TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response [2]	Total hours
Main Study:					
Consumers: number of main study screener completes (assumes 70% eligible).	566	1	566	0.08 (5 min.)	45
Consumers: number of completes, main study	396	1	396	0.33 (20 min.)	131
PCPs: number of main study screener completes (assumes 60% eligible).	660	1	660	0.08 (5 min.)	53
PCPs: number of completes, main study	396	1	396	0.33 (20 min.)	131
Total (rounded)	.....	.....	.....	.....	520

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in decimal format.

References

The following references are on display with the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; these are not available electronically at *https://www.regulations.gov* as these references are copyright protected. Some may be available at the website address, if listed. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Aikin, K.J., K.R. Betts, A. Keisler, and K.S. Ziemer, ''Market Claims and Efficacy Information in Direct-to-Consumer Prescription Drug Print Advertisements,'' *Psychology & Marketing,* 36(8), 747–757, 2019a.
2. Aikin, K.J., K.R. Betts, K.S. Ziemer, and A. Keisler, ''Consumer Tradeoff of Advertising Claim Versus Efficacy Information in Direct-to-Consumer Prescription Drug Ads,'' *Research in Social and Administrative Pharmacy,* 15(12), 1484–1488, 2019b.
3. Arroyo, R., A.P. Sempere, E. Ruiz-Beato, D. Prefasi, et al. ''Conjoint Analysis To Understand Preferences of Patients With Multiple Sclerosis for Disease-Modifying Therapy Attributes in Spain: A Cross-Sectional Observational Study,'' *BMJ Open,* 7(3), e014433, 2017.
4. Fraenkel, L., L. Suter, C.E. Cunningham, and G. Hawker, ''Understanding Preferences for Disease-Modifying Drugs in Osteoarthritis,'' *Arthritis Care Research,* 66(8), 1186–1192, 2014.
5. Wouters, H., G.A. Maatman, L. Van Dijk, M.L. Bouvy, et al. ''Trade-Off Preferences Regarding Adjuvant Endocrine Therapy Among Women With Estrogen Receptor-Positive Breast Cancer,'' *Annals of Oncology,* 24(9), 2324–2329, 2013.
6. Betts, K.R., V. Boudewyns, K.J. Aikin, C. Squire, et al. ''Serious and Actionable Risks, Plus Disclosure: Investigating an Alternative Approach for Presenting Risk Information in Prescription Drug Television Advertisements,'' *Research in Social and Administrative Pharmacy,* 14(10), 951–963, 2018.

Dated: October 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–22586 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 for Voting Members 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 voting members, excluding consumer and industry representatives, to serve on the Digital Health Advisory Committee (the Committee) in the Center for Devices and Radiological Health. 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: Nominations received on or before December 11, 2023 will be given first consideration for membership on the Committee. Nominations received after December 11, 2023 will be considered for nomination to the committee as later vacancies occur.

ADDRESSES: All nominations for membership should be sent electronically by logging into the FDA Advisory Committee Membership Nomination Portal (*https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm*) and selecting Academician/Practitioner from the dropdown menu (regardless of whether Academician/Practitioner accurately describes the nominee), or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm 5103, Silver Spring, MD 20993–0002. Information about becoming a member on 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: James Swink, Office of Management, 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 voting members to fill current vacancies on the Digital Health Advisory Committee. This notice does not include consumer and industry representative nominations. The Agency will publish two separate notices announcing the vacancy of a representative of consumer interests and a vacancy of representatives of interests of the device manufacturing industry.

I. General Description of the Committee Duties

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 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.