4164-01-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DATES: Approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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: 8/17/2017 8:45 am; Publication Date: 8/18/2017]