

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

<sup>1</sup> 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 <sup>1</sup>

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

<sup>1</sup> 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 <sup>1</sup>

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

<sup>1</sup> 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.*

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**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.

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-2015-D-2479 for "Gastroparesis: Clinical Evaluation of Drugs for Treatment." 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Juli Tomaino, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5373, Silver Spring, MD 20993-0002, 301-796-8812.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Gastroparesis: Clinical Evaluation of Drugs for Treatment." The purpose of this draft guidance is to assist sponsors in the clinical 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 (80 FR 43781). This draft was updated to address public comments received in 2015 and to reflect FDA's current

thinking on the development of clinical outcome assessment tools and statistical considerations for use of those tools as a measure of the primary and secondary efficacy endpoints.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the FDA's current thinking of FDA on "Gastroparesis: Clinical Evaluation of Drugs for Treatment." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

##### II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910-0014 and 0910-0001, respectively.

##### III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs> or <https://www.regulations.gov>.

Dated: August 8, 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-2017-D-2163]

#### Child-Resistant Packaging Statements in Drug Product Labeling; 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 final guidance for industry entitled "Child-Resistant Packaging Statements in Drug Product Labeling." This guidance is intended to assist applicants,