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Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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]

BILLING CODE 4164–01–P

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

likely to add value in completing a human carcinogenicity risk assessment. The Addendum also adds a plasma exposure ratio-based approach for setting the high dose in the rasH2-Tg mouse model, while all other aspects of the recommendations for high-dose selection in ICH guidance for industry ''S1C(R2) Dose Selection for Carcinogenicity Studies of Pharmaceuticals'' still apply.

DATES: The announcement of the guidance is published in the **Federal Register** on November 2, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency 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–2021–D–0669 for ''S1B(R1) Addendum to S1B Testing for Carcinogenicity of Pharmaceuticals.'' 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 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; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Timothy McGovern, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6426, Silver Spring, MD 6426, 240–402–0477 *Timothy.McGovern@fda.hhs.gov*; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911, *Stephen.Ripley@fda.hhs.gov*.

Regarding the ICH: Jill Adleberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6364, Silver Spring, MD 20993–0002, 301–796–5259, *Jill.Adleberg@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA 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 ICH. ICH has the mission of achieving greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner.

By harmonizing the regulatory requirements in regions around the world, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, standardized marketing application submissions, and made many other improvements in the quality of global drug development and manufacturing and the products available to patients.

The six Founding Members of the ICH are the FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare;

and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. Additionally, the Membership of ICH has expanded to include other regulatory authorities and industry associations from around the world (*https://www.ich.org/*).

ICH works by involving technical experts from both regulators and industry parties in detailed technical harmonization work and the application of a science-based approach to harmonization through a consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In the **Federal Register** of October 5, 2021 (86 FR 54982), FDA published a notice announcing the availability of a draft guidance entitled ''S1B(R1) Addendum to S1B Testing for Carcinogenicity of Pharmaceuticals.'' The notice gave interested persons an opportunity to submit comments by December 6, 2021.

After consideration of the comments received and revisions to the guideline, a final draft of the guideline was submitted to the ICH Assembly and endorsed by the regulatory agencies on August 4, 2022.

The final guidance provides guidance on expanding the testing scheme for assessing human carcinogenic risk of pharmaceuticals by introducing an additional approach that is not described in the original S1B Guideline and also adds a plasma exposure ratio-based approach for setting the high dose in the rasH2-Tg mouse model. This guidance finalizes the draft guidance issued on October 5, 2021.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA. 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 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001.

III. Electronic Access

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

Dated: October 27, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–23787 Filed 11–1–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Request for Public Comment on Proposed Update to the Bright Futures Periodicity Schedule as Part of the HRSA-Supported Preventive Services Guidelines for Infants, Children, and Adolescents

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

ACTION: Notice.

SUMMARY: This notice seeks public comment on a proposed update to the Periodicity Schedule of the Bright Futures Recommendations for Pediatric Preventive Health Care (''Bright Futures Periodicity Schedule''), as part of the HRSA-supported preventive service guidelines for infants, children, and adolescents. Please see *https://mchb.hrsa.gov/maternal-child-health-topics/child-health/bright-futures.html* for additional information. Specifically, the proposed update to the Bright Futures Periodicity Schedule is to extend the upper age range for the existing universal Human Immunodeficiency Virus (HIV) screening recommendation.

In the Bright Futures Periodicity Schedule, a ''dot'' with an ''arrow'' indicates a ''range during which a service may be provided.'' In the current Bright Futures Periodicity Schedule, the age range recommended for which adolescents may be provided universal screening for HIV is between the 15-year visit and 18-year visit. The proposed update to the Bright Futures Periodicity Schedule would indicate that the recommended age range for which adolescents may be provided universal screening for HIV is between the 15-year visit and 21-year visit. The proposed update also includes an accompanying footnote to provide updated information from the American Academy of Pediatrics (AAP) about more frequent screening for youth assessed as at high risk of HIV infection.

DATES: Members of the public are invited to provide written comments no later than December 2, 2022. All comments received on or before this date will be reviewed and considered by the Bright Futures Periodicity Schedule Working Group and provided for further consideration by HRSA in determining the recommended updates that it will support.

ADDRESSES: Members of the public interested in providing comments can do so by accessing the public comment web page at: *https://mchb.hrsa.gov/maternal-child-health-topics/child-health/bright-futures.html.*

FOR FURTHER INFORMATION CONTACT: Bethany Miller, HRSA, Maternal and Child Health Bureau, email: *BMiller@hrsa.gov,* telephone: (301) 945–5156.

SUPPLEMENTARY INFORMATION: The Bright Futures Periodicity Schedule is maintained through a national cooperative agreement, the Bright Futures Pediatric Implementation Program, with the AAP. If accepted by HRSA, the proposed update to the Bright Futures Periodicity Schedule will provide additional clinical guidance to providers and, under the Public Health Service Act and pertinent regulations, would require non-grandfathered group health plans and health insurance issuers to provide coverage without cost-sharing of such updated preventive care and screenings.

When its preventive care and screening recommendations have been