Guide for Syndromic Surveillance available for public comment at *http://www.regulations.gov* and *http://www.cdc.gov/phin/library/2011/guides/Syndromic_Surveillance_Implementation_Guide_Release_1_4.pdf*

Dated: April 27, 2011.

Tanja Popovic,

Deputy Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2011–10949 Filed 5–4–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0322]

Guidance for Industry on Dosage Delivery Devices for Orally Ingested OTC Liquid Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Dosage Delivery Devices for Orally Ingested OTC Liquid Drug Products." This document is intended to provide guidance to firms that are manufacturing, marketing, or distributing orally ingested over-the-counter (OTC) liquid drug products packaged with dosage delivery devices (e.g., calibrated cups, droppers, syringes, or spoons). FDA is issuing this guidance because of ongoing concerns about potentially serious accidental drug overdoses that can result from the use of dosage delivery devices with markings that are inconsistent or incompatible with the labeled dosage directions for orally ingested OTC liquid drug products.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, 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 guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Spencer Salis, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Building 51, rm. 5216, Silver Spring, MD 20993–0002, 301–796–3327.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Dosage Delivery Devices for Orally Ingested OTC Liquid Drug Products." The Agency has determined that many orally ingested OTC liquid drug products in the marketplace are packaged with dosage delivery devices that bear markings that are inconsistent with the labeled dosage directions, contain superfluous markings, or are missing necessary markings. FDA is issuing this guidance because of ongoing concerns about potentially serious accidental drug overdoses that can result from the use of dosage delivery devices with markings that are inconsistent or incompatible with the labeled dosage directions for orally ingested OTC drug products. FDA recommends that dosage delivery devices be included for all orally ingested OTC drug products that are liquid formulations, that they should bear markings that are consistent with the labeled dosage directions, and that they should be labeled in a manner that attempts to ensure that they are used only with the products with which they are included.

In the **Federal Register** of November 5, 2009 (74 FR 57319), FDA announced the availability of a draft guidance for industry entitled "Dosage Delivery Devices for Over-the-Counter Liquid Drug Products." The notice gave interested persons an opportunity to comment by February 2, 2010. We received a number of comments from individuals, firms, and consumer groups. We have carefully considered the comments and, where appropriate, have made corrections, added information, or clarified the information in the guidance in response to the comments or on our own initiative.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on dosage delivery devices for orally ingested OTC liquid drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: April 28, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–10965 Filed 5–4–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given that the following committee will convene its sixty-seventh meeting.

Name: National Advisory Committee on Rural Health and Human Services.

Dates and Times: June 15, 2011, 9 a.m.–4:45 p.m., June 16, 2011, 9 a.m.–4:45 p.m., June 17, 2011, 8:45 a.m.–10:30 a.m.

Place: Park Place Hotel, 300 East State Street, Traverse City, MI 49684. (231) 946–5000.

Status: The meeting will be open to the public.

Purpose: The National Advisory Committee on Rural Health and Human Services provides advice and recommendations of health and human services in rural areas.

Agenda: Wednesday morning, at 9 a.m., the meeting will be called to order by the Chairperson of the Committee, the Honorable Ronnie Musgrove. The first three presentations will be overviews of rural Michigan and the relevant health indicators. The remainder of the day the Committee will hear presentations on two of the chosen

Subcommittee topics. The first panel will focus on the impact of Value-Based Purchasing Demonstrations. The second panel will focus on primary care training and placement. The Subcommittees will then move into breakout sessions to further discuss these topics. After the panel discussions, the Committee Chair will give an overview of the site visits. This will be followed by a call for public comment. The Wednesday meeting will close at 4:45 p.m.

Thursday morning, at 9 a.m., the Committee will travel to Munson Medical Center for a briefing on its role in serving the region. At 10 a.m. the Committee will break into Subcommittees and depart to the site visits. The Value-Based Purchasing Demonstrations Subcommittee will meet at Mercy Cadillac Hospital in Cadillac, MI. The Primary Care Training and Placement Subcommittee will meet at Kalkaska Rural Health Clinic in Kalkaska, MI. The Subcommittees will return to the Park Place Hotel in Traverse City at 4 p.m. Transportation to the site visits will not be provided to the public. The Thursday meeting will close at 4:45 p.m.

The Final session will be convened on Friday morning at 8:45 am. The meeting will open with a review of the Subcommittee site visits. The Committee will draft a letter to the Secretary or Designee and discuss the September 2011 meeting. The meeting will adjourn at 10:30 a.m.

For Further Information Contact: Thomas Morris, MPA, Executive Secretary, National Advisory Committee on Rural Health and Human Services, Health Resources and Services Administration, Parklawn Building, Room 10B–45, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443–0835, Fax (301) 443–2803.

Persons interested in attending any portion of the meeting should contact Deborah DeMasse-Snell at the Office of Rural Health Policy (ORHP) via Telephone at (301) 443–0835 or by e-mail at *ddemasse-snell@hrsa.gov*. The committee meeting agenda will be posted on ORHP's Web site *http://www.ruralhealth.hrsa.gov*.

Dated: April 28, 2011.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2011–10983 Filed 5–4–11; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 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.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; *telephone:* 301–496–7057; *fax:* 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Improved Standard for Immune System Recovery Assay

Description of Invention: Monitoring an immune system that has been depleted by infection (*e.g.,* HIV), chemotherapy, or progenitor cell transplantation is vital to assessing individual's recovery status. This technology provides a new plasmid standard to be used as part of the existing TREC assay. This new plasmid has a shorter insert than the commercially available one, which means it now matches the PCR product generated in the qPCR reaction in the TREC assay. Additionally, the new plasmid is easier to grow up than the existing standard.

Applications: TREC assay for T-cell concentration measurements.

Advantages:

- The insert of standard plasmid is shorter and directly matches the PCR product generated in the qPCR reaction.
- The standard plasmid is easy to grow up.

Development Status: Fully developed.

Inventors: Daniel C. Douek, Richard A. Koup, Brenna J. Hill (NIAID.)

Relevant Publications:

1. Douek *et al.* Changes in thymic function with age and during the treatment of HIV infection. Nature 1998 Dec 17;396(6712):690–695. [*PubMed:* 9872319.]

2. Douek *et al.* Assessment of thymic output in adults after haematopoietic stem-cell transplantation and prediction of T-cell reconstitution. Lancet 2000 May 27;355(9218):1875–1881. [*PubMed:* 10866444.]

Patent Status: HHS Reference No. E–067–2011/0—Research Material. Patent protection is not being pursued for this technology.

Licensing Status: Research tool available for non-exclusive licensing.

Licensing Contact: Susan Ano, Ph.D.; 301–435–5515; *anos@mail.nih.gov.*

Glucocerebrosidase Activators as a Treatment for Gaucher Disease

Description of Invention: This technology is a collection of small molecule activators of a genetically defective version of the enzyme called glucocerebrosidase (GCase), which causes Gaucher disease. Gaucher disease is a rare disease affecting 1 in 40,000 babies born. Ashkenazi Jews of eastern European descent (about 1 in 800 live births) are at particular risk of carrying this genetic defect. It is caused by inherited genetic mutations in the gene that encodes GCase, which result in reduced activity of the enzyme. This enzyme is normally made and then transported to an organelle called a lysosome, which is dedicated to the degradation and disposal of molecules the cell no longer needs. GCase is responsible for the breakdown of a fatty material called glucocerebroside (or glucosylceramide). The accumulation of this lipid occurs inside specific cells called macrophages and macrophage-derived cells. The disease has been categorized into three types: neuronopathic (types 2, 3) and non-neuronopathic (type 1) with mild to severe symptoms that can appear at anytime from infancy to adulthood. Clinical manifestations can include an enlarged spleen and liver, anemia, decreased platelets, bone disease and neurodegeneration, with varying severity depending on the type of disease and time of diagnosis. The deficient GCase activity has been attributed to insufficient GCase enzyme in the lysosome. After production in the endoplasmic reticulum (ER), defective GCase does not fold properly and is therefore degraded in the ER and not transported to the lysosome where it would hydrolyze glucocerebroside. The small molecule activators may act by increasing the concentration of GCase that reaches the lysosome by facilitating the proper folding of GCase so that it can be released from the ER and transported to lysosomes. Thus, these small molecules could be acting like "chaperones," because they facilitate proper folding which results in some active enzyme. Prior failed attempts to use small molecule chaperones to improve GCase folding and transport were made with inhibitors of GCase, which ironically properly folded active GCase that was subsequently transported to the lysosome, but the molecule also inhibited the GCase co that it could not break down glucocerebroside. On the other hand, these proposed small molecules were