Federal Requirements for Compounding

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Overview of Federal Requirements for Compounding

- Similar to other areas of pharmacy law, there is a federal overlay to compounding by state-licensed pharmacists.
- Violation of federal law could subject licensees to potential enforcement by FDA or federal Department of Justice and discipline of their state-issued licenses or permits.
- This presentation contains just a summary of some of the federal law and guidance governing compounding. Compounding pharmacists should consult their own attorney or other resources to ensure that they are aware of, and in compliance, with current federal law on compounding.
- FDA also has section on its website related to human drug compounding. Human Drug Compounding | FDA

Need for an Exemption for Compounding

- Generally compounding a substance would result in a new drug that would require FDA approval and could result in violations of federal provisions, including new drug approval process, without an exemption.
- 503A Exemption provides exemption from certain provisions under the federal Food, Drug and Cosmetic (FDCA) Act, including Section 505, Section 502(f), and 501(a)(2)(B).
- Non-compliance with ALL of the requirements of the 503A exemption could result in violations of one or all of these three statutory provisions or other provisions of the FDCA.
- Section 503A exemption does not provide an exemption from other provisions of the FDCA.

What is the 503A Exemption

Section 503A generally provides an exemption from the following provisions of the FDCA for drug products compounded by a state-licensed pharmacist or state-licensed physician:

1) Section 501(a)(2)(B) (concerning requirement to comply with current good manufacturing practices);
2) Section 502(f)(1) (concerning the labeling of drugs with adequate directions for use)
3) Section 505 (concerning the approval of drugs under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)).

Section 503A exemption does not provide relief from any other provision of the FDCA.

Summary of the 503A Exemption

- Section 503A(b)(1) contains the specific substantive requirements for a state-licensed pharmacist and pharmacy to qualify for the exemption. There are detailed requirements set out in this section. The FDA has put out written guidance discussing the specific requirements. Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance (fda.gov) (Pharmacy Compounding Guidance). FDA has other guidance documents applicable to compounding. Regulatory Policy Information | FDA.
- Section III.A of the Pharmacy Compounding Guidance, pages 2-5 detail the conditions of the exemption.
- Other guidance documents also apply and clarify some definitions. *See e.g.*, Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry (fda.gov) (pages 2-3 makes clear an applicable USP or NF monograph means a drug monograph.

Summary of 503A Exemption

- Finally, when the FDA publishes guidance documents and proposed and final rules, they issue proposing and adopting releases that accompany those documents. You should read both releases as the FDA addresses substantive comments raised by commenters.
- Under legal decisions, positions taken in notices subject to notice and comment may constitute interpretations of the agency that are accorded deference if deemed to be a reasonable interpretation.
- Accordingly, it is important that you raise comments to proposed FDA rules and guidance as part of the federal notice and comment process. Making such comments to this Board does not make it part of the FDA record.
- Given the end of COVID emergency, as FDA gets more time, we anticipate further guidance and rules to implement the 2012 amendments.
- Compounding pharmacists and pharmacies are responsible for knowing and complying with federal law and should keep abreast of changes in this area by following the FDA.

State Requirements also Apply

- California law, including pharmacy and health and safety code provisions, also establish requirements for human drug compounding.
- This Committee will be considering changes to California law in response to the USP changes that go into effect in November 2023.
- The Committee does not intend to summarize operative federal law in its regulations as federal law could and will change or evolve over time. The requirement to comply with existing federal law is independent of state law.
- If you have questions regarding operative federal law, you should consult an attorney or other resources, including contacting the FDA.