TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR part 1271; human cells, tissues, and cellular and tissue-based products	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
1271.55(a)	1,632	1,589.715	2,594,415	0.5 (30 minutes)	1,297,208
1271.60(c) and (d)(2)	1,611	355.06	572,000	0.5 (30 minutes)	286,000
1271.290(c)	2,109	1,163.781	2,454,415	0.083 (5 minutes)	203,716
1271.290(f)	2,109	1	2,109	1	2,109
1271.370(b) and (c)	2,109	1,163.781	2,454,415	0.25 (15 minutes)	613,604
Total					2,402,637

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Rounded to the nearest whole number.

Our estimated burden for the information collection reflects an overall increase of 628,585 hours (111 reporting burden hours; 305,118 recordkeeping hours; and 323,356 disclosure burden hours) and a corresponding increase of annual responses, annual records, and annual disclosures. We attribute this adjustment to an increase in the number of HCT/P establishments and an increase in the number of HCT/Ps distributed over the past few years.

Dated: March 26, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–06981 Filed 4–2–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0487]

Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

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 collection of information for the ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.''

DATES: Submit either electronic or written comments on the collection of information by June 2, 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 June 2, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 2, 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. FDA–2014–N–0487 for ''Agency Information Collection Actitivites; Proposed Collection; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.'' 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.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.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *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.

Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

OMB Control Number 0910–0697—Extension

The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative, and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address the following: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

Respondents to this collection of information cover a broad range of stakeholders who have specific characteristics related to certain products or services regulated by FDA. These stakeholders include members of the general public, healthcare professionals, the industry, and other stakeholders who are related to a product under FDA's jurisdiction.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Focus groups	800	1	800	1.75	1,400
Customer comment cards/forms	1,325	1	1,325	0.25 (15 minutes)	331.25
Small discussion groups	800	1	800	1.75	1,400
Customer satisfaction surveys	12,000	1	12,000	0.33 (20 minutes)	3,960
Total					7,091.25

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: March 24, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–06992 Filed 4–2–20; 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; Submission for Office of Management and Budget Review; Comment Request; Special Protocol Assessment; Guidance for Industry

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: Submit written comments (including recommendations) on the collection of information May 4, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0470. 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.

Special Protocol Assessment

OMB Control Number 0910–0470—Revision

This information collection request supports Agency guidance entitled ''Special Protocol Assessment'' (Revision 1) (83 FR 16367, April 16, 2018), which describes procedures FDA uses 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