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: Jessica Seo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–7699, email: *CRDAC@fda.hhs.gov,* 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 FDA'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 and/or video conferencing platform. The Committee will discuss supplemental new drug application (sNDA) 218276 S–004, for FABHALTA (iptacopan) oral capsules, submitted by Novartis Pharmaceuticals Corporation, for the treatment of adults with complement 3 glomerulopathy (C3G).

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. Background material and the link to the online teleconference and/or video conference meeting will be available at the location of the advisory committee meeting and at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The online presentation of materials will include slide presentations with audio and video 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. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before February 7, 2025, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately 1:15 p.m. and 2:15 p.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, whether they would like to present online or in-person, and an indication of the approximate time requested to make their presentation on or before January 30, 2025. 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. Similarly, room for interested persons to participate in-person may be limited. If the number of registrants requesting to speak in-person during the open public hearing is greater than can be reasonably accommodated in the venue for the in-person portion of the advisory committee meeting, FDA may conduct a lottery to determine the speakers who will be invited to participate in-person. The contact person will notify interested persons regarding their request to speak by January 31, 2025. Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

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 Jessica Seo (see **FOR FURTHER INFORMATION CONTACT**) 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. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform in conjunction with the physical meeting room (see location). This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: December 20, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–31309 Filed 12–27–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–5601]

E6(R3) Good Clinical Practice: Annex 2; 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 ''E6(R3) Good Clinical Practice: Annex 2.'' The draft guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The draft guidance is the second annex to ''E6(R3) Good Clinical Practice'' published June of 2023. This annex provides additional considerations for the application of good clinical practices to a variety of trial designs and data sources.

Specifically, this draft guidance discusses trials with decentralized and pragmatic elements and real-world data sources. This draft guidance highlights the importance of quality by design and focusing efforts and resources on critical aspects of the trials that might impact the safety of participants and the reliability of results. The draft guidance is intended to encourage innovation in trial design and provides flexible, modern, and clear good clinical practices for conducting trials, while avoiding unnecessary complexities.

DATES: Submit either electronic or written comments on the draft guidance by February 28, 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–2024–D–5601 for ''E6(R3) Good Clinical Practice: Annex 2.'' 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, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: *Regarding the guidance:* Amy Chi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6334, Silver Spring, MD 20993–0002, *amy.chi@fda.hhs.gov;* or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

Regarding the ICH: Jill Adleberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6364, Silver Spring, MD 20993–0002, 301–796–5259, *Jill.Adleberg@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''E6(R3) Good Clinical Practice: Annex 2.'' The draft guidance was prepared under the auspices of ICH. ICH seeks to achieve greater regulatory harmonization worldwide to ensure that safe, effective, and high-quality medicines are developed, registered, and maintained in the most resource-efficient manner.

By harmonizing the regulatory requirements in regions around the world, ICH guidelines enhance global drug development, improve manufacturing standards, and increase the availability of medications. For example, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, and standardized marketing application submissions.

The six Founding Members of the ICH are FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of

Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. ICH membership continues to expand to include other regulatory authorities and industry associations from around the world (refer to *https://www.ich.org*).

ICH works by engaging global regulatory and industry experts in a detailed, science-based, and consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In November 2024, the ICH Assembly endorsed the draft guideline entitled ''E6(R3) Good Clinical Practice: Annex 2'' and agreed that the guideline should be made available for public comment. The draft guideline is the product of the Efficacy Expert Working Group of the ICH. FDA and the Efficacy Expert Working Group will consider comments on this draft.

The draft guidance provides guidance on good clinical practices for trial design and conduct, with a focus on trials with decentralized and pragmatic elements as well as trials that utilize real-world data. Since the original E6 guidance was published in 1996, clinical trials have evolved significantly with new designs and technological innovations. Annex 2 provides additional considerations to the previously published draft guidance entitled ''E6(R3) Good Clinical Practice (GCP),'' which includes a Principles document and Annex 1. This draft guidance, entitled ''E6(R3) Good Clinical Practice: Annex 2,'' is intended to be read and implemented with E6(R3) Principles and Annex 1.

This draft guidance has been left in the original ICH format. The final guidance will be reformatted and edited to conform with FDA's good guidance practices regulation (21 CFR 10.115) and style before publication. The draft guidance, when finalized, will represent the current thinking of FDA on ''E6(R3) Good Clinical Practice: Annex 2.'' 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 (44 U.S.C. 3501–3502). The collections of information in 21 CFR part 312.145 pertaining to good clinical practices have been approved under OMB control number 0910–0014. The collections of information in 21 CFR parts 50 and 56 pertaining to protection of human subjects, institutional review boards, and informed consent have been approved under OMB control number 0910–0130. The collections of information in 21 CFR part 11 pertaining to electronic records and electronic signatures have been approved under OMB control number 0910–0303.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.regulations.gov, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

Dated: December 20, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–31275 Filed 12–27–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5702]

Transfer of Regulatory Responsibility From the Center for Devices and Radiological Health to the Center for Biologics Evaluation and Research; Medical Maggots and Medicinal Leeches

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; announcement of transfer.

SUMMARY: The Food and Drug Administration (FDA) is announcing the transfer of regulatory responsibility for medical maggots and medicinal leeches to the Center for Biologics Evaluation and Research (CBER). These products are currently regulated by the Center for Devices and Radiological Health (CDRH). FDA is transferring regulatory responsibility of these products to CBER because these products are living organisms that more closely align with products regulated by CBER. This action affects only Center assignment and does not change requirements applicable to these products.

DATES: FDA is transferring regulatory responsibility to CBER on December 30, 2024.

FOR FURTHER INFORMATION CONTACT: Annette Marthaler, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Silver Spring, MD 20993, 301–796–8930, *annette.marthaler@fda.hhs.gov* or *combination@fda.gov.*

SUPPLEMENTARY INFORMATION: FDA is announcing the transfer of regulatory responsibility for medical maggots (*Phaenicia sericacta* (blow fly) larvae) and medicinal leeches (*Hirudo medicinalis*) from CDRH to CBER. Medical maggots (including maggots and larvae) (product code NQK) (also referred to as maggot therapy) are harvested and provided disinfected for use in debriding non-healing necrotic skin and soft tissue wounds, including pressure ulcers, venous stasis ulcers, neuropathic foot ulcers, and non-healing traumatic or post-surgical wounds. Medicinal leeches (product code NRN) belong to the *Annelida* worm classification. The animal is a bloodsucking aquatic animal living in fresh water indicated as an adjunct to graft tissue healing when problems of venous congestion may delay healing, or to overcome the problem of venous congestion by creating prolonged localized bleeding.

FDA is transferring the regulatory responsibility for medical maggots and medicinal leeches to CBER so that these products are regulated by the same Center that regulates other living organisms for human use. The transfer will help ensure the consistent and effective regulation of products that are living organisms for human use. This transfer affects only Center assignment and does not change requirements applicable to these products.

For the transferred products, submissions, communications, and required reports should be directed to CBER after December 30, 2024. CDRH will continue to handle submissions