

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]

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DATES: Approval is withdrawn as of August 18, 2017.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

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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.