review the information and assess potential risk of bias from both published and unpublished studies and its impact on the EPC Program's findings. This study is being conducted by AHRQ, pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare services. 42 U.S.C. 299a(a)(1).

Method of Collection

To achieve the goals of this project the following data collections will be implemented:

• *Online Submission Form Instrument.* This information is collected for the purposes of providing supplemental evidence and data for systematic reviews (SEADS). The purpose of SEADS requests is not to collect generalizable data, but to supplement the published and grey literature searches EPC investigators are conducting. The online submission form (OSF) collects data from respondents on their name and the information packet. This happens following notification of opportunity to submit via email listserv and/or **Federal Register** notice as needed, with one request per topic. For the purposes of meta-analyses, trial summary data from missing and unidentified studies are sought. For the purposes of constructing evidence tables and quality ratings (*e.g.,* on public reporting of cost measures or health information exchange), data can vary (*e.g.,* URLs, study designs, and consumer-mediated exchange forms). Submitters are informed of the types of information that would be most helpful to include in the information packet, which includes a list of all sponsored but unpublished studies (both completed and ongoing), as well as comment on the completeness of information provided.

The EPC Program currently uses a broad-based email announcement via email listserv and a **Federal Register** notice, as needed, to publicize the opportunity to submit scientific information about each topic. The proposed project does not duplicate other available sources of this information. Available study registries and databases may not sufficiently inform the Program's research. The EPC Program does not anticipate more than 15 topics per year with SEADS requests.

Estimated Annual Respondent Burden

Exhibit 1 presents estimates of the reporting burden hours for the data collection efforts. Time estimates are based on pilot testing of materials and what can reasonably be requested of respondents. The number of respondents listed in ''Number of respondents per SEADS request'' of Exhibit 1 reflects a projected 33% response rate with approximately 1–2 responses per request and assumes about 15 SEADS requests per year.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of SEADS requests	Number of SEADS request that receive response	Number of responses per SEADS request	Annual number of SEADS responses	Hours per response	Total burden hours per annum
Online Submission Form (OSF)	15	5	1.5	7.5	15/60	1.87

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of SEADS requests	Total burden hours per SEADS	Average hourly wage rate *	Total cost burden
OSF	15	1.87	[a] $61.39	$115.10

* Occupational Employment Statistics, May 2017 National Occupational Employment and Wage Estimates United States, U.S. Department of Labor, Bureau of Labor Statistics. *https://www.bls.gov/oes/current/oes_nat.htm#11-0000.*

[a] Based on the mean wages for *Public Relations and Fundraising Managers, 11–2031,* the occupational group most likely tasked with completing the OSF.

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Virginia L. Mackay-Smith,

Associate Director.

[FR Doc. 2019–11949 Filed 6–6–19; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–1516]

Nonalcoholic Steatohepatitis With Compensated Cirrhosis: 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 ''Nonalcoholic Steatohepatitis with

Compensated Cirrhosis: Developing Drugs for Treatment.'' The purpose of this draft guidance is to provide the Agency's current recommendations regarding the important components of a drug development program for nonalcoholic steatohepatitis (NASH) with compensated cirrhosis. This draft guidance focuses on the enrollment criteria, trial design, efficacy endpoints, and safety considerations for phase 3 trials.

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–1516 for ''Nonalcoholic Steatohepatitis with Compensated Cirrhosis: 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.

- *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. 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: Frank A. Anania, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5387, Silver Spring, MD 20993, 240–402–9725.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Nonalcoholic Steatohepatitis with Compensated Cirrhosis: Developing Drugs for Treatment.''

This draft guidance focuses on the design of clinical trials to study patients who have compensated cirrhosis secondary to NASH. This draft guidance is in addition to a draft guidance published in 2018 which discusses the Agency's thinking for the design of clinical trials for patients who have NASH but do not have cirrhosis (see the draft guidance for industry entitled ''Noncirrhotic Nonalcoholic Steatohepatitis with Liver Fibrosis: Developing Drugs for Treatment'' available at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm627376.pdf*).

NASH is the hepatic manifestation of insulin resistance syndrome and is associated with type 2 diabetes, hypertension, hypertriglyceridemia, and obesity, among other diseases. NASH-related cirrhosis is becoming a major public health problem and is anticipated to be the leading indication for orthotopic liver transplantation within a decade.

This draft guidance applies only to compensated cirrhosis and specifically excludes patients with decompensated cirrhosis, *i.e.* patients who have already experienced any of several clinical events (*e.g.,* variceal bleeding, ascites, hepatic encephalopathy) that are associated with high morbidity and significantly reduce their life expectancies. This draft guidance describes the criteria for enrolling patients with compensated cirrhosis in clinical trials, including the histologic criteria to establish the pathological diagnosis of cirrhosis.

This draft guidance provides recommendations on the selection of primary efficacy endpoints in clinical trials intended to study pharmacological treatments for compensated NASH

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