effective date for repackagers to ''affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction in commerce'' under section 582(e)(2)(A) of the FD&C Act, is not later than November 27, 2018.

This guidance is intended to assist manufacturers and repackagers in understanding the requirements to affix or imprint a product identifier on each package and homogenous case of product that they introduce in a transaction into commerce to satisfy the product identifier requirement of section 582 of the FD&C Act. The recommendations in this guidance are intended to assist manufacturers and repackagers in standardizing both the human-readable and machine-readable format of the information that is contained in the product identifier. This guidance also intends to clarify that these requirements do not change the linear barcode requirements.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Product Identifiers Under the Supply Chain Security Act Questions and Answers.''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This draft guidance includes information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) of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Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: September 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–20502 Filed 9–19–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration Meeting of the Advisory Committee on Heritable Disorders in Newborns and Children

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

ACTION: Notice.

SUMMARY: The Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) has scheduled a public meeting. Information about the ACHDNC, a roster of members, the meeting agenda, as well as past meeting summaries is located on the ACHDNC website at *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html.*

DATES: November 1, 2018, 10:30 a.m.–5:30 p.m. ET and November 2, 2018, 9:00 a.m.–3:00 p.m. ET.

ADDRESSES: This meeting will be held in person and by webinar. Advanced registration is required. Please register online at *http://www.achdncmeetings.org/* by 12:00 p.m. ET on October 29, 2018. The address for the meeting is 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Ann Ferrero, Maternal and Child Health Bureau (MCHB), HRSA, 5600 Fishers Lane, Room 18N100C, Rockville, Maryland 20857; 301–443–3999; or *AFerrero@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The ACHDNC provides advice and recommendations to the Secretary of HHS (Secretary) on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. In addition, ACHDNC's recommendations regarding inclusion of additional conditions for screening, following adoption by the Secretary, are evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA through the Recommended Uniform Screening Panel (RUSP) pursuant to section 2713 of the Public Health Service Act (42 U.S.C. 300gg–13). Under this provision, non-grandfathered group health plans and health insurance issuers offering group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (*i.e.,* policy years) beginning on or after the date that is one year from the Secretary's adoption of the condition for screening.

During the November meeting, the ACHDNC will hear from experts in the field and discuss issues related to newborn screening information, education, training activities, and training resources. The ACHDNC will hear presentations on the use of genomic sequencing in newborn screening as well as the clinical setting for both well and sick infants. The ACHDNC will also discuss the nomination of cerebrotendinous xanthomatosis (CTX) to the RUSP and vote on whether to move the nomination forward to evidence review. Note that this vote is not on a proposed addition of a condition to the RUSP. Agenda items are subject to change as priorities dictate. Refer to the ACHDNC website for any updated information concerning the meeting. Members of the public will have the opportunity to provide comments, which are part of the official Committee record. To submit written comments or request time for an oral comment at the meeting, please register online by 12:00 p.m. ET on October 26, 2018, at *http://www.achdncmeetings.org.* Oral comments will be honored in the order they are requested and may be limited as time allows. Individuals associated with groups or who plan to provide comments on similar topics may be asked to combine their comments and present them through a single representative. No audiovisual presentations are permitted. Written comments should identify the individual's name, address, email, telephone number, professional or organization affiliation, background or area of expertise (*i.e.,* parent, family member, researcher, clinician, public health, etc.) and the topic/subject matter.

Individuals who plan to attend and need special assistance or another reasonable accommodation should notify Ann Ferrero at the address and phone number listed above at least 10 business days prior to the meeting. Since this meeting occurs in a federal government building, attendees must go through a security check to enter the building. Non-U.S. Citizens attendees planning to attend must notify HRSA of their planned attendance at least 10 business days prior to the meeting in

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 webcast. Instructions on how to access the meeting via webcast 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, NIH, 31 Center Drive, Building 31, Room 10A28, Bethesda, MD 20892, 240–781–3360 *williaam@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://deainfo.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).

Intellectual Property: HHS Reference Number E–083–2017 includes U.S. Provisional Patent Application Number 62/476,397 filed 03/24/2017 and PCT