DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–2562]

Drug Products That Present Demonstrable Difficulties for Compounding Under the Federal Food, Drug, and Cosmetic Act; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of public docket.

SUMMARY: The Food and Drug Administration (FDA or Agency) is developing a list of drug products and categories of drug products that present demonstrable difficulties for compounding (the Difficult to Compound List). The Agency previously solicited nominations for this list and received approximately 71 unique nominations. FDA is establishing a new public docket so that interested parties can nominate drug products or categories of drug products that were not previously nominated for inclusion on the Difficult to Compound List, resubmit previous nominations with additional supporting information, or submit comments.

DATES: Nominations for the Difficult to Compound List and comments may be submitted to this docket at any time.

ADDRESSES: You may submit nominations or comments as follows:

Electronic Submissions

Submit electronic nominations or comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting nominations or comments. Nominations or comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your nomination or comment will be made public, you are solely responsible for ensuring that your nomination or comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your nomination or comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a nomination or comment with confidential information that you do not wish to be made available to the public, submit the nomination or comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper nominations or comments submitted to the Division of Dockets Management, FDA will post your nomination or comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. [Docket No. FDA–2017–N–2562] for ''Drug Products That Present Demonstrable Difficulties for Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act; Establishment of a Public Docket.'' Received nominations and comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a nomination or comment with confidential information that you do not wish to be made publicly available, submit your nomination or comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of nominations or comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your nomination or comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper nominations and comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Pawanprit Singh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5206, Silver Spring, MD 20993–0002, 240–402–8866.

SUPPLEMENTARY INFORMATION:

I. Background

Section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353a) describes the conditions under which a human drug product compounded for an identified individual patient based on a prescription qualifies for exemption from three sections of the FD&C Act: (1) Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice for drugs); (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and (3) section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications or abbreviated new drug applications). One of the conditions for these exemptions is that the compounded drug product is not ''a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product'' (section 503A(b)(3)(A) of the FD&C Act). Section 503A(c)(1) of the FD&C Act requires that, before issuing regulations to implement section 503A(b)(3)(A) of the FD&C Act, an advisory committee on compounding be convened and consulted ''unless the Secretary determines that the issuance of such

regulations before consultation is necessary to protect the public health.''

Section 503B of the FD&C Act (21 U.S.C. 353b) describes the conditions that must be met for human drugs compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility to qualify for exemptions from three sections of the FD&C Act: (1) Section 502(f)(1) (21 U.S.C. 352(f)(1)); (2) section 505 (21 U.S.C. 355); and section 582 (21 U.S.C. 360eee–1) (concerning drug supply chain security requirements). Section 503B does not provide an exemption from section 501(a)(2)(B).

One of the conditions in section 503B that must be satisfied for a compounded drug to qualify for the exemptions in that section is that the drug either (1) is not identified (directly or as part of a category of drugs) on a list published by the Secretary, of drugs or categories of drugs that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug or category of drugs, taking into account the risks and benefits to patients, or (2) is compounded in accordance with all applicable conditions identified on the list as conditions that are necessary to prevent the drug or category of drugs from presenting such demonstrable difficulties (see section 503B(a)(6)(A) and (a)(6)(B) of the FD&C Act). Section 503B(c)(2) of the FD&C Act requires that before issuing regulations to implement section 503B(a)(6) of the FD&C Act, an advisory committee on compounding be convened and consulted.

At a meeting on July 13 and 14, 2000, an advisory committee on compounding (specifically, the Pharmacy Compounding Advisory Committee (PCAC)) discussed and provided FDA with advice about the Agency's efforts to develop a list of drugs that present demonstrable difficulties for compounding under section 503A of the FD&C Act. FDA published a notice of that meeting in the **Federal Register** on June 29, 2000 (65 FR 40104). In the **Federal Register** of December 4, 2013 (78 FR 72840), FDA invited all interested persons to nominate drug products or categories of drug products for inclusion on the Difficult to Compound List. Nominators were asked to include the name of the drug product or category of drug products being nominated, as well as the reason the drug product or category of drug products should be included on the list, taking into account the risks and benefits to patients. The notice also included a list of factors that may be relevant to determining whether or not a drug product or category of drug products should or should not be included on the Difficult to Compound List. Approximately 71 unique drug products or categories of drug products were nominated for this list.

On June 18, 2015, the PCAC reviewed and discussed FDA's proposed criteria for evaluating whether drug products or categories of drug products are demonstrably difficult to compound under sections 503A and 503B of the FD&C Act. After considering the PCAC's discussion, FDA refined the criteria and presented the changes to the PCAC on March 9, 2016. The six criteria presented to the PCAC for evaluating whether a drug product or category of drug products is demonstrably difficult to compound are the following: (1) The complexity of the formulation; (2) the complexity of the drug delivery mechanism; (3) the complexity of the dosage form; (4) the complexity of achieving bioavailability; (5) the complexity of the compounding process; and (6) the complexity of physicochemical or analytical testing. Additional information regarding these criteria can be found in the briefing package for the March 2016 PCAC meeting. See *http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/UCM486146.pdf*.

II. Establishment of a Public Docket

FDA is establishing a public docket so that interested parties can nominate drug products or categories of drug products for inclusion on the Difficult to Compound List, resubmit previous nominations with additional supporting information, or submit comments.

Nominations should include the following two items for each drug product or category of drug products nominated, and any other relevant additional information available:

- The name of the drug product or drug product category;
- The reason the drug product or drug product category should be included on the list, taking into account any risks and benefits to patients.

To facilitate FDA's review, nominations may include responses to the following six questions, which are related to the criteria FDA presented to the PCAC for evaluating whether drug products and categories of drug products are difficult to compound under sections 503A and 503B of the FD&C Act:

1. Does the drug product or category of drug products have a complex formulation that presents a demonstrable difficulty for compounding that is reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug product?

2. Does the drug product or category of drug products have a complex drug delivery mechanism that presents a demonstrable difficulty for compounding that is reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug product?

3. Does the drug product or category of drug products involve a complex dosage form that presents a demonstrable difficulty for compounding that is reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug product?

4. Does the drug product or category of drug products involve complexities in achieving and/or assessing bioavailability that present a demonstrable difficulty for compounding that is reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug product?

5. Does compounding the drug product or category of drug products involve a complex compounding process that presents a demonstrable difficulty for compounding that is reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug product?

6. Does compounding the drug product or category of drug products necessitate complex physicochemical or analytical testing that presents a demonstrable difficulty for compounding that is reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug product?

It is not necessary for a previously nominated drug product or category of drug products to be renominated to this docket. Previously nominated drug products or categories of drug products may be renominated to this docket if the nominator wants to provide additional supporting information, *e.g.,* information specific to the six questions listed above related to FDA's proposed evaluation criteria. Interested parties can also submit comments on nominated drug products or categories of drug products, or on this document, via this docket.

Previous nominations to the Difficult to Compound List or comments submitted in response to the December 4, 2013 **Federal Register** notice can be viewed on *https://www.regulations.gov* under docket number FDA–2013–N–1523, or by going to the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 24, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–15900 Filed 7–27–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–4301]

Fostering Medical Innovation: A Plan for Digital Health Devices; Software Precertification Pilot Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA, the Agency, or we) Center for Devices and Radiological Health (CDRH or Center) is announcing its Software Precertification Pilot Program. The program aims to evaluate a new approach toward software products, including a precertification program for the assessment of companies that perform high-quality software design and testing. This voluntary pilot program is part of FDA's ongoing efforts to develop pragmatic approaches to balance benefits and risks of digital health products. FDA intends to develop a precertification program that could replace the need for a premarket submission in some cases and allow for decreased submission content and/or faster review of marketing applications for software products in other cases. During the pilot program, FDA customers, including pilot participants, will have the opportunity to provide input on the development of the precertification program.

DATES: FDA is seeking participation in the voluntary Software Precertification pilot program beginning August 1, 2017. See the ''Participation'' section for instructions on how to submit a request to participate. The voluntary Software Precertification pilot program will select up to nine participants who best match the selection criteria. This pilot program will begin September 1, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–N–4301 for ''Fostering Medical Innovation: A Plan for Digital Health Devices; Software Precertification Pilot Program.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Bakul Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5458, Silver Spring, MD 20993, 301–796–5528, *Bakul.Patel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA recognizes that an efficient, risk-based approach to regulating digital health technology will foster innovation of digital health products. FDA's traditional approach to moderate and higher risk hardware-based medical devices is not well suited for the faster iterative design, development, and type of validation used for software products. An agile paradigm is necessary to accommodate the faster rate of development and innovation of software devices as compared to other types of devices. Traditional implementation of the premarket requirements may impede or delay patient access to critical evolutions of software technology, particularly those presenting a lower risk to patients. To evaluate a new approach toward software, FDA is launching a pilot of a precertification program for the assessment of companies that perform high-quality software design and testing. The Software Precertification (Pre-Cert) pilot program is part of FDA's ongoing efforts