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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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comments on the document entitled ''Interpreting Sameness of Gene Therapy Products Under the Orphan Drug Regulations; Draft Guidance for Industry.''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Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*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.