

*biologics-guidances* or <https://www.regulations.gov>.

Dated: January 27, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-D-2236]

#### Human Gene Therapy for Retinal Disorders; Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration is announcing the availability of a final guidance entitled “Human Gene Therapy for Retinal Disorders; Guidance for Industry.” The final guidance provides recommendations to stakeholders developing human gene therapy (GT) products for retinal disorders affecting adult and pediatric patients. The guidance focuses on issues specific to GT products for retinal disorders and provides recommendations related to product development, preclinical testing, and clinical trial design for such GT products. The guidance announced in this notice finalizes the draft guidance of the same title dated July 2018.

**DATES:** The announcement of the guidance is published in the **Federal Register** on January 30, 2020.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances 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-2018-D-2236 for “Human Gene Therapy for Retinal Disorders; Guidance for Industry.” 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.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.

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 guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), 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 the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

#### **FOR FURTHER INFORMATION CONTACT:**

Jenifer Stach, 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 document entitled “Human Gene Therapy for Retinal Disorders; Guidance for Industry.” This guidance provides recommendations to stakeholders developing human GT products for retinal disorders affecting adult and pediatric patients. These disorders vary in etiology, prevalence, diagnosis, and management, and include genetic as well as age-related diseases. These disorders manifest with central or peripheral visual impairment and often with progressive visual loss. This guidance focuses on issues specific to GT products for retinal disorders and provides recommendations related to product development, preclinical testing, and clinical trial design for such GT products.

In the **Federal Register** of July 12, 2018 (83 FR 32302), FDA announced the availability of the draft guidance of the same title. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated July 2018.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of two other human gene therapy final guidance documents entitled “Human Gene Therapy for Hemophilia; Guidance for Industry” and “Human Gene Therapy for Rare Diseases; Guidance for Industry.”

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Human Gene Therapy for Retinal Disorders.” 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 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. 3501–3521). The collections of information in 21 CFR part 50 have been approved under OMB control number 0910–0755; 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 guidance at either <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance->

[regulatory-information-biologics](https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics) or <https://www.regulations.gov>.

Dated: January 27, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020–01703 Filed 1–29–20; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Nurse Corps Loan Repayment Program, OMB No. 0915–0140 Revision

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA’s ICR only after the 30-day comment period for this Notice has closed.

**DATES:** Comments on this ICR should be received no later than March 2, 2020.

**ADDRESSES:** Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to (202) 395–5806.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443–1984.

#### SUPPLEMENTARY INFORMATION:

*Information Collection Request Title:* Nurse Corps Loan Repayment Program OMB No. 0915–0140—Revision.

*Abstract:* The Nurse Corps Loan Repayment Program (Nurse Corps LRP) assists in the recruitment and retention of professional Registered Nurses (RNs) by decreasing the financial barriers associated with pursuing a nursing education. RNs in this instance include advanced practice RNs (e.g., nurse practitioners, certified registered nurse

anesthetists, certified nurse-midwives, and clinical nurse specialists) dedicated to working at eligible health care facilities with a critical shortage of nurses (i.e., a Critical Shortage Facility) or working as nurse faculty in eligible, accredited schools of nursing. The Nurse Corps LRP provides loan repayment assistance to these nurses to repay a portion of their qualifying educational loans in exchange for full-time service at a public or private nonprofit Critical Shortage Facility (CSF) or in an eligible, accredited school of nursing.

A 60-day notice was published in the **Federal Register** on October, 10, 2019 vol. 84, No. 197; pp. 54617–51619.

*Need and Proposed Use of the Information:* This information collection is used by the Nurse Corps program to make award decisions about Nurse Corps LRP applicants and to monitor a participant’s compliance with the program’s service requirements. Individuals must submit an application in order to participate in the program. The application asks for personal, professional, educational, and financial information required to determine the applicant’s eligibility to participate in the Nurse Corps LRP.

The revised information collection request includes a new form and updates to existing forms for the Nurse Corps LRP in order to expand the service options for awarded participants, promote the use of telehealth for delivering care throughout the nation especially in rural areas, and to reduce the application burden on respondents.

New Form #1—Applicants will be asked to submit a Disadvantaged Background Form. This new form asks the applicant’s site Point of Contact to certify whether the applicant is from a disadvantaged background. The form provides eligibility criteria for the determination.

Updated Form #1—The Participant Semi-Annual Employment Verification Form will be updated to include additional information about the participant’s service including information about telehealth services and whether they work at multiple CSF sites. Telehealth helps expand the reach of providers especially in rural areas where medical service sites are more remote. The information collected will assist Program with determining the impact and utilization of telehealth services in various health care settings which will be used to inform our telehealth policies. Enabling multiple CSF site service will also allow greater flexibility for providers who rotate or split time between multiple sites which