cirrhosis. Finally, the Agency discusses the rationale for recommending that sponsors conduct clinical outcome trials for drugs treating compensated NASH cirrhosis. The Agency also provides recommendations to help ensure safety in patients with hepatic impairment and strategies to deal with drug-induced liver injury during a compensated NASH cirrhosis clinical trial.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Nonalcoholic Steatohepatitis with Compensated Cirrhosis: Developing Drugs for Treatment.''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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These 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. 3501–3520). The collections of information under 21 CFR part 312 (Investigational New Drug Application) have been approved under OMB control number 0910–0014. The collections of information in 21 CFR parts 50 and 56 (Protection of Human Subjects: Documentation of Informed Consent; Institutional Review Boards) have been approved under OMB control number 0910–0755. The collection of information under 21 CFR part 314, including the submission of information under subpart H (''Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses''), has been approved under OMB control number 0910–0001. The collection of information under the guidance for industry entitled ''Expedited Programs for Serious Conditions—Drugs and Biologics'' (available at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm358301.pdf*) has been approved under OMB control number 0910–0765.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: June 3, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–11951 Filed 6–6–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–1264]

Enhancing the Diversity of Clinical Trial Populations—Eligibility Criteria, Enrollment Practices, and Trial Designs; 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 ''Enhancing the Diversity of Clinical Trial Populations—Eligibility Criteria, Enrollment Practices, and Trial Designs.'' This draft guidance recommends approaches that sponsors of clinical trials to support a new drug application or a biologics license application can take to broaden eligibility criteria, when scientifically and clinically appropriate, and increase enrollment of underrepresented populations in their clinical trials. The draft guidance reflects FDA policy encouraging inclusion in clinical trials of participants representative of the broad population of patients who will be exposed to a marketed drug and is being issued to satisfy the FDA Reauthorization Act of 2017 (FDARA) mandate.

DATES: Submit either electronic or written comments on the draft guidance by August 6, 2019 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–2019–D–1264 for ''Enhancing the Diversity of Clinical Trial Populations—Eligibility Criteria, Enrollment Practices, and Trial Designs.'' 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.

- 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.gpo.gov/fdsys/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.

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: Ebla Ali-Ibrahim, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 6302, Silver Spring, MD 20993, 301–796–3691; 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 ''Enhancing the Diversity of Clinical Trial Populations—Eligibility Criteria, Enrollment Practices, and Trial Designs.'' This draft guidance recommends approaches that sponsors of clinical trials to support a new drug application or a biologics license application can take to broaden eligibility criteria, when scientifically and clinically appropriate, and increase enrollment of underrepresented populations in their clinical trials. This draft guidance reflects FDA policy encouraging inclusion in clinical trials of participants representative of the broad population of patients who will be exposed to a marketed drug. FDA is also issuing this guidance to satisfy the mandates under section 610(a)(3) of FDARA (Pub. L. 115–52).

Certain populations are often excluded from trials without strong clinical or scientific justification (*e.g.,* the elderly, those at the extremes of the weight range, individuals with organ dysfunction, those with malignancies or certain infections such as HIV, and children). In addition, participants with multiple concomitant illnesses and those receiving other drugs often do not meet eligibility criteria because of concerns that such conditions or other drugs could affect a determination of an investigational drug's safety or effectiveness. Pregnant women are also frequently excluded out of concern for fetal health. This draft guidance provides recommendations for more inclusive trial practices, trial designs, and methodological approaches sponsors can take to broaden eligibility criteria for clinical trials.

Aspects of clinical trial recruitment practices, logistics, site selection, and design may affect the ability to recruit certain participants or to retain them in clinical trials. For example, a trial requiring participants to make frequent visits to specific sites may result in added burden for participants, including the elderly, children, disabled and cognitively impaired individuals who require transportation or caregiver assistance, or participants who live far from research facilities, such as those in rural or remote locations. For individuals under current clinical care on a regularly scheduled basis (*e.g.,* individuals with multiple chronic conditions), additional clinical trial study visits may be burdensome and a disincentive for enrollment in clinical trials. This draft guidance provides recommendations on approaches sponsors can take to improve the diversity of enrolled participants in clinical trials by making trial participation less burdensome for participants and by adopting enrollment practices that enhance inclusiveness.

Clinical trials of investigational drugs intended to treat rare diseases or conditions present a unique set of challenges. Because rare diseases often affect small, geographically dispersed patient populations with disease-related travel limitations, special efforts may be necessary to enroll and retain these patients to ensure that a broad spectrum of the patient population is represented in clinical trials. This draft guidance provides recommendations on approaches sponsors can take to broaden the eligibility criteria for clinical trials of investigational drugs intended to treat rare diseases and to improve the enrollment and retention of participants with rare diseases.

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 ''Enhancing the Diversity of Clinical Trial Populations—Eligibility Criteria, Enrollment Practices, and Trial Designs.'' 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, or *https://www.regulations.gov.*

Dated: June 3, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–11978 Filed 6–6–19; 8:45 am]

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