TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1] [2]

Type of respondent/survey	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
General Public					
Individual indepth interviews	420	1	420	0.75 (45 minutes)	315
General public focus group interviews.	288	1	288	1.50 (1 hour, 30 minutes)	432
Intercept interviews: central location	200	1	200	0.25 (15 minutes)	50
Intercept interviews: telephone	4,000	1	4,000	0.08 (5 minutes)	320
Self-administered surveys	2,400	1	2,400	0.25 (15 minutes)	600
Gatekeeper reviews	400	1	400	0.50 (30 minutes)	200
Omnibus surveys	1,200	1	1,200	0.17 (10 minutes)	204
Total (general public)					2,121
Healthcare Professional					
Healthcare professional individual indepth interviews.	72	1	72	0.75 (45 minutes)	54
Healthcare professional focus group interviews.	144	1	144	1.50 (1 hour, 30 minutes)	216
Total (healthcare professional)					270
Total (overall)					2,391

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded.

Over the next 3-year approval period, we anticipate increasing our capability to conduct more communication surveys, which aligns with CDRH's strategic priorities. We have adjusted our burden estimates accordingly. Additionally, we have added an estimated hour burden for ''healthcare professional individual indepth interviews.'' These changes reflect an overall increase of 315 burden hours and a corresponding increase of 276 responses annually.

Dated: October 27, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–23781 Filed 11–1–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–2336]

Assessing User Fees Under the Over-the-Counter Monograph Drug User Fee Program; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Assessing User Fees Under the Over-the-Counter Monograph Drug User Fee Program.'' This guidance provides stakeholders with information regarding FDA's implementation of the Over-the-Counter Monograph Drug User Fee Program authorized under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the draft guidance by January 3, 2023 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 guidances 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–2022–D–2336 for ''Assessing User Fees Under the Over-the-Counter Monograph Drug User Fee Program.'' 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, 240–402–7500.

- 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, 240–402–7500.

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

Submit written requests for single copies of this 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: Over-the-Counter Monograph Drug User Fee Staff, Division of User Fee Management, Office of Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Silver Spring, MD 20993, 301–796–7900, *CDERCollections@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Assessing User Fees Under the Over-the-Counter Monograph Drug User Fee Program.'' This guidance provides stakeholders with information regarding FDA's implementation of the Over-the-Counter Monograph Drug User Fee Program. On March 27, 2020, new provisions were added to the FD&C Act (21 U.S.C. 9) by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136). Among these new FD&C Act provisions were sections 744L (21 U.S.C. 379j–71) and 744M (21 U.S.C. 379j-72), which authorize FDA to assess and collect user fees from qualifying manufacturers of over-the-counter (OTC) monograph drugs and submitters of OTC Monograph Order Requests (OMOR), other than OMORs for certain safety changes. FDA refers to the OTC Monograph Drug User Fee program as ''OMUFA'' throughout this document. The draft guidance also describes the types of OMUFA fees authorized by the FD&C Act, the due dates of the fees, and explains the exceptions to certain fees. In addition, this guidance describes the process for submitting fee payments to FDA, the consequences for failing to pay the required fees, and the process for submitting refund requests or disputing FDA's assessment of OMUFA fees. This guidance does not address how FDA calculates OMUFA fee rates for each fiscal year, nor does it address FDA's implementation of other user fee programs (*e.g.,* under the Prescription Drug User Fee Act, Biosimilar User Fee Act, or Generic Drug User Fee Amendments).

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 current thinking of FDA on ''Assessing User Fees Under the Over-the-Counter Monograph Drug User Fee Program.'' 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the over-the-counter drug user fee program have been approved under OMB Control Number 0910–0340. The collection of information associated with completing and submitting FDA 3913 (User Fee Payment Refund Request) is approved under OMB control number 0910–0805.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: October 27, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–23791 Filed 11–1–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0669]

S1B(R1) Addendum to S1B Testing for Carcinogenicity of Pharmaceuticals; International Council for Harmonisation; 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 ''S1B(R1) Addendum to S1B Testing for Carcinogenicity of Pharmaceuticals.'' The guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), formerly the International Conference on Harmonisation. The final guidance expands the testing scheme for assessing human carcinogenic risk of pharmaceuticals by introducing an additional approach that is not described in the original S1B Guideline. The final guidance is intended to offer an integrative approach that provides specific weight of evidence criteria that inform whether a 2-year rat study is