

preliminary admissibility assessment of the associated products and firms. This submission typically contains the information FDA requests for multiple products (*i.e.*, the respondent wishes to file weekly entries for multiple products and submits the information for each product together). Generally, submissions involving multiple products are significantly less burdensome on a per-product basis. We estimate that the burden for each product in a WEF submission is approximately 52.5 minutes, for a total of 13.125 hours annually. Depending on the product and scale of submission, this estimated burden can fall to as low as 15 minutes per product. The reason why this burden can be significantly higher than an ACE submission is that the WEF submission is done manually, typically through a spreadsheet. Filers submitting in ACE typically use software that is developed to specifically automate and expedite the entry submission process and allows filers to automatically upload entry information. While the WEF submission includes an initial one-time submission burden, we expect reduced burden over a long term because filers can subsequently submit one entry covering multiple withdrawals from the FTZ in any given seven-day period.

Finally, since developing and implementing ITACS we believe that most respondents to the information collection have realized the one-time burden associated with creating an account and we have therefore adjusted our estimate downward by 2,500 hours. At the same time, we retain our estimate that 500 new accounts will be established annually for a total of 250 burden hours.

Cumulatively these changes and adjustments result in a reduction in annual responses by 40,112,208, and an increase in burden hours by 124,891. These changes and adjustments reflect the realization of one-time burden associated with conforming to new CBP electronic reporting requirements since last OMB approval of the information collection that we believe no longer applies, together with the consolidation of related information collection activities associated with ITACS.

Dated: December 30, 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-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, Agency, or we) 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 April 2018 guidance for industry entitled “Special Protocol Assessment” (Revision 1).

**DATES:** Submit either electronic or written comments on the collection of information by March 3, 2020.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 3, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 3, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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; Guidance for Industry.” 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.

- **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:** 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](mailto:PRASStaff@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 approval request is for the 2018 FDA guidance for industry, “Special Protocol Assessment” (Revision 1) (83 FR 16367, April 16, 2018), that describes Agency procedures to evaluate issues related to the adequacy (e.g., design, conduct, analysis) of certain proposed studies. A copy of the guidance is available from our website at <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>. The guidance 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 of 1997 and the specific Prescription Drug User Fee Act of 1992 (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 with Form FDA 1571 (<https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/>

[UCM083533.pdf](#)) attached. 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 Center with each request for special protocol assessment so that the Center 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.

*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 188 notifications of an intent to request special protocol assessment of a carcinogenicity protocol per year from approximately 105 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 108 requests for special protocol assessment per year from approximately 105 sponsors. CBER estimates that it will receive approximately eight requests from approximately eight 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.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Notification for Carcinogenicity Protocols .....	106	1.78	189	8	1,510
Requests for Special Protocol Assessment Reports .....	113	1.66	116	15	1,740
<b>Total .....</b>			<b>305</b>		<b>3,250</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The information collection reflects an adjustment in burden by 608 hours. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: December 30, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Countermeasures Injury Compensation Program OMB No. 0915-0334—Extension**

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for

review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA’s ICR only after the 30 day comment period for this Notice has closed.

**DATES:** Comments on this ICR should be received no later than February 3, 2020.

**ADDRESSES:** Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA\_submission@omb.eop.gov* or by fax to 202-395-5806.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443-1984.

**SUPPLEMENTARY INFORMATION:**

*Information Collection Request Title:* Countermeasures Injury Compensation Program OMB No. 0915-0334—Extension.

*Abstract:* This is a request for continued OMB approval of the information collection requirements for the Countermeasures Injury Compensation Program (CICP) for

Program). The CICP, within the Division of Injury Compensation Programs (DICP), Healthcare Systems Bureau, HRSA, administers this compensation program as specified by the Public Readiness and Emergency Preparedness Act of 2005 (PREP Act).

The Secretary of HHS (Secretary) can issue a PREP Act declaration. When issued, the purpose of a declaration is to identify a disease, health condition, or a threat to health that is currently, or may in the future constitute, a public health emergency. The Secretary’s declaration may recommend and encourage the development, manufacturing, distribution, dispensing, and administration or use of one or more covered countermeasures (*e.g.*, anthrax vaccine) to treat, prevent, or diagnose the disease, condition, or threat specified in the declaration.

A 60-day notice was published in the **Federal Register** on July 16, 2019, vol. 84, No. 136; pp. 33954-55. There were no public comments.

*Need and Proposed Use of the Information:* The CICP provides compensation to eligible individuals who suffer serious injuries directly caused by a covered countermeasure administered or used pursuant to a PREP Act Declaration or to their estates and/or to certain survivors.