it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collection of information are subject to review by OMB under the PRA. The collections of information pertaining to the submissions of controlled correspondence, GDUFA III commitment letter, and meetings related to generic drug development have been approved under OMB control number 0910–0797. The collections of information pertaining to the Generic Drug User Fee Program have been approved under OMB control number 0910–0727. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs*, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov*.

Dated: February 15, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–03517 Filed 2–17–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–P–2438]

Determination That ASACOL HD (Mesalamine) Delayed-Release Tablet, 800 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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(FDA or Agency) has determined that ASACOL HD (Mesalamine) Delayed-Release Tablet, 800 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness.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 this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Donna Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6213, Silver Spring, MD 20993–0002, 301–796–3600, *Donna.Tran@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.

ASACOL HD (Mesalamine) Delayed-Release Tablet, 800 mg, is the subject of NDA 021830, held by Allergan Pharmaceuticals International Ltd., and initially approved on May 29, 2008. ASACOL HD is indicated for the treatment of moderately active ulcerative colitis in adults.

In a letter dated May 13, 2022, Allergan Pharmaceuticals International Ltd. notified FDA that ASACOL HD (Mesalamine) Delayed-Release Tablet, 800 mg, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Aurobindo Pharma USA, Inc., submitted a citizen petition dated October 4, 2022 (Docket No. FDA–2022–P–2438), under 21 CFR 10.30, requesting that the Agency determine whether ASACOL HD (Mesalamine) Delayed-Release Tablet, 800 mg, was 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 ASACOL HD (Mesalamine) Delayed-Release Tablet, 800 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ASACOL HD (Mesalamine) Delayed-Release Tablet, 800 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ASACOL HD (Mesalamine) Delayed-Release Tablet, 800 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ASACOL HD (Mesalamine) Delayed-Release Tablet, 800 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 this drug product 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 this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: February 15, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–03521 Filed 2–17–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information on Promising Practices for Advancing Health Equity for Intersex Individuals; Correction

ACTION: Notice; correction.

SUMMARY: The Office of the Assistant Secretary for Health published a document in the **Federal Register** of February 10, 2023, announcing a request for information on Promising Practices for Advancing Health Equity for Intersex Individuals. The document included incorrect information regarding the **ADDRESSES** section and also **SUPPLEMENTARY INFORMATION** and also the collection for public comment.

FOR FURTHER INFORMATION CONTACT: Adrian Shanker, *Adrian.shanker@hhs.gov* or by phone at (202) 961–6483.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of February 10, 2023, in FR Doc 2023–02826, on page 8876 in the first column, correct the **ADDRESSES** section to read, ''Please see the supplementary information to view the questions. Comments must be submitted via *Regulations.gov*. Mailed paper and emailed submissions will not be reviewed.''

At the second column, tenth line, after the end of the sentence ''conversation therapy.'' the sentence should continue with the following: ''(efforts to change an individual's sexual orientation, gender identity, or gender expression, a practice not supported by any credible evidence that has been rejected and disavowed by behavioral health experts and associations). Conversion therapy perpetuates outdated views of gender roles and identities as well as the negative stereotype that being a sexual or gender minority or identifying as LGBTQI+ is an abnormal aspect of human development. Most importantly, it may put young people at risk of serious harm.''

At the second column, second paragraph to the end of the document is to be replaced as follows: ''*Request for Comments on the Report Development on Promising Practices for Advancing Health Equity for Intersex Individuals:* The OASH invites input from intersex people, stakeholders throughout the scientific research community, clinical and behavioral practice communities, patient and family advocates, school and university-based campus health care providers, persons from rural and frontier areas, scientific or professional organizations, federal partners, internal HHS stakeholders, and other interested members of the public on the two questions highlighted below. This input will serve as a valuable element in the development of the report, and the community's time and consideration are highly appreciated.

- What do you see as the current clinical/behavioral, research, services, and/or policy gaps that you are hoping this report addresses?
- What recent or ongoing research, innovative clinical/behavioral approaches and/or policy actions do you think are important for us to know about as we begin this work?
- What are the barriers to intersex individuals receiving clinical/behavioral care? Are there innovative policies or practices that overcome such barriers?
- What are the social factors that impact clinical/behavioral care (*e.g.,* the medical community's perceptions or biases around sex/gender) and how do these impact delivery and quality of care for intersex individuals?
- What promising practices for advancing health equity for intersex individuals should we be aware of?

Responses to this RFI are voluntary. Do not include any personally identifiable, proprietary, classified, confidential, trade secret, or sensitive information in your response. The responses will be reviewed by OASH staff, and individual feedback will not be provided to any responder. The Government will use the information submitted in response to this RFI at its discretion. The Government reserves the right to release comments publicly and to use any submitted information on public HHS websites; in reports; in summaries of the state of the science; in any possible resultant solicitation(s), grant(s), or cooperative agreement(s); or in the development of future funding opportunity announcements.

This RFI is for information and planning purposes only and should not be construed as a solicitation for applications or proposals, or as an obligation in any way on the part of the United States Federal Government, the HHS, or individual HHS Agencies and Offices to provide support for any ideas identified in response to it. The Federal Government will not pay for the preparation of any information submitted or for the Government's use of such information.

No basis for claims against the U.S. Government shall arise as a result of a response to this RFI or from the Government's use of such information. Additionally, the Government cannot guarantee the confidentiality of the information provided.''

Dated: February 15, 2023.

Rachel L. Levine,

Assistant Secretary for Health.

[FR Doc. 2023–03539 Filed 2–17–23; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Chemistry, Biochemistry and Biophysics A.

Date: March 14–15, 2023.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Vandana Kumari, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496–3290, *vandana.kumari@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: HEAL Initiative—Helping to End Addiction Long-term.

Date: March 14, 2023.

Time: 11:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: David Erik Pollio, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1006F, Bethesda, MD 20892, (301) 594–4002, *polliode@csr.nih.gov*.