Ming Marine Transport Corp.; Zim Integrated Shipping Services, Ltd.; and Matson Navigation Company, Inc.

Filing Party: Robert Magovern; Cozen O'Connor.

Synopsis: The Amendment adds Matson Navigation Company, Inc. as a party to the Agreement.

Proposed Effective Date: 1/15/2021.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/34503.

Dated: December 4, 2020.

Rachel E. Dickon,

Secretary.

[FR Doc. 2020–27067 Filed 12–9–20; 8:45 am]

BILLING CODE 6730–02–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DATES: Approval is withdrawn as of December 10, 2020.

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.

[FR Doc. 2020–27082 Filed 12–9–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2227]

Food and Drug Administration Fiscal Year 2020 Performance Review Board

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the names of the members who will serve on its fiscal year (FY) 2020 Performance Review Board (PRB). The purpose of the PRB is to provide fair and impartial review of Senior Executive Service (SES), Senior Professional, 21st Century Cures Act, and Title 42(f) (SES Equivalents) performance appraisals, bonus recommendations, and pay adjustments.

DATES: Approved October 1, 2020.

FOR FURTHER INFORMATION CONTACT: Abu Sesay, Office of Human Capital Management (OHCM), Three White Flint North, 02C47, 11601 Landsdown St., North Bethesda, MD 20852, Office Number: 240–402–0440 (not a toll-free number).

SUPPLEMENTARY INFORMATION: This action is being taken pursuant to 5 U.S.C. 4314(c)(4), which requires that members of performance review boards be appointed in a manner to ensure consistency, stability, and objectivity in performance appraisals and requires that notice of the appointment of an individual to serve as a member be published in the **Federal Register**.

The following persons will serve on the FDA FY 2020 Performance Review Board, which oversees the evaluation of performance appraisals of FDA's Senior Executives and Equivalents:

- James Sigg, PRB Chair
- Tania Tse, PRB Officiator
- Glenda Barfell
- Janelle Barth
- Vincent Bunning
- Mary Beth Clarke
- Elizabeth Dickinson
- Tracey Forfa
- Denise Huttenlocker
- Diane Maloney
- William Tootle

Dated: December 4, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–27123 Filed 12–9–20; 8:45 am]

BILLING CODE 4164–01–P