CutisPharma
Transforming Medicine through Innovation™

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

FIRST® Compounding Kits help pharmacists comply with the requirements for compounding under Section 503A of the Federal Food, Drug and Cosmetic Act and the USP <795> guidelines 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 CutisPharma, which we verify by our own independent analytical testing.
- Beyond use date established by stability testing, conducted by independent analytical laboratories commissioned by CutisPharma, to verify potency and purity.
- Our products are manufactured in compliance with cGMP regulations. Our facility, as well those of each of our pharmaceutical contract manufacturers, are subject to regular FDA inspections, in addition to rigorous third party audits on a recurring basis. The most recent FDA inspection of our facility was in April 2016 with no observations (no “483”) issued by the Agency.
- Adverse events and product complaints received by CutisPharma or its affiliated parties are actively tracked and monitored, and MedWatch safety reporting is performed in accordance with FDA regulations.