



August 23, 2023

Beth Kraemer, RPh
Director of Quality, Regulatory & Technical Compliance
dba SpectronRx
9550 Zionsville Rd Suite 1
Indianapolis, IN 46268

Re: Revocation of EUA200415

Dear Beth Kraemer:

This letter is in response to the request from dba SpectronRx, received via email on March 24, 2023, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Hymon SARS-CoV-2 Test Kit issued on May 22, 2020, and amended on August 11, 2020. dba SpectronRx indicated that they are discontinuing the distribution of the Hymon SARS-CoV-2 Test Kit and requested that the EUA be revoked. FDA understands that as of the date of this letter there will no longer be any viable Hymon SARS-CoV-2 Test Kit reagents remaining in distribution in the United States.

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 dba SpectronRx has requested that FDA terminate the EUA for the Hymon SARS-CoV-2 Test Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200415 for the Hymon SARS-CoV-2 Test Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Hymon SARS-CoV-2 Test Kit 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//

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

Dated: October 2, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-22188 Filed 10-4-23; 8:45 am]

BILLING CODE 4164-01-C

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Food and Drug Administration

[Docket No. FDA-2023-D-1848]

**Stimulant Use Disorders: Developing
Drugs for Treatment; Draft Guidance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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Stimulant Use Disorders: Developing Drugs for Treatment.” The purpose of this draft guidance is to assist sponsors in the clinical development of drugs for the treatment of stimulant use disorders. Specifically, this guidance addresses FDA’s current recommendations regarding the overall development program and clinical trial designs for the development of drugs to support indications of treatment of moderate to

severe cocaine use disorder, treatment of moderate to severe methamphetamine use disorder, or treatment of moderate to severe prescription stimulant use disorder.

DATES: Submit either electronic or written comments on the draft guidance by December 4, 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-2023-D-1848 for "Stimulant Use Disorders: Developing Drugs for Treatment." 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: Matthew Sullivan, Center for Drug

Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3126, Silver Spring, MD 20993-0002, 301-796-1245.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Stimulant Use Disorders: Developing Drugs for Treatment." The purpose of this draft guidance is to assist sponsors in the clinical development of drugs for the treatment of stimulant use disorders. This draft guidance is intended to serve as a focus for continued discussions among the Division of Anesthesiology, Addiction Medicine, and Pain Medicine, pharmaceutical sponsors, the academic community, and the public. This draft guidance does not address treatment of intoxication or poisoning with various stimulants or treatment of withdrawal from stimulants.

Because FDA has yet to approve any medication treatments for stimulant use disorders, this guidance reflects current recommendations based on a number of uncertainties about the best approach for treating stimulant use disorders and the best approach for evaluating response to treatment. FDA is engaged in an ongoing process to learn more about stimulant use disorders and their treatments to provide the best possible advice to sponsors.

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 "Stimulant Use Disorders: Developing Drugs for Treatment." 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. 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 (PRA) (44 U.S.C. 3501-3521). The collections of information in 21 CFR part 312 relating to the submission of investigational new drug applications have been approved under OMB control number 0910-0014. The collections of information in 21 CFR part 314 relating to the submission of new drug applications have been approved under OMB control number

0910–0001. The collections of information in 21 CFR 201.56 and 201.57 relating to certain prescription product labeling requirements have been approved under OMB control number 0910–0572. The collections of information pertaining to expedited programs for serious conditions for drugs and biologics and breakthrough therapy-designation for drugs and biologics have been approved under OMB control number 0910–0765.

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 2, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–22189 Filed 10–4–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0008]

Radiological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Radiological Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will take place virtually on November 7, 2023, from 9 a.m. to 12:15 p.m. eastern time.

ADDRESSES: All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing platform. Answers to commonly asked questions including information regarding special accommodations due to a disability may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FOR FURTHER INFORMATION CONTACT:

Jarrold Collier, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring, MD 20993–0002, Jarrod.Collier@fda.hhs.gov, 240–672–5763, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572) in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On November 7, 2023, the committee will discuss and make recommendations on the classification of blood irradiator devices for the prevention of metastasis, which are currently unclassified pre-amendments devices, to class III (general controls and premarket approval).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material and the link to the online teleconference meeting room will be available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down and select the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 25, 2023. Oral presentations from the public will be scheduled on November 7, 2023, between approximately 9:20 a.m. and 10:20 a.m. eastern time. Those

individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 17, 2023. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 18, 2023.

For press inquiries, please contact the Office of Media Affairs at fdaoma@fda.hhs.gov or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Ann Marie Williams at Annmarie.williams@fda.hhs.gov or 240–507–6496 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 29, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–22106 Filed 10–4–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0937–0025]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.