and software, may be considered by the Committee. The Committee advises the Commissioner of Food and Drugs (Commissioner) on issues related to DHTs, including, for example, real-world data, real-world evidence, patient-generated health data, interoperability, personalized medicine/genetics, decentralized clinical trials, use of DHTs in clinical trials for medical products, cybersecurity, DHT user experience, and Agency policies and regulations regarding these technologies. The Committee provides relevant expertise and perspective to improve Agency understanding of the benefits, risks, and clinical outcomes associated with use of DHTs. The Committee performs its duties by providing advice and recommendations on new approaches to develop and evaluate DHTs and to promote innovation of DHTs, as well as identifying risks, barriers, or unintended consequences that could result from proposed or established Agency policy or regulation for topics related to DHTs.

II. Criteria for Voting Members

The Committee consists of a core of nine voting members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities who are knowledgeable in the fields of digital health, such as artificial intelligence/machine learning, augmented reality, virtual reality, digital therapeutics, wearables, remote patient monitoring, software development, user experience, real-world data, real-world evidence, patient-generated health data, interoperability, personalized medicine/genetics, decentralized clinical trials, cybersecurity, and implementation in clinical practice of and patient experience with digital health, as well as other relevant areas. Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this Committee will serve either as Special Government Employees or nonvoting representatives. Federal members will serve as Regular Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who serves as an individual, but who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. The Commissioner or designee shall also have the authority to select from a group of individuals nominated by industry to serve temporarily as nonvoting members who are identified with and represent industry interests.

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on the Committee with the exception of the following: Individuals who are not U.S. citizens or nationals cannot be appointed as Advisory Committee Members (42 U.S.C. 217(a)) in the FDA. Self-nominations are also accepted. Nominations must include a cover letter; a current, complete résumé or curriculum vitae for each nominee, including current business and/or home address, telephone number, and email address if available, and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Nomination Portal (see **ADDRESSES**). Nominations must specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination, unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: October 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–22569 Filed 10–11–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–P–1795]

Determination That MEKINIST (Trametinib Dimethyl Sulfoxide) Tablets, 1 Milligram, 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 the Agency) has determined that MEKINIST (trametinib dimethyl sulfoxide) tablets, 1 milligram (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for trametinib dimethyl sulfoxide tablets, 1 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nikki Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6280, Silver Spring, MD 20993–0002, 301–796–3601, *Nicole.Mueller@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.

MEKINIST (trametinib dimethyl sulfoxide) tablets, 1 mg, is the subject of NDA 204114, held by Novartis Pharmaceuticals Corp., and initially approved on May 29, 2013. MEKINIST is a kinase inhibitor indicated as a single agent for the treatment of BRAF-inhibitor treatment-naïve patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test.

MEKINIST (trametinib dimethyl sulfoxide) tablets, 1 mg, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. Apotex Inc., submitted a citizen petition dated May 4, 2023 (Docket No. FDA–2023–P–1795), under 21 CFR 10.30, requesting that the Agency determine whether MEKINIST (trametinib dimethyl sulfoxide) tablets, 1 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 MEKINIST (trametinib dimethyl sulfoxide) tablets, 1 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that MEKINIST (trametinib dimethyl sulfoxide) tablets, 1 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of MEKINIST (trametinib dimethyl sulfoxide) tablets, 1 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 MEKINIST (trametinib dimethyl sulfoxide) tablets, 1 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. ANDAs that refer to MEKINIST (trametinib dimethyl sulfoxide) tablets, 1 mg, may 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: October 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–22464 Filed 10–11–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0008]

Request for Nominations of Individuals and Consumer Organizations for the Digital Health Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is requesting nominations for a voting consumer representative to serve on the Digital Health Advisory Committee. FDA is also requesting that any consumer organizations interested in participating in the selection of a voting consumer representative to serve on the Digital Health Advisory Committee notify FDA in writing. Nominees recommended to serve as a voting consumer representative may either be self-nominated or may be nominated by a consumer organization. Nominations will be accepted for the current vacancy effective with this notice. FDA seeks to include the views of members of all gender groups, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore encourages nominations of appropriately qualified candidates from these groups.

DATES: Any consumer organization interested in participating in the selection of an appropriate voting member to represent consumer interests on the Digital Health Advisory Committee may send a letter or email stating that interest to FDA (see **ADDRESSES**) by November 27, 2023 for vacancy listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA (see **ADDRESSES**) by November 27, 2023. Nominations will be accepted for current vacancy.

ADDRESSES: All statements of interest from consumer organizations interested in participating in the selection process should be submitted electronically to *ACOMSSubmissions@fda.hhs.gov* or by mail to Advisory Committee and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5122, Silver Spring, MD 20993–0002.

Consumer representative nominations should be submitted electronically by logging into the FDA Advisory Committee Membership Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm* or by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, Rm. 5122, Silver Spring, MD 20993–0002. Additional information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT:

For questions relating to participation in the selection process: Kimberly Hamilton, Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5122, Silver Spring, MD 20993–0002, 301–796–8220, *Kimberly.Hamilton@fda.hhs.gov.*

For questions relating to the Digital Health Advisory Committee: James Swink, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5211, Silver Spring, MD 20993–0002, 301 796–6313, *James.Swink@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for a voting consumer representative on the Digital Health Advisory Committee. Elsewhere in this **Federal Register**, FDA is publishing separate documents regarding:

1. Digital Health Advisory Committee; Notice of Establishment
2. Request for Nominations for Voting Members on a Public Advisory Committee: Digital Health Advisory Committee
3. Request for Nominations of Individuals and Industry Organizations for the Digital Health Advisory Committee

I. Function and General Description of the Committee Duties

Digital Health Advisory Committee

The Committee provides advice on complex scientific and technical issues related to Digital Health Technologies (DHTs). This also may include advice on the regulation of DHTs, and/or their use, including use of DHTs in clinical trials or postmarket studies subject to FDA regulation. Topics relating to DHTs, such as artificial intelligence/machine learning, augmented reality, virtual reality, digital therapeutics, wearables, remote patient monitoring, and software, may be considered by the Committee. The Committee advises the Commissioner on issues related to DHTs, including, for example, real-world data, real-world evidence, patient-generated health data,