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Enforcement Policy for Digital Health Devices For Treating Psychiatric Disorders During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Guidance for Industry and Food and Drug Administration Staff

April 2020

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Office of Product Evaluation and Quality (OPEQ)**

Preface

Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This guidance is being implemented without prior public comment because the Food and Drug Administration (FDA or the Agency) has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to <https://www.regulations.gov>. All comments should be identified with the docket number FDA-2020-D-1138 and complete title of the guidance in the request.

Additional Copies

Additional copies are available from the FDA webpage titled "COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders," *available at* <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>, and the FDA webpage titled "Search for FDA Guidance Documents," *available at* <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive an additional copy of the guidance. Please include the document number 20023 and complete title of the guidance in the request.

Questions

For questions about this document, contact 1-888-INFO-FDA or CDRH-COVID19-DigitalHealthForPsychiatricDisorders@fda.hhs.gov.

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Enforcement Policy for Digital Health Devices For Treating Psychiatric Disorders During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The Food and Drug Administration (FDA or the Agency) plays a critical role in protecting the United States from threats such as emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic.

FDA is issuing this guidance to provide a policy to help expand the availability of digital health therapeutic devices for psychiatric disorders to facilitate consumer and patient use while reducing user and healthcare provider contact and potential exposure to COVID-19 during this pandemic.

Psychiatric symptoms and psychiatric disorders are presented in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition and the International Classification of Diseases, 10th Revision. Common symptoms and disorders include depression, alcohol use disorder, anxiety, insomnia, suicidality, autism, attention deficit hyperactivity disorder, obsessive compulsive disorder, and post-traumatic stress disorder.

This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Department of Health and Human Services (HHS), including

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any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Services (PHS) Act.

Given this public health emergency, and as discussed in the Notice in the *Federal Register* of March 25, 2020, titled “Process for Making Available Guidance Documents Related to Coronavirus Disease 2019,” available at <https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf>, this guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency’s good guidance practices.

In general, FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named “SARS-CoV-2” and the disease it causes has been named “Coronavirus Disease 2019” (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.¹ In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.²

FDA believes the policy set forth in this guidance will help address these urgent public health concerns by helping to expand the availability of digital health therapeutic devices (as defined below) for psychiatric conditions. Device availability may increase patient access to digital therapeutics while individuals are following “stay at home” orders or practicing social distancing, without the need for in-clinic visits during the COVID-19 public health emergency. Furthermore, increased utilization of digital therapeutic devices may ease burdens on hospitals and other healthcare facilities and reduce the risk of exposure to SARS-CoV-2 for patients and health care providers.

This policy also clarifies how FDA Guidance Documents, “[General Wellness: Policy for Low Risk Devices](#)”³ and “[Policy for Device Software Functions and Mobile Medical Applications](#),”⁴ apply to products that may be beneficial to individuals experiencing psychiatric conditions or have mental health concerns during this public health emergency.

¹ Secretary of Health and Human Services Alex M. Azar, Determination that a Public Health Emergency Exists. (Jan. 31, 2020), available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

² Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

³ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices>

⁴ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications>

III. Scope

The enforcement policy described in this guidance applies to the following digital health devices used during the COVID-19 public health emergency:

A. Computerized Behavioral Therapy devices and other digital health therapeutic devices for psychiatric disorders.

- As defined in 21 CFR 82.5801, a computerized behavioral therapy device for psychiatric disorders is a Class II, prescription only, device (product code PWE) intended to provide a computerized version of condition-specific behavioral therapy as an adjunct to clinician supervised outpatient treatment to patients with psychiatric conditions. The digital therapy is intended to provide patients access to therapy tools used during treatment sessions to improve recognized treatment outcomes. Examples of such devices are described further in Section IV.A.
- Digital health therapeutic devices for psychiatric disorders that operate using a different fundamental technology than computerized behavioral therapy and would not fit within the scope of 21 CFR 82.5801, but are intended to treat patients with psychiatric conditions are also subject to the policies in this guidance.
- In addition, variations of computerized behavioral therapy devices that are outside the scope of 21 CFR 82.5801, such as non-prescription devices, are also subject to the policies in this guidance.

B. Low-risk general wellness and digital health products for mental health or psychiatric conditions.

For the purposes of this guidance, and consistent with FDA’s General Wellness⁵ and Software Functions and Mobile Medical Applications⁶ guidances, “general wellness products” are products that may meet the definition of a device under section 201(h) of the FD&C Act and (1) are intended for only general wellness use, as explained in the General Wellness Guidance, and (2) present a low risk to the safety of users and other persons. These products are the focus of this guidance in Section IV.B.

Digital health devices that are intended to be solely or primarily relied upon by the health care professional or patient to make a clinical diagnosis or treatment decision are not within the scope of this guidance document.

⁵ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices>

⁶ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications>

IV. Policy

In the context of the COVID-19 public health emergency, the use of digital health technologies, including software as a medical device or other digital therapeutics solutions, may improve mental health and well-being of patients with psychiatric conditions during periods of shelter-in-place, isolation, and quarantine. In addition, the use of such technologies has the potential to facilitate “social distancing” by reducing patient contact with, and proximity to, health care providers, and can ease the burden on hospitals, other health care facilities, and health care professionals that are experiencing increased demand due to the COVID-19 public health emergency.

Given these public health benefits, for the duration of the COVID-19 public health emergency, FDA does not intend to object to the distribution and use of computerized behavioral therapy devices and other digital health therapeutic devices for psychiatric disorders, which are described in Section III.A, without compliance with the following regulatory requirements, as applicable, where such devices do not create an undue risk in light of the public health emergency: Submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81; Reports of Corrections and Removals requirements in 21 CFR 806; Registration and Listing requirements in 21 CFR Part 807; and Unique Device Identification (UDI) requirements in 21 CFR Part 830 and 21 CFR 801.20. FDA believes such devices will not create such an undue risk where the performance and labeling elements described in Section IV.A are met. This policy does not apply to previously 510(k)-cleared computerized behavioral therapy devices.

Additionally, for computerized behavioral therapy devices for psychiatric disorders subject to this policy, FDA does not intend to enforce compliance with the special controls identified in 21 CFR 882.5801, which include the requirement of prospective clinical data, to assist with more efficient access to these devices in light of the public health emergency.

Where the software products with low-risk general wellness indications or functionality described in Section III.B would otherwise meet the definition of a medical device pursuant to section 201(h) of the FD&C Act, as described in Section IV.B, FDA does not intend to enforce applicable regulatory requirements in line with existing policies described in FDA’s General Wellness⁷ and Software Functions and Mobile Medical Applications⁸ guidances.

FDA does not regulate software for videoconferencing, even when intended for use in telemedicine, because software intended for video communication is not a medical device.⁹

⁷ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices>

⁸ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications>

⁹ See FDA Guidance “Policy for Device Software Functions and Mobile Medical Applications”, available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications>, which states “...Software that serves as a videoconferencing portal specifically intended for medical use and to enhance communications between patients, health care providers, and caregivers” are not medical devices (p. 19, #11).

A. Computerized behavioral therapy and other digital health therapeutic devices for psychiatric disorders

As described in Section III.A., a computerized behavioral therapy device for psychiatric disorders regulated under 21 CFR 882.5801 is a prescription-only device intended to provide a computerized version of condition-specific behavioral therapy as an adjunct to clinician supervised outpatient treatment to patients with psychiatric conditions. The digital therapy is intended to provide patients access to therapy tools used during treatment sessions to improve recognized treatment outcomes. FDA has granted marketing authorization for digital health devices to treat several psychiatric disorders, such as substance use disorder and chronic insomnia, although other indications or uses could be considered within the scope of the regulation. Other digital health therapeutic devices intended to treat psychiatric disorders that are not within the scope of 21 CFR 882.5801, such as devices that use a different fundamental technology than computerized behavioral therapy or devices that are marketed for use without a prescription, are also subject to the policies in this guidance document as further described in this subsection.

In developing this policy, FDA's intent is to provide flexibility for software developers of devices when these devices may assist those with psychiatric conditions during the COVID-19 public health emergency. Relevant psychiatric conditions include, but are not limited to:

- Obsessive Compulsive Disorder
- Generalized Anxiety Disorder
- Insomnia Disorder
- Major Depressive Disorder
- Substance Use Disorder
- Post-traumatic Stress Disorder
- Autism Spectrum Disorder
- Attention Deficit Hyperactivity Disorder

The psychiatric condition could be a pre-existing condition, or the symptoms and/or diagnosis of the condition might have arisen during the course of this public health emergency. If the condition is not pre-existing, diagnosis can be made by means of a telehealth or virtual physician visit, even if a formalized treatment plan for the condition has not yet been developed. These products implement condition-specific therapy for temporary relief of symptoms through modalities, such as Acceptance Commitment Therapy, Cognitive Behavioral Therapy, or other types of therapies.

The following are recommendations regarding the performance and labeling elements relevant to the enforcement policies set forth above. As previously stated, FDA does not intend to object to the distribution and use of computerized behavioral therapy devices and other digital health therapeutic devices for psychiatric disorders, which are described in Section III.A, without compliance with the regulatory requirements outlined in Section IV, as applicable, where such devices do not create an undue risk in light of the public health emergency. FDA encourages firms to discuss any alternatives to these recommendations with FDA (CDRH-COVID19-DigitalHealthForPsychiatricDisorders@fda.hhs.gov). FDA believes such devices will not create such an undue risk where:

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- 1) Software verification, validation, and hazard analysis has been performed and demonstrates that the device implements the therapy model as intended;
- 2) Appropriate cybersecurity protections are in place consistent with FDA premarket and postmarket recommendations;¹⁰
- 3) The labeling, including user instructions, specifically instruct the patient to contact a physician before using the device, even if the device is marketed directly to the consumer; and
- 4) The user is prompted to acknowledge the recommendation to contact a physician before use, such as by providing a standalone check-box that is separate from any end user license agreement.

An example of a circumstance where FDA currently believes devices *would* create such an undue risk includes treatment claims for specific psychiatric conditions where the underlying psychiatric condition may require an urgent or immediate clinical intervention and the delay of the intervention may pose significant harm to the patient, such as treatment of suicidality.

FDA recommends that the devices described in this guidance use labeling that helps users better understand the device. FDA recommends that the labeling include the following elements:

- 1) A clear statement that the patient contact a physician before using the device, even if the device is marketed directly to the consumer;
- 2) The labeling, including the user instructions, provide information about how to access additional resources related to the treatment of psychiatric conditions, such as references to recommendations for the public made by healthcare professional organizations, such as the American Psychological Association or other associations;
- 3) A clear description of the device’s indication including the psychiatric condition/disorder the device is intended to treat and a description of the intended patient population (type of symptoms, duration, severity, and age range (adult vs child/adolescent) where it is expected to be effective, etc.);
- 4) A description of the therapeutic method (behavioral therapy, cognitive restructuring, etc.);
- 5) A clear description of the recommended duration and frequency of use;
- 6) Instructions for use, including images that demonstrate how to interact with the device;
- 7) A summary of the clinical testing with the device including:

¹⁰ See the following FDA guidances for additional information: “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices,” (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0>); “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices,” (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices>); “Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software,” (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-networked-medical-devices-containing-shelf-ots-software>); “Postmarket Management of Cybersecurity in Medical Devices,” (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarket-management-cybersecurity-medical-devices>).

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- i) An outline of available clinical performance testing including methods (e.g., clinical endpoints studied, study type, sample size, etc.) and results (e.g., group/responder analyses, performance goals, etc.), OR
 - ii) An explicit statement that the device has not been clinically tested and may therefore have unknown benefits and risks;
- 8) A description of the method of determining any treatment recommendations;
 - 9) A prominent notice to both the patient and health care provider, as applicable, that recommendations provided by the device are adjunctive (supporting) and should not be solely or primarily relied upon to treat psychiatric conditions;
 - 10) A warning that the device does not represent a substitution for the patient’s medication;
 - 11) A statement as to whether the device is available with or without a prescription;
 - 12) Instructions on when (under what circumstances, frequency) the user should consult a health care provider;
 - 13) A clear statement of what to do if the symptoms are not improving, and in what time period improvement should be expected;
 - 14) Instructions on what to do in case of a medical emergency; and
 - 15) A clear identification of any device indications/functions that are not FDA-cleared.

B. Low-risk general wellness and digital health products for mental health or psychiatric conditions

Consistent with FDA’s General Wellness¹¹ Guidance Document, FDA does not intend to (a) examine low-risk digital health products that make certain claims for mental health or psychiatric conditions to determine whether they are devices as described in section 201(h) of the FD&C Act, or (b) if they are devices, enforce applicable regulatory requirements. In light of the public health emergency, FDA is providing clarity on our policy, set forth in the General Wellness and Software Functions and Mobile Medical Applications Guidance Documents, for low-risk general wellness and digital health products for mental health or psychiatric conditions, arising due to situations created by the COVID-19 public health emergency, such as isolation, quarantining, and social distancing, to help foster the continued availability of these products, particularly without the need for in-clinic visits.

Software functions that are not devices

Section 520(o)(1)(B) of the FD&C Act, states that software that is intended “for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition” is not a device under section 201(h) of the FD&C Act. FDA believes the following software functions for mental health or psychiatric conditions, including those arising due to situations created by the COVID-19 public health emergency, are not devices as defined in section 201(h) of the FD&C Act:

- 1) General Wellness software functions unrelated to a specific disease or condition, such as:

¹¹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices>

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- promoting relaxation, mindfulness, meditation
 - reducing stress, fatigue, or feelings of isolation due to the COVID-19 public health emergency
- 2) General Wellness software functions related to sleep, such as:
 - Promoting good sleep
 - Improving your sleep experience
 - Having more relaxing or restful sleep
 - Sleeping through the night or sleeping all night
 - 3) General Wellness software functions related to mental health or psychiatric conditions due to the current period of increased public health awareness related to the COVID-19 pandemic. Example claims may include software functions such as: “Software Z provides motivational tips via text and other messages that are intended to reduce stress and promote a positive mental outlook, which may aid users in living well during the COVID-19 public health emergency.”
 - 4) Software functions that provide reminders, at opportune times, to keep safe physical (or “social”) distancing practices during the current public health emergency.

Software functions that may meet the definition of a device but for which FDA does not intend to enforce requirements under the FD&C Act

FDA believes that the following software functions, related to psychiatric conditions and the COVID-19 pandemic, may be devices as defined in section 201(h) of the FD&C Act, but consistent with FDA’s General Wellness and Software Functions and Mobile Medical Applications Guidance Documents, does not intend to enforce requirements under the FD&C Act for such devices because, based on our current understanding at this time, they pose a low risk to patients:

- 1) General Wellness software functions to promote, track, and/or encourage choices, which, as part of a healthy lifestyle, may help living well with or reduce the risk of certain chronic psychiatric diseases or conditions where the link between living well and reducing the risk or impact of a chronic psychiatric disease or medical condition is well understood. Chronic psychiatric conditions may include (but are not limited to):
 - Depression
 - Anxiety
 - Obsessive Compulsive Disorder
 - Autism
 - Attention Deficit Hyperactive Disorder

Such General Wellness software functions could include claims as follows:

- “Device X provides daily motivational reminders to perform physical activity, which may help patients with chronic depression live well.”
 - “Device Y provides mindfulness and meditation activities, which may help patients with chronic anxiety live well.”
- 2) Software functions that help patients with diagnosed psychiatric conditions maintain their

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behavioral coping skills by providing a “Skill of the Day” behavioral technique or audio messages that the user can access when experiencing increased anxiety related to the COVID-19 public health emergency.

- 3) Software functions that help teach users to “just notice,” accept, and embrace difficult or previously unwanted thoughts and feelings during the COVID-19 public health emergency, so that the users open up to these unpleasant feelings and learn not to overreact to them or avoid situations where they are invoked.
- 4) Software functions that display, at opportune times, images or other messages for a substance user who wants to stop addictive behavior due to increased anxiety during the COVID-19 public health emergency.
- 5) Software functions that help patients or users self-manage their disease or conditions without providing specific treatment or treatment suggestions.
- 6) Software functions that use a checklist or a questionnaire of common signs and symptoms for a psychiatric disorder (e.g., anxiety due to stay-in-place orders) and to provide a list of possible medical conditions and advice on when to consult a health care provider.
- 7) Software functions that guide a user through a questionnaire of signs and symptoms for a psychiatric disorder (e.g., anxiety or stress due to stay-in-place orders) and to provide a recommendation for the type of health care facility most appropriate to their needs.

Examples of circumstances where FDA currently believes devices do not represent low risk general wellness or digital health products for psychiatric conditions and would fall outside the scope of this guidance and the enforcement discretion policies in the General Wellness¹² and Software Functions and Mobile Medical Application¹³ Guidance Documents include:

- 1) Software functions for the treatment of a specific psychiatric condition (e.g., intended to increase abstinence from a patient’s substances of abuse during treatment).
- 2) Treatment claims for specific psychiatric conditions where the underlying psychiatric condition may require an urgent or immediate clinical intervention and the delay of the intervention may pose significant harm to the patient, such as treatment of suicidality.
- 3) Treatment claims for specific psychiatric conditions where the device is intended to replace face-to-face or telehealth treatment sessions.

¹² <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices>

¹³ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications>