forms that are equivalent. The State program maintains the documents and verifies records required for each standard. The information contained in the documents must be current and fit-for-use. If the State program fails to meet all program elements and documentation requirements of a standard, it develops a strategic plan which includes the following: (1) The individual element of documentation requirement of the standard that was not met, (2) improvements needed to meet the program element or documentation requirement of the standard, and (3) projected completion dates for each task.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Respondent	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
State Departments of Agriculture or Health	42	1	42	750	31,500

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden has been calculated as 750 hours per respondent. This burden was determined by capturing the average amount of time for each respondent to assess the current state of the program and work toward implementation of each of the 10 standards contained in MFRPS. The hours per respondent will change as accounted for in the continuing improvement and self-sufficiency of the program.

Dated: February 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–02888 Filed 2–11–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0114]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Request for Samples and Protocols

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Request for Samples and Protocols'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On September 24, 2015, the Agency submitted a proposed collection of information entitled ''Request for Samples and Protocols'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0206. The approval expires on December 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: February 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–02882 Filed 2–11–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Gastrointestinal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Gastrointestinal Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 7, 2016, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

Contact Person: Cindy Hong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, *GIDAC@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss new drug application (NDA) 207999, obeticholic acid oral tablets, submitted by Intercept Pharmaceuticals, Inc., proposed for the treatment of primary biliary cirrhosis in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background

material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 24, 2016. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 16, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 17, 2016.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Cindy Hong at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 8, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016–02857 Filed 2–11–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0268]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On December 9, 2015, the Agency submitted a proposed collection of information entitled ''Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0728. The approval expires on January 31, 2019. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: February 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–02880 Filed 2–11–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0148]

Government-Owned Inventions; Availability for Licensing; Influenza Virus Neuramindase

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The invention listed in this document is owned by an Agency of the U.S. Government and is available for licensing in accordance with Federal regulations to achieve expeditious commercialization of results of Federally funded research and development.

FOR FURTHER INFORMATION CONTACT:

For licensing information and copies of the patent applications: Alice Welch, Technology Transfer Program Office, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4226, Silver Spring, MD 20993, 240–402–2561, FAX: 301–847–3539. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

For parties interested in licensing or collaborative research activities: William Ronnenberg, Technology Transfer Program Office, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4214, Silver Spring, MD 20993, 240–402–4561, *William.ronnenberg@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Technology description.

Title of Abstract: Therapeutic and prophylactic anti-Influenza virus neuraminidase 1 (N1) antibody (CD6) with a novel epitope that spans neuramindase (NA) dimers.

Description of Technology: Influenza virus neuramindase (NA) protein is a surface protein that plays an essential role in virus replication. Drugs and antibodies that block NA function can reduce both the symptoms and the length of illness; however, variants of influenza virus are resistant to NA inhibitors. The neuramindase 1 (N1) subtype of NA is important because it is found in the two pandemic H1N1 influenza virus strains (1918 Spanish flu and 2009 swine flu) and the H5N1 avian influenza virus. Anti-neuramindase antibody CD6 is a novel antibody that spans a conserved 30 amino acid epitope across the lateral face of a neuramindase (NA) dimer.

The subject technology may offer an alternative to therapeutic NA inhibitors