guidance has also been revised to make clear that, in determining whether to seek civil money penalties, FDA intends to take into consideration any corrective action taken by a responsible party or submitter after receiving a Notice of Noncompliance. The guidance further explains that FDA intends to post Notices of Noncompliance on its website and to transmit the Notices of Noncompliance to the National Institutes of Health (NIH), so NIH can include the notice regarding noncompliance required under section 402(j)(5)(E) of the PHS Act in the ClinicalTrials.gov data bank. The guidance also provides some limited examples of applicable clinical trials of products that potentially may pose a higher risk to human subjects or applicable clinical trials of products intended to address significant public health need. In addition, editorial changes were made to the guidance to improve clarity. The guidance announced in this notice finalizes the draft guidance dated September 21, 2018.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on civil money penalties relating to the ClinicalTrials.gov data bank. 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. Paperwork Reduction Act of 1995

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required.

However, this guidance refers to previously approved collections of information. This collection of information is subject to review by OMB under the PRA. The collection of information referenced in this guidance is related to information required under section 402(j)(5)(B) of the PHS Act and has been approved under OMB control number 0910-0616.

III. Electronic Access

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

Dated: August 11, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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