activities; and wish to be a peer mentor; or (2) are over 18 years of age; are newly diagnosed patients but have been on in-center dialysis for at least six months; are looking for peer support to help them transition to their new reality; and are known as a peer mentee.

To participate in the ESRD Network Peer Mentoring Program, peer mentors and mentees will complete an online application form stored in Confluence. The application serves to validate the peer mentor or peer mentee interest in the ESRD Network Peer Mentoring Program. Information collection is important to the process of pairing peer mentors and mentees with similarly lived experience and interests with their kidney disease. In addition, the application collects information about the peers' interest in kidney disease, treatment modality, age range, preferred gender recognition, and attitudes toward their kidney disease diagnosis. It also supports aligning hobbies, and genders to support best matched peers with each other. *Form Number:* CMS–10768 (OMB control number: 0938–NEW); *Frequency:* Once; *Affected Public:* Individuals and Households; *Number of Respondents:* 75; *Total Annual Responses:* 75; *Total Annual Hours:* 19. (For policy questions regarding this collection, contact Lisa Rees at 816–426–6353.)

3. *Type of Information Collection Request:* Revision of a previously approved collection; *Title of Information Collection:* Conditions of Coverage for Portable X-ray Suppliers and Supporting Regulations; *Use:* The requirements contained in this information collection request are classified as conditions of participation or conditions for coverage. Portable X-rays are basic radiology studies (predominately chest and extremity X-rays) performed on patients in skilled nursing facilities, residents of long-term care facilities and homebound patients. The CoPs are based on criteria described in the law, and are designed to ensure that each portable X-ray supplier has properly trained staff and provides the appropriate type and level of care for patients. The information collection requirements described below are necessary to certify portable X-ray suppliers wishing to participate in the Medicare program. There are currently 506 portable X-ray suppliers participating in the Medicare program.

On September 30, 2019 (84 FR 51732), CMS updated the personnel requirements for portable X-ray technicians at 42 CFR 486.104(a), to focus on the qualifications of the individual performing services removing school accreditation requirements and simplifying the structure of the requirements. Additionally, CMS also revised the requirements for referral of service at 42 CFR 486.106(a) for portable X-ray requirements for orders. This change removed the requirement that physician or non-physician practitioner's orders for portable X-ray services must be written and signed and replacing the specific requirements related to the content of each portable X-ray order with a cross-reference to the requirements at 42 CFR 410.32, which also apply to portable X-ray services. *Form Number:* CMS–R–43 (OMB Control number: 0938–0338); *Frequency:* Yearly; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 506; *Total Annual Responses:* 1,012; *Total Annual Hours:* 324. (For policy questions regarding this collection contact James Cowher at 410–786–1948.)

Dated: September 29, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021–21580 Filed 10–4–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0031]

Best Practices for Development and Application of Disease Progression Models; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Center for Drug Evaluation and Research, and Center for Biologics Evaluation and Research, are announcing a public workshop entitled ''Best Practices for Development and Application of Disease Progression Models.'' The purpose of this public workshop is to discuss the best practices for developing disease progression models and their application to support drug development decisions, share experiences and case studies that highlight the opportunities and limitations in the development and application of disease progression models including models for natural history of disease and clinical trial simulations, and discuss the knowledge gaps and research needed to advance the development and use of disease progression models.

DATES: The public workshop will be held on November 19, 2021, from 9:30 a.m. to 2:30 p.m., Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: This workshop will be virtual only.

FOR FURTHER INFORMATION CONTACT: Maryanne Dingman, Office of Clinical Pharmacology, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–8777; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Under the FDA Reauthorization Act of 2017 (Pub. L. 115–52), FDA agreed, in accordance with section I of the Prescription Drug User Fee Act (PDUFA) VI Performance Goals, ''Ensuring the Effectiveness of the Human Drug Review, part J, Enhancing Regulatory Decision Tools to Support Drug Development and Review,'' to hold several workshops to identify best practices for model-informed drug development. This workshop, ''Best Practices for Development and Application of Disease Progression Models,'' fulfills FDA's performance commitment under PDUFA VI.

II. Topics for Discussion at the Public Workshop

The following topics will be discussed at the public workshop:

- Role of disease models in drug development and regulatory review;
- Lessons learned from past experiences of applying disease models in drug development;
- Best practice considerations for disease modeling to support drug development and regulatory decisions; and
- Best practice considerations for clinical trial simulations based on disease progression/natural history models to support drug development and regulatory decisions.

III. Participating in the Public Workshop

Registration: Persons interested in attending this public workshop must register by November 9, 2021, at *https://go.usa.gov/xMxPZ.*

If you need special accommodations due to a disability, please contact

Maryanne Dingman (see **FOR FURTHER INFORMATION CONTACT**) no later than November 9, 2021.

Streaming Webcast of the Public Workshop: This public workshop will be webcast. A live webcast of this workshop will be available at *https://go.usa.gov/xMxPZ* on the day of the workshop.

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. It will also be accessible at *https://go.usa.gov/xMxPZ.*

Dated: September 28, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21758 Filed 10–4–21; 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; 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 ''S1B(R1) Addendum to S1B Testing for Carcinogenicity of Pharmaceuticals''. The draft guidance was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. The draft guidance expands the testing scheme for assessing human carcinogenic risk of small molecule pharmaceuticals by introducing an additional approach that is not described in the original S1B Guideline. The draft guidance is intended to offer an integrative approach that provides specific weight of evidence (WoE) criteria that inform whether or not a 2-year rat study adds 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 S1C(R2) Guideline would still apply.

DATES: Submit either electronic or written comments on the draft guidance by December 6, 2021 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–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 the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food