TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Agreement and labeling requirements, 801.150(e)	100	20	2,000	4	8,000

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

Our estimated burden for the information collection reflects an overall increase of 900 total hours and a corresponding increase of 400 records/disclosures. We attribute this increase to an increase in the number of agreements that we have seen in inspection data received over the last few years.

Dated: August 7, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17477 Filed 8–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0403]

Agency Information Collection Activities; Proposed Collection; Comment Request; Protection of Human Subjects; Informed Consent; and Institutional Review Boards

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 provisions found in Agency regulations pertaining to the protection of human subjects and responsibilities of institutional review boards (IRBs).

DATES: Submit either electronic or written comments on the collection of information by October 15, 2019.

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 October 15, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 15, 2019. 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–2013–N–0403 for ''Protection of Human Subjects; Informed Consent; and Institutional Review Boards.'' 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, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), 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.

Protection of Human Subjects; Informed Consent; and Institutional Review Boards—21 CFR Parts 50 and 56

OMB Control Numbers 0910–0755 and 0910–0130—Revision

This information collection supports Agency regulations pertaining to the protection of human subjects, informed consent, and responsibilities of IRBs as set forth in parts 50 and 56 (21 CFR parts 50 and 56). Parts 50 and 56 apply to all clinical investigations regulated by FDA under sections 505(i) and 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i) and 360j(g), respectively), as well as clinical investigations that support applications for research or marketing permits for products regulated by FDA. The regulations in parts 50 and 56 are intended to protect the rights and safety of subjects involved in investigations filed under sections 403, 406, 409, 412, 413, 503, 505, 510, 513–515, 520, 531–539, 541, 542, 701, and 721 of the FD&C Act (21 U.S.C. 343, 346, 348, 350a, 350b, 353, 355, 360, 360c, 360c–1, 360d, 360e, 360j, 360hh–360pp, 360rr, 360ss, 371, and 379e) and section 351 of the Public Health Service Act (42 U.S.C. 262). The regulations also contain the standards for composition, operation, and responsibilities of IRBs that review clinical investigations regulated by FDA.

I. Part 50—Protection of Human Subjects

With few exceptions, no investigator may involve a human being as a subject in FDA-regulated research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. Basic elements of informed consent are set forth in § 50.25 (21 CFR 50.25) and include a statement of the purpose and duration of a subject's participation in the research, as well as a description of the procedures to be followed, risks, benefits, experimental nature, contact information, that participation is voluntary, and additional elements as may be appropriate. Exceptions to these requirements are governed by § 50.23 (21 CFR 50.23), which requires both investigator and physician to certify in writing that necessary elements for exception from general requirements have been satisfied, and § 50.24 (21 CFR 50.24), which covers exception from informed consent requirements for emergency research. In accordance with § 50.27 (21 CFR 50.27), informed consent must be documented.

II. Part 56—Institutional Review Boards

The general standards for the composition, operation, and responsibility of an IRB are set forth in part 56. Administrative activities are also covered and documentation that must be prepared and maintained is identified. Required recordkeeping includes documentation pertaining to written procedures, committee membership, meeting minutes, correspondence, as well as other functional and operational aspects of the IRB. Finally, the regulations describe administrative actions for non-compliance, including both disqualification of IRBs or IRB parent institutions, as well as reinstatement and alternative and additional actions.

On our own initiative, we are revising the information collection by consolidating the information collection currently approved under OMB control number 0910–0130 with the information collection currently approved under OMB control number 0910–0755 pertaining to human subject protection and IRB responsibilities. Because of the related nature of the information collections and the applicable regulations in parts 50 and 56, we believe taking this action will improve our operational efficiency.

We estimate the annual burden for the collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
50.24; exceptions from informed consent for emergency research.	8	3	24	1	24
50.25; elements of informed consent—required statements.	2,520	40	100,800	0.5 (30 minutes)	50,400
50.27; documentation of informed consent	2,520	40	100,800	0.5 (30 minutes)	50,400
56.109(d); written statement about minimal risk research when documentation of informed consent is waived.	2,520	2	5,040	0.5 (30 minutes)	2,520
56.109(e); written notification to approve or disapprove research.	2,520	40	100,800	0.5 (30 minutes)	50,400

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

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
56.113; suspension of research	2,520	1	2,520	0.5 (30 minutes)	1,260
56.120(a); IRB response to lesser administration actions for noncompliance.	7	1	7	10	70
56.123; reinstatement of an IRB or an institution.	1	1	1	5	5
Total					155,079

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

Based on a review of data, there are currently 2,520 IRBs overseeing FDA-regulated clinical research. We have revised the table to list only one requirement per row, rather than estimating the combination of several requirements. The estimated burden resulted in an increase from 1 hour to 1.5 hours when these combined requirements were estimated separately. We believe this is a more accurate measure of the cumulative time necessary for these activities. We invite comment on this estimate.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
56.115; IRB records	2,520	14.6	36,792	40	1,471,680

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

We assume each of the 2,520 IRBs meets an average of 14.6 times annually and that approximately 40 hours of person-time per meeting are required to meet the requirements of the regulation. We have reduced the average burden per record from 100 hours to 40 hours because we believe the original estimate of 100 hours has decreased with the use of electronic recordkeeping and new technologies available to maintain records. We request comments on this revision.

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

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
56.109(g) IRB written statement about public disclosures to sponsor of emergency research under 50.24	8	2	16	1	16

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

For the third-party disclosure burden, we estimate that eight IRBs per year will receive a request to review emergency research under § 50.24. We estimate that it will take an IRB approximately 1 hour to prepare each written statement, for a total of 2 hours per study. The total annual third-party disclosure burden for IRBs to fulfill this requirement is estimated at 16 hours.

Dated: August 6, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17462 Filed 8–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–2479]

Gastroparesis: Clinical Evaluation of Drugs for Treatment; 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 ''Gastroparesis: Clinical Evaluation of Drugs for Treatment.'' This draft guidance is intended to provide the FDA's current thinking regarding clinical trial design and clinical endpoint assessments to support development of drugs for the treatment of diabetic and idiopathic gastroparesis. This draft guidance replaces the draft guidance for industry of the same name issued July 23, 2015.

DATES: Submit either electronic or written comments on the draft guidance by October 15, 2019 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.