Accordingly, the Agency will continue to list Cupric Sulfate Injection, EQ 0.4 mg copper/mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to Cupric Sulfate Injection, EQ 0.4 mg copper/mL, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: April 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09238 Filed 4–28–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0091]

Crohn's Disease: Developing Drugs for Treatment; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Crohn's Disease: Developing Drugs for Treatment.'' This draft guidance addresses FDA's current thinking about necessary attributes of clinical trials for developing drugs for the treatment of Crohn's disease in adults, including recommendations for trial population, trial design, and efficacy and safety considerations.

DATES: Submit either electronic or written comments on the draft guidance by June 28, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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–2022–D–0091 for ''Crohn's Disease: 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, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Jay Fajiculay, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5353, Silver Spring, MD 20993–0002, 301–796–9007, or Stephen Ripley, 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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Crohn's Disease: Developing Drugs for Treatment.'' This guidance addresses FDA's current thinking about clinical trials for the treatment of Crohn's disease in adults, including recommendations for trial population, trial design, and efficacy and safety considerations.

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 ''Crohn's Disease: 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. 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 have been approved under OMB control number 0910–0014. FDA receives information described in FDA's guidance entitled ''Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims'' to support the medical product's effectiveness and to support claims in approved medical product labeling; the collections of information in 21 CFR 314.50(d)(5) and 21 CFR 601.2 have been approved under OMB control numbers 0910–0001 and 0910–0338, respectively, and the collections of information in 21 CFR 201.56 and 201.57 for medical product labeling have been approved under OMB control number 0910–0572. The collections of information in 21 CFR parts 50 and 56 for protection of human subjects in clinical trials and institutional review board considerations have been approved under OMB control number 0910–0130.

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/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics*, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov.*

Dated: April 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09240 Filed 4–28–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Screening Framework Guidance for Providers and Users of Synthetic Oligonucleotides

AGENCY: Office of the Secretary, Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Assistant Secretary for Preparedness and Response is issuing this revised guidance on a screening framework guidance for providers and users of synthetic oligonucleotides. The Revised Guidance sets forth recommended baseline standards for the gene and genome synthesis industry, as well as best practices for Institutions, Principal Users, End Users, and Third-Party Vendors of oligonucleotides, regarding screening orders and maintaining records consistent with current U.S. regulations. In addition, this Revised Guidance seeks to encourage best practices to address biosecurity concerns associated with the potential misuse of synthetic oligonucleotides to bypass existing regulatory controls and commit unlawful acts.

FOR FURTHER INFORMATION CONTACT: Dr. Mariam Lekveishvili; Division of Policy; Office of Strategy, Policy, Planning, and Requirements; Office of the Assistant Secretary for Preparedness and Response; U.S. Department of Health and Human Services; phone: (202) 260–3586; email: *Mariam.Lekveishvili@hhs.gov.*

SUPPLEMENTARY INFORMATION: Questions regarding aspects of the Guidance that may be appropriate to update based on changes in technologies since the Guidance was originally issued in 2010 were published as a Notice in the **Federal Register** on August 26, 2020, for a period of more than 120 days for public comment. Fourteen individual responses were received. The responses to that Notice are available at the following website: *https://aspr.hhs.gov/legal/syndna/Pages/comment.aspx.*

Screening Framework Guidance for Providers and Users of Synthetic Oligonucleotides

Introduction: Continuing advances in oligonucleotide synthesis technology and the open availability of genetic sequence data pose potential concerns among the scientific community, the oligonucleotide synthesis industry, the U.S. Government, and the public that individuals with ill intent could exploit biotechnology for harmful purposes. The U.S. Government has acted to reduce dangers to human, animal, and plant health due to biological pathogens and toxins. For instance, it has issued the federal Select Agent Regulations, which regulate a subset of microbial organisms and toxins determined to have the potential to pose a severe threat to public health and safety, animal health, plant health, or animal or plant products. These regulations are administered by the Federal Select Agent Program (FSAP), which sets forth requirements for the possession, use, and transfer of biological select agents and toxins.[1] A second layer of regulation is provided by the Export Administration Regulations' Commerce Control List (CCL) [2] which identifies agents and genetic sequences that require licenses before export from the United States. However, these regulated pathogens and toxins do not represent the entirety of the potential risks to public health, agriculture, plants, animals, or the environment that could arise from the misuse of synthetic oligonucleotides. Non-regulated pathogens and toxins as well as other novel types of sequences or specific types of batch orders, may also pose significant risks if they are misused.

Individuals with no legitimate, bona fide, and peaceful need should be prevented from accessing genetic materials that could contribute to pathogenicity or harm, even when they are not from FSAP- or CCL-listed pathogens or toxins. Purchasing or synthesizing oligonucleotides could enable individuals without a legitimate and peaceful purpose to possess genetic sequences that would pose risks if misused. Such synthesis, through directly ordering either long genomic sequences or short genomic sequences—that can be used to create longer genomic-length oligonucleotides, using molecular techniques that have become increasingly available—to modify non-

[1] *https://www.selectagents.gov/sat/list.htm.*

[2] *https://www.bis.doc.gov/index.php/regulations/commerce-control-list-ccl.*