## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[Document Identifier: CMS–R–262]**

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

**ACTION:** Notice; partial withdrawal.

**SUMMARY:** On Wednesday, April 15, 2020, the Centers for Medicare & Medicaid Services (CMS) published a notice entitled, ''Agency Information Collection Activities: Submission for OMB Review; Comment Request.'' That notice invited public comments on two separate information collection requests specific to document identifiers: CMS–10716 and CMS–R–262. Through the publication of this document, we are withdrawing the portion of the notice requesting public comment on the information collection request titled ''CMS Plan Benefit Package (PBP) and Formulary CY 2021.'' Form number CMS–R–262 (OMB control number 0938–0673).

**DATES:** The original comment period for the document that published on April 15, 2020, remains in effect and ends May 15, 2020.

**SUPPLEMENTARY INFORMATION:** In FR document, 2020–07884, published on April 15, 2020, (85 FR 21009), we are withdrawing item 2 ''CMS Plan Benefit Package (PBP) and Formulary CY 2021'' which begins on page 21010.

Dated: April 20, 2020.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2020–08651 Filed 4–22–20; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2019–D–5392]**

### Interpreting Sameness of Gene Therapy Products Under the Orphan Drug Regulations; Draft Guidance for Industry; Extension of Comment Period

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

**ACTION:** Notice of availability; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is extending the comment period for the notice of availability entitled ''Interpreting Sameness of Gene Therapy Products Under the Orphan Drug Regulations; Draft Guidance for Industry'' that appeared in the **Federal Register** of January 30, 2020. The Agency is taking this action to allow interested persons additional time to submit comments.

**DATES:** FDA is extending the comment period on the notice published January 30, 2020 (85 FR 5445). Submit either electronic or written comments on the draft guidance by July 28, 2020, to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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–5392 for ''Interpreting Sameness of Gene Therapy Products Under the Orphan Drug Regulations.'' 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 draft guidance to 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:** Shruti Modi, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

**SUPPLEMENTARY INFORMATION:**

## I. Background

In the **Federal Register** of January 30, 2020 (85 FR 5445), FDA published a notice with a 90-day comment period to request comments on the document entitled ''Interpreting Sameness of Gene Therapy Products Under the Orphan Drug Regulations; Draft Guidance for Industry.'' FDA is extending the comment period, in response to a request from a stakeholder, until July 22, 2020. The Agency believes that a 90-day extension allows adequate time for interested persons to submit comments without significantly delaying publication of the final version of the guidance.

## II. Reference

The following reference is on display in the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *https://www.regulations.gov.*

1. Email from Mr. Aleksandr Merenkov, Regulatory Intelligence Specialist, Regeneron Pharmaceuticals, Inc., to Jenifer Roe, Regulatory Counsel, Center for Biologics Evaluation and Research, FDA (March 26, 2020).

## II. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: April 16, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020–08609 Filed 4–22–20; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

### Notice of Interest Rate on Overdue Debts

Section 30.18 of the Department of Health and Human Services' claims collection regulations (45 CFR part 30) provides that the Secretary shall charge an annual rate of interest, which is determined and fixed by the Secretary of the Treasury after considering private consumer rates of interest on the date that the Department of Health and Human Services becomes entitled to recovery. The rate cannot be lower than the Department of Treasury's current value of funds rate or the applicable rate determined from the ''Schedule of Certified Interest Rates with Range of Maturities'' unless the Secretary waives interest in whole or part, or a different rate is prescribed by statute, contract, or repayment agreement. The Secretary of the Treasury may revise this rate quarterly. The Department of Health and Human Services publishes this rate in the **Federal Register**.

The current rate of 9⅝%, as fixed by the Secretary of the Treasury, is certified for the quarter ended March 31, 2020. This rate is based on the Interest Rates for Specific Legislation, ''National Health Services Corps Scholarship Program (42 U.S.C. 254o(b)(1)(A))'' and ''National Research Service Award Program (42 U.S.C. 288(c)(4)(B)).'' This interest rate will be applied to overdue debt until the Department of Health and Human Services publishes a revision.

**David C. Horn,**

*Director, Office of Financial Policy and Reporting.*

[FR Doc. 2020–08564 Filed 4–22–20; 8:45 am]

**BILLING CODE 4150–04–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**FOR FURTHER INFORMATION CONTACT:** Chris Kornak at 240–627–3705 or *Chris.Kornak@nih.gov.* Licensing information may be obtained by communicating with the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301–496–2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

**SUPPLEMENTARY INFORMATION:** Technology description follows:

**Use of the Intracellular Signaling Domain of Receptor CD28H as a Component of Chimeric Antigen Receptors To Overcome Inhibition of Cytotoxic Lymphocytes by Checkpoint Receptors**

*Description of Technology:* Engineered chimeric antigen receptors (CARs) that are expressed in cytotoxic T cells and natural killer (NK) cells have been used to specifically target tumor cells. However, CAR–T and CAR–NK cells are still subject to downregulation by their inhibitory receptors after injection into patients.

Scientists at NIAID have developed CAR constructs that overcome inhibition of NK cells by receptors for human major histocompatibility complex molecules HLA–E and HLA–C, based on *in vitro* studies. The CAR contains an antigen binding domain of receptor CD28 homolog (CD28H), a CD28H transmembrane domain (TM), a CD28H signaling domain, and other intracellular signaling domains, such as 2B4 (CD244) and CD3 zeta chain (CD3zeta). A variant of this CAR, in which the antigen binding domain of CD28H is replaced by a single-chain antibody variable region (scFv) that binds to CD19, rendered NK cells resistant to inhibition by HLA–E and HLA–C on $CD19^+$ tumor cells.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

*Potential Commercial Applications:*

- Method of adoptive therapy where CAR–NK cell or CAR–T cell is the effector cell.

*Competitive Advantages:*

- Resistant to inhibition of NK cells or T cells by HLA–E and HLA–C.
- Manufacturing efficiency.
- CAR–NK can be developed without the need to genetic silencing of TCR.