
If you need special accommodations due to a disability, please contact Elizabeth Sanford (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance. Persons attending the meeting are advised that FDA is not responsible for providing access to electrical outlets.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. Login URL: https://www.adobe.com/go/connectpro

If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit https://www.adobe.com/go/connectpro_overview. FDA has verified the website addresses in this document, as of the date this document publishes in the Federal Register, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, FDA will post it at http://wcms-internet.fda.gov/news-events/fda-meetings-conferences-and-workshops/advancing-development-pediatric-therapeutics-adopt6-pediatric-clinical-trial-endpoints-rare.

Dated: October 4, 2019.

Lowell J. Schiller,
Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1428]

Agency Information Collection Activities: Submission for Office of Management and Budget Review; Comment Request: Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by November 12, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910–0827. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, PRASstaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910–0827—Extension

The Drug Quality and Security Act added section 503B to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b) creating a category of entities called “outsourcing facilities.” Outsourcing facilities, as defined in section 503B(d)(4) of the FD&C Act, are facilities that must meet all the requirements described in section 503B, including registering with FDA as an outsourcing facility and submitting regular reports identifying the drugs compounded by the outsourcing facility during the previous 6-month period. The first of these reports must be submitted upon initial registration as an outsourcing facility. Thereafter, semiannual product reports must be submitted, once during the month of June and once during the month of December, for as long as an establishment remains registered as an outsourcing facility.

In addition, drug products compounded in an outsourcing facility can qualify for exemptions from the FDA approval requirements in section 505 of the FD&C Act (21 U.S.C. 355) and the requirement to label products with adequate directions for use under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) if the requirements in section 503B are met.

To help respondents understand the statutory requirements, how we interpret them, and the associated information collection, we developed the guidance document entitled “Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.” The guidance is available from our website at: https://www.fda.gov/media/90173/download. The guidance explains that, once an entity has elected to register as an outsourcing facility, it must submit reports identifying the drugs compounded by the outsourcing facility. The guidance also communicates who must report, the format of the report, the content to include in each report, when to report, how reports are submitted to FDA, and the consequences of outsourcing facilities’ failure to submit reports.

In the Federal Register of July 17, 2019 (84 FR 34184), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We therefore estimate the burden of the information collection as follows:
The 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 entitled “Investigational In Vitro Diagnostics in Oncology Trials: Streamlined Submission Process for Study Risk Determination; 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 final guidance for industry entitled “Investigational In Vitro Diagnostics in Oncology Trials: Streamlined Submission Process for Study Risk Determination.” This guidance, developed by the Oncology Center of Excellence at FDA, describes an optional streamlined submission process to determine whether use of an investigational in vitro diagnostic in an oncology clinical trial is considered significant risk, nonsignificant risk, or exempt from investigational device exemption requirements. In the streamlined process, the sponsor submits all information about the oncology trial (including information about the investigational in vitro diagnostic) to the investigational new drug application (IND). As part of IND review, the Center for Biologics Evaluation and Research (CBER) works with the Center for Drug Evaluation and Research (CDER), or CDER or CBER works with the Center for Devices and Radiological Health (CDRH), as appropriate, to determine if the investigational in vitro diagnostic is significant risk, nonsignificant risk, or exempt.

DATES: The announcement of the guidance is published in the Federal Register on October 10, 2019.

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