U.S. FOOD & DRUG ADMINISTRATION

C H A R T E R

DIGITAL HEALTH ADVISORY COMMITTEE

COMMITTEE'S OFFICIAL DESIGNATION

Digital Health Advisory Committee

AUTHORITY

The Digital Health Advisory Committee (the Committee) is established under 15 U.S.C. 1451 et seq.; 21 U.S.C. 321, 341, 342, 343, 343-1, 344, 345, 346, 348, 349, 350, 350a, 351, 352, 353(f), 355, 355h, 360b, 360c-j, 371, 375, 376, 378, 379e, 381, 393, 394, 881(b); 42 U.S.C. 217a, 241, 242, 242a, 262, 264; 21 CFR Part 14; and is governed by Pub. L. 92-463, the Federal Advisory Committee Act, as amended (5 U.S.C. §1001 et seq.).

OBJECTIVES AND SCOPE OF ACTIVITIES

The Digital Health Advisory Committee advises the Commissioner of Food and Drugs or designee in discharging responsibilities as they relate to assuring that digital health technologies (DHTs) intended for use as a stand-alone medical product, as part of a medical product, or as a companion, complement, or adjunct to a medical product are safe and effective for human use.

DESCRIPTION OF DUTIES

The Committee provides advice to the Commissioner of Food and Drugs on complex scientific and technical issues related to 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. 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.

AGENCY OR OFFICIAL TO WHOM THE COMMITTEE REPORTS

The Committee provides advice and recommendations to the Commissioner of Food and Drugs.

SUPPORT

Management and support services shall be provided by the Center for Devices and Radiological Health (CDRH).

ESTIMATED ANNUAL OPERATING COSTS AND STAFF YEARS

The estimated annual cost for operating the Committee, including compensation and travel expenses for members but excluding staff support, is $20,039. The estimated person years of staff support required is .35, at an estimated annual cost of $97,722.

DESIGNATED FEDERAL OFFICER

FDA will select a full-time or permanent part-time Federal employee to serve as the Designated Federal Officer (DFO) to attend each Committee meeting and ensure that all procedures are within applicable statutory, regulatory, and HHS General Administration Manual directives. The DFO will approve and prepare all meeting agendas, call all the Committee and subcommittee meetings, adjourn any meeting when the DFO determines adjournment to be in the public interest and chair meetings when directed to do so by the official to whom the Committee reports. The DFO shall be present at all meetings of the full committee and subcommittees.

ESTIMATED NUMBER AND FREQUENCY OF MEETINGS

Meetings shall be held approximately twice annually. Meetings shall be open to the public except as determined otherwise by the Commissioner or designee in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)) and the Federal Advisory Committee Act. Notice of all meetings shall be given to the public.

DURATION

Continuing

TERMINATION

Unless renewed by appropriate action, the Digital Health Advisory Committee will terminate two years from the date the charter is filed.

MEMBERSHIP AND DESIGNATION

The Committee shall consist of a core of 9 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities 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 four years. Non-Federal members of this committee will serve either as Special Government Employees or non-voting 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 non-voting members who are identified with and represent industry interests. The number of temporary members selected for a particular meeting will depend on the meeting topic.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees (normally not to exceed 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members), or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. Because of the size of the Committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than a majority of the current voting members. The Agency's regulations (21 CFR §14.22(d)) authorize a committee charter to specify quorum requirements.

If functioning as a medical device panel, an additional non-voting member who represents consumer interests and an additional non-voting member who represents industry interests will be included in addition to the voting members.

SUBCOMMITTEE

Temporary subcommittees consisting of two or more Committee members may be established by the Commissioner or designee as needed to address specific issues within their respective areas of expertise.

Subcommittees make preliminary recommendations to the full Committee regarding specific issues for subsequent action by the full Committee. The Department Committee Management Officer shall be notified upon establishment of each subcommittee, and shall be provided information on its name, membership, function, and estimated frequency of meetings. Subcommittees must report back to the parent committee and must not provide advice or work products directly to the agency.

RECORDKEEPING

Meetings of the Committee and its subcommittees will be conducted according to the Federal Advisory Committee Act, other applicable laws and Departmental policies. Committee and subcommittee records will be handled in accordance with General Records Schedule 6.2, Federal Advisory Committee Records or other approved Agency records disposition schedule. These records will be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

FILING DATE

APPROVED:

10/11/2023
Date

/S/
Russell Fortney
Director, Advisory Committee Oversight
and Management Staff