

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-P-2513]

Determination That FLAGYL (Metronidazole) Tablets, 250 Milligrams and 500 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that FLAGYL (metronidazole) tablets, 250 milligrams (mg) and 500 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to these products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Neerja Razdan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6217, Silver Spring, MD 20993-0002, 301-796-3600, Neerja.Razdan@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or

ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

FLAGYL (metronidazole) tablets, 250 mg and 500 mg, are the subject of NDA 012623, held by Pfizer, Inc., and initially approved prior to Jan 1, 1982. FLAGYL is indicated for treatment of symptomatic Trichomoniasis, asymptomatic Trichomoniasis, treatment of asymptomatic sexual partners, Amebiasis, anaerobic bacterial infections among other infections, as listed on the product label, and as clinically indicated for treatment.

FLAGYL (metronidazole) tablets, 250 mg and 500 mg, are currently listed in the “Discontinued Drug Product List” section of the Orange Book. Innogenix LLC submitted a citizen petition dated May 21, 2024 (Docket No. FDA-2024-P-2513), under 21 CFR 10.30, requesting that the Agency determine whether FLAGYL (metronidazole) tablets, 250 mg and 500 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that FLAGYL (metronidazole) tablets, 250 mg and 500 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that FLAGYL (metronidazole) tablets, 250 mg and 500 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of FLAGYL (metronidazole) tablets, 250 milligrams and 500 milligrams, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that these drug products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list FLAGYL (metronidazole) tablets, 250 mg and 500 mg, in the “Discontinued Drug Product

List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for these drug products may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 28, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-19721 Filed 9-3-24; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Solicitation of Nominations for Membership To Serve on the Advisory Commission on Childhood Vaccines

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Request for nominations.

SUMMARY: HRSA is seeking nominations of qualified candidates to consider for appointment as members of the Advisory Commission on Childhood Vaccines (ACCV or Commission). ACCV advises the Secretary of HHS (the Secretary) on issues related to the implementation of the National Vaccine Injury Compensation Program (VICP).

DATES: Written nominations for membership on ACCV will be received on a continuous basis.

ADDRESSES: Nomination packages must be submitted to the Director, Division of Injury Compensation Programs, Health Systems Bureau, HRSA, 5600 Fishers Lane, Room 08W-25A, Rockville, Maryland 20857. Electronic nomination packages can be submitted by email to ACCV@hrsa.gov.

FOR FURTHER INFORMATION CONTACT: Pita Gomez, Principal Staff Liaison, Division of Injury Compensation Programs, Health Systems Bureau, HRSA, at 1-800-338-2382 or email at ACCV@hrsa.gov. A copy of the ACCV charter and list of the current membership may be obtained by accessing the ACCV