This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Product Identifiers Under the Supply Chain Security Act Questions and Answers.” 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This draft guidance includes information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520) (PRA). In accordance with the PRA, prior to publication of any final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to those previously approved collections of information found in FDA regulations or guidances.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either https://www.fda.gov/Drugs/GuidanceCompliance- RegulatoryInformation/Guidances/default.htm or https://www.regulations.gov.
order to facilitate their entry into the building. Contact Ann Ferrero using the information mentioned above by Thursday, October 18, 2018, 12:00 p.m. ET. All attendees are required to present government-issued identification prior to entry. The meeting will also be accessible via webcam. Instructions on how to access the meeting via webcam will be provided upon registration.

Amy P. McNulty,
Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018–20428 Filed 9–19–18; 8:45 am]
BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
National Cancer Institute; Notice of Meeting
Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Cancer Institute Council of Research Advocates. The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (http://videocast.nih.gov).

Name of Committee: National Cancer Institute Council of Research Advocates.
Date: October 19, 2018.
Time: 9:00 a.m. to 4:30 p.m.
Agenda: Welcome and Chairman’s Remarks, NCI Updates, Legislative Update, Budget Update, and Director’s Update.
Place: National Institutes of Health, 35A Convent Drive, Building 35A, 640, Bethesda, MD 20892.
Contact Person: Amy Williams, NCI Office of Advocacy Relations, National Cancer Institute, NCI, 31 Center Drive, Building 31, Room 10A28, Bethesda, MD 20892, 240–781–3360 williams@mail.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.
In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver’s license, or passport) and to state the purpose of their visit.
Information is also available on the Institute’s Center’s home page: NCRA: http://deoinfo.nci.nih.gov/advisory/ncra/ncra.htm, where an agenda and any additional information for the meeting will be posted when available.
(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: September 14, 2018.
Melanie J. Pantoja,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–20418 Filed 9–19–18; 8:45 am]
BILLING CODE 4140–01–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:
Barry Buchbinder, Ph.D., 240–627–3678; barry.buchbinder@nih.gov.

Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with the indicated licensing contact at 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 patent applications.

SUPPLEMENTARY INFORMATION:
Technology description follows.

Glycan-Masked Engineered Outer Domains of HIV-1 GP120 and Their Use
Description of Technology:

The VRC01-class of potent, broadly neutralizing antibodies (bnAbs) targets the conserved CD4-binding site (CD4bs) of HIV-1 Env which has been a major target of HIV-vaccine design. The current best priming immunogen to engage the VRC01-class germline precursors is the eOD-GT8 60mer, which elicits VRC01-class precursors in multiple transgenic mouse models. However, a large proportion of the antibodies elicited by eOD-GT8 60mer are non-CD4bs or “off-target” antibodies, undermining its effectiveness in eliciting the VRC01-class bnAb precursors.

Researchers at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases introduced multiple N-linked glycosylation sites to mask non-CD4bs regions of eOD-GT8 60mer to focus the antibody immune response to the CD4bs.

Several glycan-masked mutants showed significantly decreased antibody binding to non-CD4bs “off-target” epitopes while maintaining strong binding to CD4bs-specific bnAbs. Furthermore, in vivo studies showed that immunization with the best glycan-masked eOD-GT8 mutants resulted in significant increases in the elicitation of CD4bs-specific serum antibodies, CD4bs-specific B cells in the spleen, and VRC01-class precursors, compared to immunization with the parental eOD-GT8 immunogen. In conclusion, because of their improved antigenic and immunogenic profiles, glycan-masked eOD-GT8 60mer mutants may serve as improved priming immunogens to elicit VRC01-class bnAbs in humans.

Potential Commercial Applications:
• HIV-1 vaccine—the priming component in a prime-boost approach.
Competitive Advantages:
• Reduced off-target immunogenicity.
• Improved efficacy in eliciting precursors for broadly neutralizing CD4bs antibodies.
• Facilitates the development of VRC01-class bnAbs in humans.
Development Stage: In vivo testing (rodents).

Inventors: John R. Mascola (NIAID), Hongying Duan (NIAID), Xuejun Chen (NIAID), Cheng Cheng (NIAID) and Jeffrey C. Boyington (NIAID).

Publications: Duan, H. et al., Glycan Masking Focuses Immune Responses to the HIV-1 CD4-Binding Site and Enhances Elicitation of VRC01-Class Precursor Antibodies. Immunity 49, 301 (2018).