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.

FOR FURTHER INFORMATION CONTACT: Suranjan De, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4307, Silver Spring, MD 20993–0002, 240–402–0498, *eprompt@fda.hhs.gov;* or Katie Rivers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7336, Silver Spring, MD 20993–0002, 301–796–1818, *eprompt@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is committed to achieving the long-term goal of improving the predictability and consistency of the electronic submission process and enhancing transparency and accountability of FDA information technology-related activities. FDA participated in the development of an ICH E2B guideline [1] pertaining to the submission of adverse event reports to the FAERS system: ''Implementation Guide for Electronic Transmission of Individual Case Safety Reports (ICSRs) E2B(R3) Data Elements and Message Specification.'' In the Prescription Drug User Fee Act VI commitment letter, FDA committed to the goal of allowing industry to participate in user acceptance testing and/or organizing a meeting to provide industry an opportunity to provide feedback in advance of the Agency's implementation of ICH E2B(R3) data standards for electronic submission of adverse event reports. The commitment letter outlines FDA's performance goals and procedures under the Prescription Drug User Fee Act VI program for the years 2018–2022 (available at *https://www.fda.gov/media/99140/download*). In 2019 and 2020 FDA had conducted a series of three public meetings to communicate FDA's implementation plan and regional requirements for ICH E2B(R3). FDA incorporated the recommendations received in the comments from the 2019 and 2020 public meetings as ICH E2B(R3) regional technical specifications.

[1] The ICH E2B(R3) IG guideline (*http://estri.ich.org/e2br3/index.htm*) provides technical and business specifications for the harmonized, core set of ICH data elements.

II. Topics for Discussion at the Public Meeting

The public meetings will include a general discussion of the updated specifications for premarketing and postmarketing ICSRs listed in the FDA Regional Implementation Guide for E2B(R3) Electronic Submission of Individual Case Safety Reports for Drug and Biological Products that published in April 2022 (available at *https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-electronic-submissions*). The goal of this discussion is to communicate the updated specific regional requirements that will enhance the quality of adverse event reports received by the Agency. The information exchange at the meetings will enhance the pharmaceutical industry's knowledge of the processes needed to implement ICH E2B(R3) into their systems. In addition, the comments provided by participating stakeholders will continue to inform CDER and CBER's plans for the implementation of ICH E2B(R3) for drugs, biological products, and drug- or biologic-led combination products.

During the public meetings, FDA intends to discuss: (1) E2B(R3) Regional (U.S.) data elements and business rules; (2) usage of data standards in E2B(R3); (3) submission paths for premarket and postmarket ICSRs; (4) forward compatible rules; (5) review of FDA Regional Implementation Specifications for ICH E2B(R3) Implementation; and (6) FDA ICSR XML Instances. One or more topics may be discussed in each meeting. FDA will consider all comments made at these public meetings or received through the docket (see **ADDRESSES**).

III. Participating in the Public Meeting

Registration: To register for the public meetings, please visit *https://fdae2br3.eventbrite.com* by March 31, 2023, for the first meeting and November 3, 2023, for the second meeting. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

An agenda will be made available at least 3 days before each public meeting at *https://www.fda.gov/drugs/news-events-human-drugs/electronic-submission-adverse-event-reports-fda-adverse-event-reporting-system-faers-using.*

Streaming Webcast of the Public Meetings and Video of the Public Meetings: These public meetings will only be webcast; the URL will be posted at *https://www.fda.gov/drugs/news-events-human-drugs/electronic-submission-adverse-event-reports-fda-adverse-event-reporting-system-faers-using* at least 1 day before each meeting. A recording of the public workshops will be available at the same website address for 1 year.

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 (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/drugs/news-events-human-drugs/electronic-submission-adverse-event-reports-fda-adverse-event-reporting-system-faers-using.*

Dated: February 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–03372 Filed 2–16–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidances; Draft and Revised Draft Guidances 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 additional draft and revised draft product-specific guidances. The guidances provide product-specific

recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website. The guidances identified in this notice were developed using the process described in that guidance.

DATES: Submit either electronic or written comments on the draft guidance by April 18, 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 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–2007–D–0369 for ''Product-Specific Guidances; Draft and Revised Draft Guidances for Industry.'' 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 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: Christine Le, Center for Drug Evaluation and Research, Food and Drug Administration, 301–796–2398, *PSG-Questions@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs.*

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific guidances and provide a meaningful opportunity for the public to consider and comment on those guidances. Under that process, draft guidances are posted on FDA's website and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final guidances or publishes revised draft guidances for comment. Guidances were last announced in the **Federal Register** on November 18, 2022 (87 FR 69278). This notice announces draft product-specific guidances, either new or revised, that are posted on FDA's website.

II. Drug Products for Which New Draft Product-Specific Guidances Are Available

FDA is announcing the availability of new draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s)
Afamelanotide.
Bismuth subsalicylate; Metronidazole; Tetracycline hydrochloride.
Cabotegravir; Rilpivirine.
Dexmethylphenidate hydrochloride; Serdexmethylphenidate chloride.
Dihydroergotamine mesylate.
Donepezil hydrochloride.
Fexinidazole.
Glucagon.
Golodirsen.
Ibrexafungerp citrate.
Infigratinib phosphate.
Leuprolide mesylate.
Mechlorethamine hydrochloride.
Olanzapine; Samidorphan L-malate.
Sirolimus.
Sotorasib.
Testosterone.
Triamcinolone acetonide.
Venlafaxine besylate.
Viltolarsen.
Vosoritide.

III. Drug Products for Which Revised Draft Product-Specific Guidances Are Available

FDA is announcing the availability of revised draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s)
Benzoyl peroxide; Clindamycin phosphate (multiple reference listed drugs).
Hydroxyurea.
Mirabegron.
Naproxen sodium.
Siponimod fumaric acid.
Sucralfate (multiple reference listed drugs).

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to *https://www.regulations.gov* and enter Docket No. FDA–2007–D–0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

IV. Paperwork Reduction Act of 1995

FDA tentatively concludes that these draft guidances contain no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. 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: February 10, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–03364 Filed 2–16–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–2044]

Termination of Authorization of Emergency Use of an In Vitro Diagnostic for Detection of Enterovirus D68

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the termination of the May 12, 2015, Emergency Use Authorization (EUA) (authorization) issued under the Federal Food, Drug, and Cosmetic Act (FD&C Act) for the Centers for Disease Control and Prevention's (CDC) Enterovirus D68 (EV–D68) 2014 Real-time RT–PCR Assay (EV–D68 2014 rRT–PCR) (CDC EV–D68 EUA). Issuance of the CDC EV–D68 EUA