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Determination That FLAGYL (Metronidazole) Tablets, 250 Milligrams and 500 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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(FDA or Agency) has determined that FLAGYL (metronidazole) tablets, 250 milligrams (mg) and 500 mg, were not withdrawn from sale for reasons of safety or effectiveness.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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness.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

website at *https://www.hrsa.gov/advisory-committees/vaccines/index.html.*

SUPPLEMENTARY INFORMATION: ACCV was established by Title XXI of the Public Health Service Act and advises the Secretary on issues related to implementation of the VICP. ACCV meets four times each calendar year, or at the discretion of the Designated Federal Officer in consultation with the Chair.

Nominations: HRSA is requesting nominations for voting members to serve as Special Government Employees (SGEs) on ACCV to fill open positions. The Secretary appoints ACCV members with the expertise needed to fulfill the duties of the Commission. The membership requirements are set forth in section 2119 of the Public Health Service Act.

ACCV consists of nine voting members appointed by the Secretary as follows: (1) three health professionals, who are not employees of the United States government, and who have expertise in the health care of children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, of whom at least two shall be pediatricians; (2) three members from the general public, of whom at least two shall be legal representatives (parents or guardians) of children who have suffered a vaccine-related injury or death; and (3) three attorneys, of whom at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death, and of whom one shall be an attorney whose specialty includes representation of vaccine manufacturers. In addition, the Director of the National Institutes of Health, the Assistant Secretary for Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of the Food and Drug Administration (or the designees of such officials) serve as nonvoting ex officio members.

HHS will consider nominations of all qualified individuals to ensure the ACCV includes the areas of subject matter expertise noted above. As indicated, at least two of the three ACCV members from the general public must be legal representatives (parents or guardians) of children who have suffered a vaccine-related injury or death. To be considered for appointment to the ACCV in that category, there must have been a finding (*i.e.,* a decision) by the U.S. Court of Federal Claims or a civil court that a VICP-covered vaccine caused, or was presumed to have caused, the represented child's injury or death. Additionally, based on a recommendation made by ACCV, the Secretary will consider having a health professional with expertise in obstetrics as one of the members from the general public. Interested applicants may self-nominate or be nominated by another individual or organization.

Individuals selected for appointment to the Commission will be invited to serve for up to 3 years. Members appointed as SGEs receive a stipend and reimbursement for per diem and travel expenses incurred for attending ACCV meetings and/or conducting other business on behalf of ACCV, as authorized by 5 U.S.C. 5703, for persons employed intermittently in government service.

The following information must be included in the package of materials submitted for each individual nominated for consideration: (1) a letter of nomination stating the name, affiliation, and contact information for the nominee, the basis for the nomination (*i.e.,* what specific attributes, perspectives, and/or skills does the individual possess that would benefit the workings of ACCV) and the nominee's field(s) of expertise; (2) the name, address, daytime telephone number, and email address at which the nominator can be contacted; and (3) a current copy of the nominee's curriculum vitae or resume. Nomination packages may be submitted directly by the individual being nominated or by the person/organization recommending the candidate. Nomination packages will be collected and retained to create a pool of possible future ACCV voting members. When a vacancy occurs, nomination packages from the appropriate category will be reviewed and nominees may be contacted at that time.

HHS endeavors to ensure that the membership of ACCV is balanced in terms of points of view represented and that individuals from a broad representation of geographic areas, gender, and ethnic and minority groups, as well as individuals with disabilities, are considered for membership. Appointments shall be made without discrimination on the basis of age, disability, race, ethnicity, gender, sexual orientation, national origin, or cultural, religious, or socioeconomic status.

Individuals who are selected to be considered for appointment will be required to provide detailed information regarding their financial holdings, consultancies, and research grants or contracts. Disclosure of this information is required for HRSA ethics officials to determine whether there is a potential conflict of interest between the SGE's public duties as a member of ACCV and their private interests, including an appearance of a loss of impartiality as defined by federal laws and regulations, and to identify any required remedial action needed to address the potential conflict.

Authority: Under the authorities that established the ACCV, the Federal Advisory Committee Act of October 6, 1972, (Pub. L. 92–463, as amended) and 42 U.S.C. 300aa–19, section 2119 of the Public Health Services (PHS) Act, HRSA is requesting nominations for voting members of ACCV.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–19808 Filed 9–3–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Infant and Maternal Mortality

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Infant and Maternal Mortality (ACIMM or Committee) has scheduled a public meeting. Information about ACIMM and the agenda for this meeting can be found on the ACIMM website at *https://www.hrsa.gov/advisory-committees/infant-mortality/index.html.*

DATES:

- October 16, 2024, from 9:30 a.m. to 5:15 p.m. Eastern Time; and
- October 17, 2024, from 9 a.m. to 1 p.m. Eastern Time.

ADDRESSES: This meeting will be held in person at the Hubert H. Humphrey Building, HHS Headquarters, 200 Independence Avenue SW, Conference Room 505A, Washington, DC 20201, and virtually via webinar. The webinar link and log-in information will be available at the ACIMM website before the meeting at *https://www.hrsa.gov/advisory-committees/infant-mortality/index.html.*

FOR FURTHER INFORMATION CONTACT: Vanessa Lee, MPH, Designated Federal Official, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane,