II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of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 in 21 CFR part 58 have been approved under OMB control number 0910–0119; the collections of information in 21 CFR part 211 have been approved under OMB control number 0910–0139; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in the guidance entitled “Expedited Programs for Serious Conditions—Drugs and Biologics” have been approved under OMB control number 0910–0765; and the collections of information in the guidance entitled “Formal Meetings Between the FDA and Sponsors or Applicants” have been approved under OMB control number 0910–0429.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either https://www.fda.gov/BiologicsBloodVaccines/ GuidanceCompliance/RegulatoryInformation/Guidances/default.htm or https://www.regulations.gov.

Dated: July 5, 2018.

Leslie Kux,
Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


Chemistry, Manufacturing, and Control Information for Human Gene Therapy Investigational New Drug Applications; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs); Draft Guidance for Industry.” The draft guidance document provides sponsors of a human gene therapy IND with recommendations regarding CMC information required to assure product safety, identity, quality, purity, and strength (including potency) of the investigational product. The draft guidance applies to human gene therapy products and to combination products that contain a human gene therapy in combination with a drug or device.


DATES: Submit either electronic or written comments on the draft guidance by October 10, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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. Since 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
Draft Guidance for Industry."

The draft guidance, when finalized, will contain recommendations regarding CMC information required to assure product safety, identity, quality, purity, and strength (including potency) of the investigational product (21 CFR 312.23(a)(7)(i)). The draft guidance applies to human gene therapy products and to combination products that contain a human gene therapy in combination with a drug or device. The field of gene therapy has progressed rapidly since FDA issued the April 2008 guidance. Therefore, FDA is updating the guidance to provide current FDA recommendations regarding the CMC content of a gene therapy IND. In addition, the draft guidance is organized to follow the structure of the FDA guidance on the Common Technical Document.

The draft guidance, when finalized, is intended to supersede the April 2008 guidance. Elsewhere in this issue of the Federal Register, FDA is announcing the availability of two other draft guidances. In a separate document, FDA is announcing the availability of a draft document entitled “Long Term Follow-Up After Administration of Human Gene Therapy Products; Draft Guidance for Industry” and the availability of a draft document entitled “Testing of Retroviral Vector-Based Human Gene Therapy Products for Replication Competent Retrovirus During Product Manufacture and Patient Follow-up; Draft Guidance for Industry.”

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 CMC information for human gene therapy INDs. 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 in 21 CFR part 211 have been approved under OMB control number 0910–0139; the collections of information in 21 CFR part 312 and Form FDA 1571 have been approved under OMB control number 0910–0014; and the collections of information in 21 CFR part 1271 have been approved under OMB control number 0910–0543.

III. Electronic Access

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

Dated: July 5, 2018.

Leslie Kux,
Associate Commissioner for Policy.