4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-2196]

Allergan Pharmaceuticals International, Ltd.; Withdrawal of Approval of a New Drug Application for ASACOL (Mesalamine) Delayed-Release Tablets, 400 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing the approval of the new drug application (NDA) for ASACOL (mesalamine) delayed-release tablets, 400 milligrams (mg), held by Allergan Pharmaceuticals International, Ltd., c/o Allergan Sales, LLC, 2525 Dupont Dr., Irvine, CA 92612 (Allergan). Pursuant to FDA's request, Allergan agreed to 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DATES: Approval is withdrawn as of **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.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: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On January 31, 1992, FDA approved NDA 019651 for ASACOL (mesalamine) delayed-release tablets, 400 mg. It is approved for the treatment of mildly to moderately active ulcerative colitis (UC) in patients 5 years of age and older, and for the maintenance of remission of mildly to moderately active UC in adults. In December 2012, FDA published the guidance for industry "Limiting the Use of Certain Phthalates as Excipients in CDER-Regulated Products," available at https://www.fda.gov/media/83029/download, describing evidence that certain phthalate esters (phthalates), including dibutyl phthalate (DBP) and di(2-ethylhexyl) phthalate from pharmaceutical products, are developmental and reproductive toxicants in laboratory animals. This evidence has raised concerns about human

exposure to phthalates, particularly in vulnerable populations such as pregnant women and infants. ASACOL (mesalamine) delayed-release tablets, 400 mg, contain DBP as an inactive ingredient. On September 6, 2017, FDA notified Allergen that because ASACOL (mesalamine) delayed-release tablets, 400 mg, contains DBP, the product presents a potential problem that is sufficiently serious to warrant withdrawal of approval. On December 22, 2017, Allergan agreed to have FDA withdraw approval of NDA 019651 for ASACOL (mesalamine) delayed-release tablets, 400 mg, under § 314.150(d) (21 CFR 314.150(d)) and waived its opportunity for a hearing.

For the reasons discussed above, and pursuant to the applicant's agreement, approval of NDA 019651 for ASACOL (mesalamine) delayed-release tablets, 400 mg, and all amendments and supplements thereto, is withdrawn under § 314.150(d).

Distribution of ASACOL (mesalamine) delayed-release tablets, 400 mg, into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Dated: December 4, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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