designation and provides examples of surrogate endpoints and intermediate clinical endpoints used to support accelerated approval.

The information collection resulting from requests for priority review designation and breakthrough therapy designation is set forth in rows 1 and 2 of table 1 and is approved by the Office of Management and Budget (OMB) under control number 0910–0765. The information collection resulting from requests for accelerated approval is approved by OMB under control numbers 0910–0001 and 0910–0338.

The provisions of the guidance relating to fast track development and other issues such as serious condition and unmet medical need replace the guidance entitled ''Fast Track Drug Development Programs—Designation, Development, and Application Review.'' Consequently, the information collection resulting from the guidance ''Fast Track Drug Development Programs—Designation, Development, and Application Review'' (OMB control number 0910–0389) is now being incorporated into OMB control number 0910–0765 (guidance for industry ''Expedited Programs for Serious Conditions—Drugs and Biologics'').

A sponsor or applicant who seeks fast track designation is required to submit a request to the Agency showing that the drug product: (1) Is intended for a serious or life-threatening condition and (2) has the potential to address an unmet medical need. The Agency expects that most information to support a designation request will have been gathered under existing requirements for preparing an investigational new drug (IND), new drug application (NDA), or biologic license application (BLA). If such information has already been submitted to the Agency, the information may be summarized in the fast track designation request. A designation request should include, where applicable, additional information not specified elsewhere by statute or regulation. For example, additional information may be needed to show that a product has the potential to address an unmet medical need where an approved therapy exists for the serious or life-threatening condition to be treated. Such information may include clinical data, published reports, summaries of data and reports, and a list of references. The amount of information and discussion in a designation request need not be voluminous, but it should be sufficient to permit a reviewer to assess whether the criteria for fast track designation have been met.

After the Agency makes a fast track designation, a sponsor or applicant may submit a premeeting package that may include additional information supporting a request to participate in certain fast track programs. The premeeting package serves as background information for the meeting and should support the intended objectives of the meeting. As with the request for fast track designation, the Agency expects that most sponsors or applicants will have gathered such information to meet existing requirements for preparing an IND, NDA, or BLA. These may include descriptions of clinical safety and efficacy trials not conducted under an IND (*e.g.,* foreign studies) and information to support a request for accelerated approval. If such information has already been submitted to FDA, the information may be summarized in the premeeting package.

The Agency estimates the total annual number of respondents submitting requests for fast track designation is approximately 140, and the number of requests received is approximately 187 annually. FDA estimates that the number of hours needed to prepare a request for fast track designation is approximately 60 hours per request (row 3 in table 1).

Of the requests for fast track designation made per year, the Agency granted approximately 132 requests from 107 respondents, and for each of these granted requests, a premeeting package was submitted to the Agency. FDA estimates that the preparation hours are approximately 100 hours per premeeting package (row 4 in table 1).

The guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 202.1 and 21 CFR parts 314, and 601, and sections 505(a), 506(a)(1), 735, and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a), 356(a)(1), 379(g), and 379(h)) have been approved under OMB control numbers 0910–0686, 0910–0001, 0910–0338, 0910–0014, and 0910–0297.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Guidance for Industry: Expedited Programs for Serious Conditions—Drugs and Biologics	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Priority review designation request	48	1.7	82	30	2,400
Breakthrough therapy designation request	87	1.29	113	70	7,910
Fast track designation request	140	1.33	187	60	11,220
Fast track premeeting packages	107	1.23	132	100	13,200
Total					34,730

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

The data pertaining to fast track designation (last two rows of table 1) has changed since the last OMB approval.

Dated: November 2, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–24296 Filed 11–7–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6100]

Intent To Review an Analysis Data Reviewer's Guide; Notice of Availability, Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; request for comments.

SUMMARY: The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), is establishing a public docket to collect comments related to a proposed Analysis Data Reviewer's Guide (ADRG) template. As part of FDA's ongoing collaboration with the Pharmaceutical Users Software Exchange (PhUSE), an

independent, non-profit consortium addressing computational science issues, a PhUSE working group developed the PhUSE ADRG template. The purpose of this review is to evaluate the template and determine whether FDA will recommend its use either as is, or in a modified form, for regulatory submissions of study data. FDA is seeking public comment on the use of the PhUSE ADRG template for regulatory submissions.

DATES: Although you can comment on the PhUSE ADRG template at any time, to ensure that the Agency considers your comments in this review, please submit either electronic or written comments by January 8, 2018.

ADDRESSES: You may submit comments 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–2017–D–6100 for ''Intent to Review an Analysis Data Reviewer's Guide Template.'' 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.

FOR FURTHER INFORMATION CONTACT: Crystal Allard, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 1518, Silver Spring, MD 20993–0002, 301–796–8856, *crystal.allard@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is a participating member of PhUSE, an independent, non-profit consortium of academic, regulatory, non-profit, and private sector entities. PhUSE provides a global platform for the discussion of topics encompassing the work of biostatisticians, data managers, statistical programmers, and e-clinical information technology professionals, with the mission of providing an open, transparent, and collaborative forum to address computational science issues. As part of this collaboration, PhUSE working groups develop and periodically publish proposals for enhancing the review and analysis of human and animal study data submitted to regulatory agencies. You can learn more about PhUSE working groups at *http://www.phuse.eu/cs-working-groups.aspx.* (FDA has verified the Web site addresses as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.)

In December 2014, FDA published the Study Data Technical Conformance Guide (the Guide, available at *https://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm*), which contains technical recommendations to sponsors for the submission of animal and human study data and related information in a standardized electronic format. In section 2.3 of the Guide, FDA recommends that sponsors should include a plan (*e.g.,* in the New Drug Application (NDA)) describing the submission of standardized study data to FDA. The FDA's Analysis Data Resources Web page provides recommendations for preparing an ADRG.

FDA now intends to review the PhUSE ADRG template, a deliverable of the working group effort described previously in this document, with the potential result that FDA could recommend the use of the template in its current form, or in a modified form, for use in the regulatory submission of study data in conformance with the Guide. FDA invites public comment on all matters regarding the use of the PhUSE ADRG template.

II. Electronic Access

The PhUSE ADRG template is available at: *http://www.phusewiki.org/wiki/index.php?title=Analysis_Data_Reviewer%27s_Guide.*

Dated: November 1, 2017.

Lauren Silvis,

Chief of Staff.

[FR Doc. 2017–24237 Filed 11–7–17; 8:45 am]

BILLING CODE 4164–01–P