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 503(a)(3)(A) of the FD&C Act). Section 503(a)(1) of the FD&C Act requires that, before issuing regulations to implement section 503(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, or drugs or categories of drugs that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect 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. The committee provided input that was considered by the Agency in developing a list of drugs that are reasonably likely to lead to an adverse effect or effectiveness of the drug product or category of drugs.

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. Approximately 71 unique drug products or categories of drug products were nominated for this list.

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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.

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III. I. Background

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