• 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.

FOR FURTHER INFORMATION CONTACT: Eric Nelson, Division of Compliance (HFV–230), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–7001, *cvmcompliance@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 20, 2019, FDA published a notice announcing the availability of draft GFI #256 entitled ''Compounding Animal Drugs From Bulk Drug Substances'' with a 90-day comment period. We requested comments on the draft guidance with respect to animal drug compounding from bulk drug substances under certain circumstances when no other medically appropriate treatment option exists.

Interested persons were originally given until February 18, 2020, to comment on the draft guidance.

The Agency has received several requests to allow interested persons additional time to comment. The requests conveyed concern that the current 90-day comment period does not allow sufficient time to develop a comprehensive response.

FDA has considered the requests and is reopening the comment period for the notice of availability for 120 days, until June 17, 2020. The Agency believes that a 120-day reopening allows adequate time for interested persons to submit comments.

Dated: February 13, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–03312 Filed 2–19–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–5607]

Nonclinical Safety Evaluation of the Immunotoxic Potential of Drugs and Biologics; 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 entitled ''Nonclinical Safety Evaluation of the Immunotoxic Potential of Drugs and Biologics.'' This guidance expands upon, consolidates, and supplements the recommendations on nonclinical immune system assessments provided across multiple guidance documents, most notably the International Conference on Harmonization (ICH) guidance for industry ''S8 Immunotoxicity Studies for Human Pharmaceuticals.'' The topics covered include various aspects of immune suppression, modulation, and stimulation. This guidance replaces the withdrawn guidance entitled ''Immunotoxicology Evaluation of Investigational New Drugs.''

DATES: Submit either electronic or written comments on the draft guidance by April 20, 2020 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–5607 for ''Nonclinical Safety Evaluation of the Immunotoxic Potential of Drugs and Biologics.'' 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: David McMillan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6387, Silver Spring, MD 20993, 240–402–1009; 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 ''Nonclinical Safety Evaluation of the Immunotoxic Potential of Drugs and Biologics.'' This guidance provides consistent recommendations for the nonclinical assessments of immune endpoints and supplements the recommendations provided in other guidances, most notably the ICH guidance for industry ''S8 Immunotoxicity Studies for Human Pharmaceuticals.'' This guidance replaces the withdrawn guidance entitled ''Immunotoxicology Evaluation of Investigational New Drugs'' issued November 1, 2002 (67 FR 66647). The topics addressed include multiple aspects of immune suppression, modulation, and stimulation, including carcinogenicity assessment, dermal sensitization, adjuvanted vaccine development, and developmental and juvenile animal studies.

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 ''Nonclinical Safety Evaluation of the Immunotoxic Potential of Drugs and Biologics.'' 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

This draft guidance refers to previously approved FDA collections of information. 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. 3501–3521). The information collection has been approved under OMB control numbers 0910–0001 and 0910–0014.

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,* or *https://www.regulations.gov.*

Dated: February 11, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–03426 Filed 2–19–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

HHS Notice of Committee Establishment, Notice of Intent To Convene, and Call for Nominations for the NIH Human Fetal Tissue Research Ethics Advisory Board for Fiscal Year 2020

AGENCY: Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The U.S. Department of Health and Human Services (HHS) announces the establishment of, and intent to convene, the National Institutes of Health (NIH) Human Fetal Tissue Research Ethics Advisory Board—FY 2020 (Ethics Board or Board), as authorized by section 492A of the Public Health Service (PHS) Act, as amended. HHS is soliciting nominations of individuals for appointment to the Ethics Board for fiscal year 2020. Nominations for qualified individuals for appointment to the Ethics Board are currently being accepted.

DATES: Nominations must be received no later than 5:00 p.m. ET 30 days after the publication of this **Federal Register** notice.

ADDRESSES: Nomination packages must be submitted to the Executive Secretary, NIH Human Fetal Tissue Research Ethics Advisory Board—FY 2020, Office of Science Policy, NIH, 6705 Rockledge Drive, Suite 750 Bethesda, MD 20892. Federal Express, Airborne, UPS, etc., mail delivery should be addressed to Executive Secretary, NIH Human Fetal Tissue Research Ethics Advisory Board—FY 2020, Office of Science Policy, NIH, at the above address, or sent via email to: *SciencePolicy@od.nih.gov*

FOR FURTHER INFORMATION CONTACT: Inquiries may be directed to Cari Young, Office of Science Policy, 6705 Rockledge Drive, Suite 750 Bethesda, MD 20892, Telephone: 301–496–9838, or *SciencePolicy@od.nih.gov*.

SUPPLEMENTARY INFORMATION: Pursuant to section 492A of the Public Health Service (PHS) Act, 42 U.S.C. 289a–1, as amended, and in accordance with the policy announced on June 5, 2019, the Secretary announces (1) his