U.S. FOOD & DRUG ADMINISTRATION

October 9, 2024

Chanda Owens
Cue Health Inc.
4890 Carroll Canyon Road, Suite 100
San Diego, CA 92121
**Re: Revocation of EUA210180**

Dear Chanda Owens:

This letter is in response to the request from Cue Health Inc., in a letter dated September 9, 2024, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Cue COVID-19 Test for Home and Over The Counter (OTC) Use issued on March 5, 2021, and amended on September 23, 2021, February 9, 2022, January 21, 2022 and August 24, 2022. Cue Health Inc. indicated that they have ceased manufacture, shipping and distribution of the authorized product and requested that the EUA be revoked. FDA understands that as of the date of this letter any remaining viable Cue COVID-19 Test for Home and Over The Counter (OTC) Use cartridges in distribution in the United States cannot be used due to the disabling of the Cue Health Mobile Application (Cue Health App) required to run the test.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Cue Health Inc. has requested that FDA revoke the EUA for the Cue COVID-19 Test for Home and Over The Counter (OTC) Use, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210180 for the Cue COVID-19 Test for Home and Over The Counter (OTC) Use, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Cue COVID-19 Test for Home and Over The Counter (OTC) Use is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

\\s\\

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration

Dated: November 14, 2024.

**Kimberlee Trzeciak,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2024–27094 Filed 11–19–24; 8:45 am]

**BILLING CODE 4164–01–C**

## 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 draft 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 draft 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 January 21, 2025 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:** Joseph Kotsybar, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 3623A, Silver Spring, MD 20993–0002, 240–402–1062, *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 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 August 23, 2024 (89 FR 68162). 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) |
|---|
| Acalabrutinib maleate. |
| Adapalene; Benzoyl peroxide; Clindamycin phosphate. |
| Allopurinol. |
| Aripiprazole. |
| Aripiprazole lauroxil. |
| Buspirone hydrochloride. |
| Cantharidin. |
| Cefazolin sodium. |
| Clonazepam. |
| Cyclosporine |

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

| Active ingredient(s) |
|---|
| Dexamethasone; Neomycin sulfate; Polymyxin b sulfate. |
| Enfuvirtide. |
| Eplontersen sodium. |
| Estrogens, conjugated. |
| Icatibant acetate. |
| Macitentan; Tadalafil. |
| Magnesium sulfate; Polyethylene glycol 3350; Potassium chloride; Sodium chloride; Sodium sulfate. |
| Memantine hydrochloride. |
| Mitomycin. |
| Paclitaxel. |
| Palovarotene. |
| Pemetrexed disodium. |
| Phentolamine mesylate. |
| Phytonadione (multiple reference listed drugs). |
| Quizartinib dihydrochloride. |
| Risperidone. |
| Ritlecitinib tosylate. |
| Treprostinil. |

## 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). |
|---|
| Allopurinol. |
| Azelaic acid. |
| Bictegravir sodium; Emtricitabine; Tenofovir alafenamide fumarate. |
| Budesonide; Formoterol fumarate dihydrate. |
| Enzalutamide. |
| Ferric carboxymaltose. |
| Ferumoxytol. |
| Fluticasone propionate. |
| Fluticasone propionate; Salmeterol xinafoate. |
| Formoterol fumarate. |
| Formoterol fumarate; Mometasone furoate. |
| Labetalol hydrochloride. |
| Lenvatinib mesylate. |
| Levonorgestrel. |
| Liraglutide. |
| Losartan potassium. |
| Mometasone furoate. |
| Nepafenac (multiple reference listed drugs). |
| Nitroglycerin. |
| Olaparib. |
| Phytonadione (multiple reference listed drugs). |
| Primidone. |
| Rasagiline mesylate. |
| Ruxolitinib phosphate. |
| Salmeterol xinafoate. |
| Tacrolimus. |
| Tazarotene. |

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

| Active Ingredient(s). |
|---|
| Tiotropium bromide. |
| Tramadol hydrochloride. |

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

While these guidances contain no collection of information, they do refer to previously approved FDA collections of information. The previously approved 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. 3501–3521). The collections of information in 21 CFR part 312 for investigational new drugs have been approved under 0910–0014. The collections of information in 21 CFR part 314 for applications for FDA approval to market a new drug and in 21 CFR part 320 for bioavailability and bioequivalence requirements have been approved under OMB control number 0910–0001.

## 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: November 7, 2024.

**Kimberlee Trzeciak,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2024–27048 Filed 11–19–24; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2024–N–4604]**

### Per- and Polyfluoroalkyl Substances in Seafood; Request for Information

**AGENCY:** Food and Drug Administration, Department of Health and Human Services (HHS).

**ACTION:** Notice; request for information.

**SUMMARY:** The Food and Drug Administration (FDA or we) is requesting information to help fill data gaps that remain regarding per- and polyfluoroalkyl substances (PFAS) in seafood. The purpose of this request is to help increase our understanding of the potential for PFAS exposure from seafood. We intend to use the information submitted in response to this request to help inform future activities to reduce dietary exposure to PFAS that may pose a health concern.

**DATES:** Either electronic or written comments on the notice must be submitted by February 18, 2025.

**ADDRESSES:** You may submit comments and information as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 18, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

*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