Food, Drug & Cosmetic Act Section 503A

(Pharmacy Compounding)

	FDCA 503A Provision	How FIRST® KITS help facilitate pharmacists obligations under FDCA 503A
1	The drug must be compounded using bulk drug substances, as defined in 21 CFR 207.3(a)(4) [FDCA 503A(b)(1)(A)] • 21 CFR 207.3(a)(4) defines "bulk drug substance" in relevant part as "any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient	Each FIRST® Kit contains an ingredient that meets the regulatory definition of "bulk drug substance," in that it is (1) represented for use in a (compounded) drug product, and (2) when used in the compounding of a product, becomes the active ingredient in that product.
2	The bulk drug substance must comply with an applicable USP or NF monograph, if one exists, or be a component of an approved drug, or be on an FDA-issued list of drug substances that are acceptable for compounding [FDCA 503A(b)(1)(A)(i)(I)-(III)]	Each bulk drug substance used in a FIRST® Kit complies with the standards of an applicable USP or NF monograph and/or is a component of an approved drug.
3	The bulk drug substance must comply with the USP chapter on pharmacy compounding [FDCA 503A(b)(1)(A)(i)(I)]	See USP Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations - "How FIRST® Kits help pharmacists USP <795>" available on Firstkits.com.
4	The bulk drug substances must be manufactured by an establishment that is registered with FDA [FDCA 503A(b)(1)(A)(ii)]	Every supplier of bulk drug substances to Azurity Pharmaceuticals is registered with the FDA. Additionally, Azurity Pharmaceuticals has obtained from each supplier a letter of assurance that the facility at which the bulk drug substances are manufactured is registered with the FDA. Further, Azurity Pharmaceuticals is itself registered with FDA, is subject to FDA inspection, and has been assigned a Facility Establishment Identification (FEI) number 3003395329.
5	Each bulk drug substance must be accompanied by a valid certificate of analysis [FDCA 503A(b)(1)(A)(iii)]	Every shipment of bulk drug substances received by Azurity Pharmaceuticals is accompanied by a certificate of analysis, as is every shipment of inactive ingredients contained within the diluent with which the bottled API is to be mixed when the pharmacist compounds the finished product. Materials provided to the compounding pharmacist inform him/her that certificates of analysis are on file at Azurity Pharmaceuticals and available upon request.

(continued on back)

Reference: 1. Excludes Progesterone VGS. Data on file, Azurity Pharmaceuticals, Inc. KIT-112

FIRST® KITS UNIT-OF-USE PRESCRIPTION COMPOUNDING KITS

Single prescription compounding made **quick & easy**

Convenient and easy - saves time with less than 3 minute preparation[1]

Conforming to the needs of pharmacists

Consistent formulation promotes accurate dosing

azurity™ pharmaceuticals

Food, Drug & Cosmetic Act Section 503A

(Pharmacy Compounding - continued)

	FDCA 503A Provision	How FIRST® KITS help facilitate pharmacists obligations under FDCA 503A
6	The ingredients other than bulk drug substances must comply with the standards of an applicable USP or NF monograph, if one exists, and the USP chapter on pharmacy compounding [FDCA 503A(b)(1)(B)]	Each incoming component of a FIRST® Kit is accompanied by a certificate of analysis, as noted above, and complies with USP/NF monographs, if one exists. With regard to both the bulk drug substance and the inactive ingredients, Azurity Pharmaceuticals conducts full USP/NF monograph testing on the first three shipments from a supplier, abbreviated USP testing on samples from each subsequent shipment, and full USP/NF testing on 1 lot per year, if a USP/NF monograph exists.
7	The compounded drug product cannot appear on an FDA issued list of drug product withdrawn or removed from the market because they or a component of them have been found to be unsafe or ineffective [FDCA 503A(b)(1)(C)]	None of the products that would be compounded from a FIRST® Kit would be a product that has been withdrawn from the market because the product or a component was found to be unsafe or ineffective.
8	The pharmacy cannot compound regularly or inordinate amounts (to be defined by FDA) any drug products that are "essentially copies of a commercially available drug product" [FDCA 503A(b)(1)(D)] • A compounded product isn't "essentially a copy of a commercially available drug product" if there is a change, made for an identified individual patient that the prescriber determines produces a significant difference for the patient [FDCA 503A(b)(2)]	None of the products intended to be compounded with a FIRST® Kit is "essentially a copy of a commercially available drug product," as that term is defined.
9	The compounded product cannot be identified by FDA as a drug product "that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on" the product's safety or effectiveness [FDCA 503A(b)(3)(A)]	None of the products intended to be compounded with a FIRST® Kit is on FDA's proposed list of difficult to compound products.

FIRST® KITS

LESS than 3 Mins to prepare[1]

Faster, more convenient compounding

To learn more, visit **www.firstkits.com** or call **1-800-461-7449,** for assistance.

Azurity Pharmaceuticals™, Inc. was formerly known as CutisPharma®, Inc. Product packaging may reflect either name.

Reference: 1. Excludes Progesterone VGS. Data on file, Azurity Pharmaceuticals, Inc.