Frequency: Annually; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions and Individuals; *Number of Respondents:* 16; Total *Annual Responses:* 16; *Total Annual Hours:* 160. (For policy questions regarding this collection contact Michelle Peterman at 410–786–2591.)

Dated: August 15, 2017.

Martique Jones,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2017–17495 Filed 8–17–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–4069]

Bayer Healthcare Pharmaceuticals; Withdrawal of Approval of a New Drug Application for BAYCOL (cerivastatin sodium) Tablets, 0.05 Milligrams, 0.1 Milligrams, 0.2 Milligrams, 0.3 Milligrams, 0.4 Milligrams, and 0.8 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of new drug application (NDA) 020740 for BAYCOL (cerivastatin sodium) tablets, 0.05 milligrams (mg), 0.1 mg, 0.2 mg, 0.3 mg, 0.4 mg, and 0.8 mg, held by Bayer Healthcare Pharmaceuticals (Bayer). Bayer requested withdrawal of this application, and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of August 18, 2017.

FOR FURTHER INFORMATION CONTACT: Kristiana Brugger, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6262, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION: NDA 020740 for BAYCOL (cerivastatin sodium) tablets, 0.05 mg, 0.1 mg, 0.2 mg, and 0.3 mg, was received on June 26, 1996, under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA approved NDA 020740 on June 26, 1997, as safe and effective as an adjunct to diet for the reduction of elevated total and LDL cholesterol levels in patients with primary hypercholesterolemia and mixed dyslipidemia (Frederickson Types IIa and IIb) when the response to dietary restriction of saturated fat and cholesterol and other non-pharmacological measures alone has been inadequate. Supplemental NDAs were received by FDA on July 17, 1998, for the 0.4 mg strength of the drug (approved on May 24, 1999) and on September 23, 1999, for the 0.8 mg strength of the drug (approved on July 21, 2000). The most recently approved labeling (May 21, 2001) for this drug stated that: ''BAYCOL® (cerivastatin sodium tablets) is indicated as an adjunct to diet to reduce elevated Total–C, LDL–C, apo B, and TG and to increase HDL–C levels in patients with primary hypercholesterolemia and mixed dyslipidemia (Fredrickson Types IIa and IIb) when the response to dietary restriction of saturated fat and cholesterol and other non-pharmacological measures alone has been inadequate.''

Over time, however, reports associating cerivastatin with rhabdomyolysis, a potentially fatal condition involving muscle weakness, increased. Because of these reports, Bayer withdrew BAYCOL from the market on August 8, 2001. On January 24, 2014, Bayer wrote to FDA asking the Agency to withdraw approval of NDA 020740 under 21 CFR 314.150(d) and waived its opportunity for a hearing.

Accordingly, under section 505(e) of the FD&C Act (21 U.S.C. 355(e)) and section 314.150(d), approval of NDA 020740, and all amendments and supplements thereto, is withdrawn. Distribution of BAYCOL (cerivastatin sodium) tablets, 0.05 mg, 0.1 mg, 0.2 mg, 0.3 mg, 0.4 mg, and 0.8 mg in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Dated: August 15, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–17510 Filed 8–17–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 Advisory Mental Health Council.

The meeting will be open to the public as indicated below, 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 meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Mental Health Council.

Date: September 14, 2017.

Open: 9:00 a.m. to 12:45 p.m.

Agenda: Presentation of the NIMH Director's Report and discussion.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Closed: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Jean G. Noronha, Ph.D., Director, Division of Extramural Activities, National Institute of Mental Health, NIH Neuroscience Center, 6001 Executive Blvd., Room 6154, MSC 9609, Bethesda, MD 20892–9609, 301–443–3367, *jnoronha@mail.nih.gov.*

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their 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.

Information is also available on the Institute's/Center's home page: *www.nimh.nih.gov/about/advisory-boards-and-groups/namhc/index.shtml.,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: August 14, 2017.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–17430 Filed 8–17–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Initial Review Group Epidemiology, Prevention and Behavior Research Review Subcommittee.

Date: October 23, 2017.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, Terrace Level Conference Rooms, 5635 Fishers Lane, Rockville, MD 20852.

Contact Person: Anna Ghambaryan, M.D., Ph.D., Scientific Review Officer, Extramural Project Review Branch, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 5635 Fishers Lane, Room 2019, Rockville, MD 20852, 301–443–4032, *anna.ghambaryan@nih.gov*.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Initial Review Group Clinical, Treatment and Health Services Research Review Subcommittee.

Date: November 1, 2017.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, Terrace Level Conference Room 508, 5635 Fishers Lane, Rockville, MD 20852

Contact Person: Ranga V. Srinivas, Ph.D. Chief Extramural Project Review, Branch National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 5365 Fishers Lane, Room 2085, Rockville, MD 20852, (301) 451–2067 *srinivar@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards., National Institutes of Health, HHS)

Dated: August 14, 2017.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–17428 Filed 8–17–17; 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: Peter Soukas, J.D., (301) 594–8730; *peter.soukas@nih.gov*. Licensing information and copies of the patent applications 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.

Development of a Transferrable Norwalk Virus Epitope and Detector Monoclonal Antibody

Description of Technology

Noroviruses are now recognized as the major cause of non-bacterial gastroenteritis in all age groups, and efforts are underway to develop an effective vaccine. The lack of a robust cell culture system for human noroviruses has complicated vaccine development. Hence, norovirus virus like particles (VLPs) have played an important role in the understanding of virus structure, immune response, antigenic diversity, and vaccine design. The development of monoclonal antibodies (MAbs) against norovirus VLPs has allowed the identification and characterization of key antigenic sites of the virus capsid and facilitated the development of diagnostic assays. During characterization of a panel of MAbs raised against Norwalk virus (NV), a prototype norovirus strain, the inventors identified a monoclonal antibody (MAbNV10) that proved useful in the identification of NV in tissue and in the characterization of an insertion site in the feline calicivirus (FCV) genome. The inventors mapped the precise binding site of the MAb by peptide screening and discovered that the epitope could be expressed when fused to other proteins. The sequence of this peptide (epitope) along with the detector antibody could be used as a new way to tag proteins for functional studies. The small size of the linear epitope, along with the strong avidity of the detector monoclonal antibody makes this system especially useful for many techniques, including immunofluorescence, Western blot, immunoprecipitation (including ''pulldown'' assays), and immunohistochemistry. The inventors' epitope system may be comparable to that of the HA tag of influenza virus that is widely used in molecular biology.

This technology is further described in Parra et al., ''Mapping and modeling of a strain-specific epitope in the Norwalk virus capsid inner shell,'' *Virology.* 2016 May;492:232–41. doi: 10.1016/j.virol.2016.02.019. Epub 2016 Mar 21.

Materials available for licensing comprise: (1) Hybridoma cell line NV10, (2) Plasmid expressing NV10 epitope as positive control, and (3) Plasmid expressing the NV10 scFV.

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

- Diagnostics
- Vaccines

Competitive Advantages

- Cross-reactive norovirus antibody