events/fda-meetings-conferences-and-workshops/advancing-development-pediatric-therapeutics-adept-6-pediatric-clinical-trial-endpoints-rare.

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://collaboration.fda.gov/adept6/.*

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-adept-6-pediatric-clinical-trial-endpoints-rare.*

Dated: October 4, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–22187 Filed 10–9–19; 8:45 am]

BILLING CODE 4164–01–P

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, *PRAStaff@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:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Product reporting for compounding outsourcing facilities	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Initial product reports	75	1.01	76	2	152
Waiver request from electronic submission of initial product reports	1	1	1	1	1
June product reports	75	1.01	76	0.5	38
December product reports	75	1.01	76	0.5	38
Waiver request from electronic submission of product reports	1	1	1	1	1
Total					230

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on current data for outsourcing facilities, we estimate that 75 outsourcing facilities will submit an initial report identifying all drugs compounded in the facility in the previous 6 months. For the purposes of this estimate, each product's structured product labeling (SPL) submission is considered a separate response, and therefore each facility's product report will include multiple responses. Taking into account that a particular product that is compounded into different strengths from different sources of active ingredient can be reported in a single SPL response, we estimate that each facility will average 76 products. Our estimate is based on current product reporting data.

We expect each product report will consist of multiple SPL responses per facility and estimate that preparing and submitting this information electronically may take up to 2 hours for each initial SPL response. We also estimate that the 75 registered outsourcing facilities will submit a report twice each year identifying all drugs compounded at the facility in the previous 6 months.

As stated above, we estimate on average 76 SPL responses per facility and that preparing and submitting this information electronically will take approximately 30 minutes per response. We have reduced our burden estimate for semiannual product submissions because outsourcing facilities can save each SPL response once initially created and submitted. For subsequent reports, an outsourcing facility may resubmit the same file(s) after changing the RootID and version number (both SPL metadata), effective date (to identify the reporting period), and the number of units produced, along with other data as appropriate, to appropriate values for the reporting period. Furthermore, if a product was not compounded during a particular reporting period, no SPL response needs be sent for that product during that reporting period.

We expect to receive no more than one waiver request, each, from the electronic submission process for initial product reports and semiannual reports, and that each waiver request will take 1 hour to prepare and submit.

Based on submissions we have received, we have reduced the number of responses significantly since our original estimate establishing the collection. This results in an overall reduction to the information collection by 36,072 hours.

Dated: October 4, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–22189 Filed 10–9–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–0944]

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