Our estimated burden for the information collection reflects an overall increase of 467,907 hours and a corresponding increase in responses. We attribute part of this adjustment in the total hours to an increase in the number of submissions that we have received under 601.12(b)(1) and (3), (e), and (f)(4), and 601.45 over the last few years, which accounts for an increase of 467,549 hours. An additional increase of 358 hours is associated with certifications on Form FDA 3674.

Dated: October 27, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–23728 Filed 10–31–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2016–N–3535]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Special Protocol Assessment; Guidance for Industry

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection in the guidance for industry entitled ''Special Protocol Assessment'' (Revision 1).

**DATES:** Either electronic or written comments on the collection of information must be submitted by January 3, 2023.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 3, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

*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. 2016–N–3535 for ''Special Protocol Assessment'' (Revision 1). Received comments, those filed in a timely manner (see **ADDRESSES**), 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, 240–402–7500.

• 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, 240–402–7500.

**FOR FURTHER INFORMATION CONTACT:** Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this

requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Special Protocol Assessment**

**OMB Control Number 0910–0470—Extension**

This information collection request supports Agency guidance entitled ''Special Protocol Assessment'' (Revision 1) (2018) that describes Agency procedures to evaluate issues related to the adequacy (*e.g.,* design, conduct, analysis) of certain proposed studies. The guidance (available at *https://www.fda.gov/media/97618/download*) describes procedures for sponsors to request special protocol assessment and for FDA to act on such requests. The guidance provides information on how FDA interprets and applies provisions of the Food and Drug Administration Modernization Act and specific Prescription Drug User Fee Act (PDUFA) goals for special protocol assessment associated with the development and review of PDUFA products. The guidance describes the following two collections of information: (1) the submission of a notice of intent to request special protocol assessment of a carcinogenicity protocol; and (2) the submission of a request for special protocol assessment.

**I. Notification for a Carcinogenicity Protocol**

As described in the guidance, a sponsor interested in an FDA assessment of a carcinogenicity protocol should notify the appropriate division in FDA's Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) of an intent to request special protocol assessment at least 30 days prior to submitting the request. With such notification, the sponsor should submit relevant background information so that FDA may review reference material related to carcinogenicity protocol design before receiving the carcinogenicity protocol.

**II. Request for Special Protocol Assessment**

The guidance asks that a request for special protocol assessment be submitted as an amendment to the investigational new drug application (IND) for the underlying product and that it be submitted to FDA in triplicate along with Form FDA 1571.[1] The guidance also suggests that the sponsor submit the cover letter to a request for special protocol assessment via Fax to the appropriate division in CDER or CBER. FDA regulations (21 CFR 312.23(d)) state that information provided to us as part of an IND is to be submitted in triplicate and with the appropriate cover form (Form FDA 1571). An IND is submitted to FDA under existing regulations in part 312 (21 CFR part 312), which specifies the information that manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of investigational drugs and biological products. The information collection requirements resulting from the preparation and submission of an IND under part 312 have been estimated by FDA, and the reporting and recordkeeping burden has been approved by OMB under OMB control number 0910–0014.

FDA suggests that the cover letter to the request for special protocol assessment be submitted via Fax to the appropriate division in CDER or CBER to enable FDA staff to prepare for the arrival of the protocol for assessment. FDA recommends that a request for special protocol assessment be submitted as an amendment to an IND for two reasons: (1) to ensure that each request is kept in the administrative file with the entire IND and (2) to ensure that pertinent information about the request is entered into the appropriate tracking databases. Use of the information in FDA's tracking databases enables the appropriate Agency official to monitor progress on the evaluation of the protocol and to ensure that appropriate steps will be taken in a timely manner.

The guidance recommends that the following information should be submitted to the appropriate CBER or CDER division with each request for special protocol assessment so that the division may quickly and efficiently respond to the request:

- Questions to FDA concerning specific issues regarding the protocol.
- All data, assumptions, and information needed to permit an adequate evaluation of the protocol, including: (1) the role of the study in the overall development of the drug; (2) information supporting the proposed trial, including power calculations, the choice of study endpoints, and other critical design features; (3) regulatory outcomes that could be supported by the results of the study; (4) final labeling that could be supported by the results of the study; and (5) for a stability protocol, product characterization, and relevant manufacturing data.

*Description of Respondents:* A sponsor, applicant, or manufacturer of a drug or biologic product that FDA regulates under the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act (42 U.S.C. 262) requesting special protocol assessment.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Information collection activity; guidance document section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Notification for Carcinogenicity Protocols; Sections III. and V | 99 | 0.94 | 93 | 8 | 744 |
| Requests for Special Protocol Assessment Reports; Sections IV. and VI | 100 | 1.54 | 154 | 15 | 2,310 |

[1] Form FDA 1571 is available at *https://www.fda.gov/media/116608/download.*

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

| Information collection activity; guidance document section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Total | | | 247 | | 3,054 |

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

*Burden Estimate:* Table 1 provides an estimate of the annual reporting burden for notifications for a carcinogenicity protocol and requests for a special protocol assessment.

*Notification for a Carcinogenicity Protocol:* Based on the number of notifications for carcinogenicity protocols and the number of carcinogenicity protocols currently submitted to CDER and CBER, CDER estimates that it will receive approximately 92 notifications of an intent to request special protocol assessment of a carcinogenicity protocol per year from approximately 98 sponsors. CBER estimates that it will receive approximately one notification of an intent to request special protocol assessment of a carcinogenicity protocol per year from approximately one sponsor. The hours per response, which is the estimated number of hours that a sponsor would spend preparing the notification and background information to be submitted in accordance with the guidance, is estimated to be approximately 8 hours.

*Requests for Special Protocol Assessment:* Based on the number of requests for special protocol assessment currently submitted to CDER and CBER, CDER estimates that it will receive approximately 152 requests for special protocol assessment per year from approximately 98 sponsors. CBER estimates that it will receive approximately two requests from approximately two sponsors. The hours per response is the estimated number of hours that a respondent would spend preparing the information to be submitted with a request for special protocol assessment, including the time it takes to gather and copy questions to be posed to the Agency regarding the protocol and data, assumptions, and information needed to permit an adequate evaluation of the protocol. Based on our experience with these submissions, we estimate approximately 15 hours on average would be needed per response.

The information collection reflects an adjustment decrease in burden by 196 hours. We attribute this adjustment to a decrease in the number of notifications for carcinogenicity protocols and an increase in the number of requests for special protocol assessment reports we received over the last few years.

Dated: October 25, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–23727 Filed 10–31–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2022–D–0760]**

### Measuring Growth and Evaluating Pubertal Development in Pediatric Clinical Trials; 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 ''Measuring Growth and Evaluating Pubertal Development in Pediatric Clinical Trials.'' The purpose of this draft guidance is to outline the most appropriate methods for measuring and recording growth and evaluating pubertal development for drugs or biological products in development for pediatric use when such an assessment is necessary to support safety. This draft guidance is intended to encourage a consistent approach to collecting interpretable and accurate growth and pubertal development data. This draft guidance does not address use of growth or pubertal development data to support primary evidence of efficacy in growth disorders and does not address evaluation of nutritional status.

**DATES:** Submit either electronic or written comments on the draft guidance by January 3, 2023 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–2022–D–0760 for ''Measuring Growth and Evaluating Pubertal Development in Pediatric Clinical Trials.'' 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, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be