

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21 CFR 10.30, requesting that the Agency determine whether MEKINIST (trametinib dimethyl sulfoxide) tablets, 1 mg, was withdrawn from sale for reasons of safety or effectiveness.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at this time, FDA has determined under § 314.161 that MEKINIST (trametinib dimethyl sulfoxide) tablets, 1 mg, was not withdrawn for reasons of safety or effectiveness.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has identified no data or other information suggesting that MEKINIST (trametinib dimethyl sulfoxide) tablets, 1 mg, was withdrawn for reasons of safety or effectiveness.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 We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.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]

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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,

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.

II. Criteria for Members

Persons nominated for membership as a consumer representative on this committee should meet the following criteria: (1) demonstrate an affiliation with and/or active participation in in consumer or community-based organizations, (2) be able to analyze technical data, (3) understand research design, (4) discuss benefits and risks, and (5) evaluate the safety and efficacy of products under review. The consumer representative should be able to represent the consumer perspective on issues and actions before the advisory committee; serve as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations; and facilitate dialogue with the advisory committees on scientific issues that affect consumers.

III. Selection Procedures

Selection of members representing consumer interests is conducted through procedures that include the use of organizations representing the public interest and public advocacy groups. These organizations recommend nominees for the Agency's selection. Representatives from the consumer health branches of Federal, State, and local governments also may participate in the selection process. Any consumer organization interested in participating in the selection of an appropriate voting member to represent consumer interests should send a letter stating that interest to FDA (see **ADDRESSES**) within 30 days of publication of this document.

Within the subsequent 45 days, FDA will compile a list of consumer organizations that will participate in the selection process and will forward to each such organization a ballot listing at least two qualified nominees selected by the Agency based on the nominations received, together with each nominee's current curriculum vitae or résumé. Ballots are to be filled out and returned to FDA within 30 days. The nominee receiving the highest number of votes ordinarily will be selected to serve as the member representing consumer interests for that particular advisory committee.

IV. Nomination Procedures

Any interested person or organization may nominate one or more qualified persons to represent consumer interests on the Digital Health Advisory 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 FDA. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business and/or home address, telephone number, and email address if available; a signed copy of the Acknowledgment and Consent form available at the FDA Advisory Nomination Portal (see **ADDRESSES**), and a list of consumer or community-based organizations for which the candidate can demonstrate active participation.

Nominations should also specify the advisory committee for which the nominee is recommended. In addition, 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. Members will be invited to serve for terms up to 4 years.

FDA will review all nominations received within the specified timeframes and prepare a ballot containing the names of qualified nominees. Names not selected will remain on a list of eligible nominees and be reviewed periodically by FDA to determine continued interest. After selecting qualified nominees for the ballot, FDA will provide those consumer organizations that are participating in the selection process with the opportunity to vote on the listed nominees. Only organizations vote in the selection process. Persons who nominate themselves to serve as voting consumer representatives will not participate in the selection process.

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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0008]

Request for Nominations of Individuals and Industry 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 temporary nonvoting industry representatives to be included in a pool of individuals to serve on the Digital Health Advisory Committee. FDA is also requesting that industry organizations interested in participating in the selection of a pool of nonvoting industry representatives to serve as temporary nonvoting members on the Digital Health Advisory Committee (the Committee) in the Center for Devices and Radiological Health notify FDA in writing. Nominees recommended to serve as a temporary nonvoting industry representative may either be self-nominated or nominated by an industry organization. This position may be filled by representatives of different medical device areas based on areas of expertise relevant to the topics being considered by the Committee. Nominations will be accepted for current vacancies 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 industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interest, must send a letter stating that interest to the FDA by *November 13, 2023*, (see sections I and II of this document for details). Concurrently, nomination materials for prospective candidates should be sent to FDA by *November 13, 2023*.

ADDRESSES: All statements of interest from interested industry organizations interested in participating in the selection process of a pool of nonvoting industry representatives should be sent electronically to Margaret Ames (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives may be submitted electronically by accessing the FDA