U.S. FOOD & DRUG ADMINISTRATION

March 9, 2023

Sue Werner
Head of Regulatory Affairs
Biocartis US, Inc.
Two Pierce Place, Suite 1510
Itasca, IL 60143

Re: Revocation of EUA160008

Dear Sue Werner:

This letter is in response to the request from Biocartis US, Inc., on behalf of Biocartis NV, in a letter received November 23, 2022, that the U.S. Food and Drug Administration (FDA) rescind the EUA for the Idylla Rapid Ebola Virus Triage Test issued on May 26, 2016. Biocartis US, Inc. indicated that Biocartis has discontinued production of the authorized product, has no plans to re-initiate production, and has requested that the EUA be rescinded. FDA understands that no Idylla Rapid Ebola Virus Triage Test reagents associated with this EUA are being produced or are available to the United States market.

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. has requested FDA rescind the EUA for the Idylla Rapid Ebola Virus Triage Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA160008 for the Idylla Rapid Ebola Virus Triage Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Idylla Rapid Ebola Virus Triage Test 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: April 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–08281 Filed 4–19–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–1146]

Acute Radiation Syndrome: Developing Drugs for Prevention and Treatment; 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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Acute Radiation Syndrome: Developing Drugs for Prevention and Treatment.'' The purpose of this draft guidance is to provide information and recommendations to assist sponsors and other interested parties in the development of drugs to prevent or treat acute radiation syndrome (ARS) caused by exposure to ionizing radiation from accidental or deliberate events. Generally, drugs developed for such indications will require approval under

the regulations commonly referred to as the Animal Rule.

DATES: Submit either electronic or written comments on the draft guidance by July 19, 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–1146 for ''Acute Radiation Syndrome: Developing Drugs for Prevention and 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: Ronald Honchel, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5426, Silver Spring, MD 20993, 301–796–0915.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Acute Radiation Syndrome: Developing Drugs for Prevention and Treatment.'' ARS is the term applied to a variety of clinical subsyndromes resulting from the exposure of humans to high doses of radiation. The predominance of expression of these clinical subsyndromes is highly dependent on the magnitude and extent of radiation exposure and the time following exposure. This draft guidance, when finalized, will help sponsors efficiently develop drugs to prevent or treat ARS. Generally, drugs developed for such indications will require approval under the regulations commonly referred to as the Animal Rule.

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 ''Acute Radiation Syndrome: Developing Drugs for Prevention and 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. 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 for investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information pertaining to expanded access to investigational drugs for treatment use have been approved under OMB control number 0910–0814. The collections of information in 21 CFR part 314 for new drug applications have been approved under OMB control number 0910–0001. The collections of information pertaining to prescription drug user fee program have been approved under OMB control number 0910–0297. The collections of

information in 21 CFR part 58 pertaining to good laboratory practices have been approved under OMB control number 0910–0119. The collections of information for general records and postmarket adverse experience reporting pertaining to biological products have been approved under OMB control number 0910–0308. The collections of information pertaining to postmarketing adverse drug experience reporting have been approved under OMB control number 0910–0230. The collections of information resulting from special protocol assessments have been approved under OMB control number 0910–0470. The collection of information pertaining to current good manufacturing practices have been approved under OMB control number 0910–0139. The collections of information in 21 CFR part 601 pertaining to biologics license applications have been approved under OMB control number 0910–0338. The collections of information in FDA's guidance entitled ''Emergency Use Authorization of Medical Products and Related Authorities'' have been approved under OMB control number 0910–0595. The collections of information pertaining to expedited review programs for serious conditions and under section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) (as amended by the Food and Drug Administration Safety and Innovation Act) have been approved under OMB control number 0910–0765. The collections of information for the content and format of prescription drug labeling in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572.

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: April 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–08331 Filed 4–19–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS–0990–0419]

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.

DATES: Comments on the ICR must be received on or before June 20, 2023.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 264–0041 and *PRA@HHS.GOV.*

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–New–60D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov, PRA@HHS.GOV* or call (202) 264–0041 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Collection: Extension.

OMB No.: 0990–0419.

Abstract: The Department of Health and Human Services; Office of the Assistant Secretary for Financial Resources, Office of Acquisitions, Acquisition Policy Division is requesting an approval by OMB for an extension of a previously approved information collection request, Acquisition Regulation Clause Patent Rights and Rights in Data. HHS found that systematically, over a period of several years, when Determination of Exceptional Circumstances (DEC) were executed, additional legal protection for the patent and data rights of third parties beyond those covered by FAR 27.306 were necessary. A DEC is executed consistent with the policy and objectives of the Bayh-Dole Act, 35 U.S.C. 200, *et seq.,* to ensure that subject inventions made under contracts and subcontracts (at all tiers) are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations including universities; to ensure that the Government obtains sufficient rights in federally supported inventions to meet its needs; to protect the public against nonuse or unreasonable use of inventions; and in the case of fulfilling the mission of the U.S. Department of Health and Human Services, to ultimately to benefit the public health.

Likely Respondents: administrative, technical, legal and management personnel.

ANNUALIZED BURDEN HOUR TABLE

Type of respondent and hours for each	Number of respondents	Number of responses per respondent	Average burden per response (hours)	Total burden hours
Technical (4), Legal (2), Management (2)	63	1	8	504
Technical (8), Legal (2), Management (2)	63	1	12	756
Technical (8), Legal (3), Management (1)	63	3	12	2,268
Technical (8), Legal (4), Management (2)	63	3	14	2,646
Technical (6), Legal (2), Management (2)	63	1	10	630
Technical (4), Legal (2), Management (2)	63	1	8	504
Administrative (8)	63	3	8	1,512
Administrative (2), Management (1)	63	3	3	567
Technical (4), Legal (2), Management (2)	63	3	8	1,512