Since the FIRST® Kits contain components for prescription compounding; they are exempt from FDA approval.

FIRST® Kits help pharmacists with their obligations for compounding under Section 503A of the Federal, Food, Drug and Cosmetic Act and the USP <795> standards for nonsterile compounded preparations, so that patients can receive a quality product.

- API used in our FIRST® Kits, as well as inactive ingredients used in our reconstituting vehicle, meet the requirements in pharmacy compounding under Section 503A of the Federal Food, Drug and Cosmetic Act:
    - *The API meets the applicable USP monograph and the USP chapter on pharmacy compounding.*
    - *The facility in which API is manufactured is registered with FDA.*
    - *The API is accompanied by a certificate of analysis when it arrives at Azurity Pharmaceuticals, which we verify by our own independent analytical testing.*
- Beyond use date established by stability testing, conducted by independent analytical laboratories commissioned by Azurity Pharmaceuticals, to verify potency and purity.
- Our products are manufactured at FDA registered sites, adhering to Current Good Manufacturing Practices (CGMPs).
- Adverse events and product complaints received by Azurity Pharmaceuticals or its affiliated parties are actively tracked and monitored, and MedWatch safety reporting is performed in accordance with FDA regulations.

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