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FDA GUIDANCE ON COMPOUNDED DRUGS THAT ARE ESSENTIALLY COPIES OF COMMERCIALLY AVAILABLE DRUGS

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To qualify for the exemptions from certain requirements of the Food, Drug and Cosmetics Act ("FDCA"), compounded drugs may not be "essentially copies of commercially available drug products." On January 18, 2018, the FDA issued new guidance for both traditional 503A compounding pharmacies and 503B outsourcing facilities on the interpretation the term "essentially copies of commercially available drug products" and how it intends to ensure compliance. The FDCA provides that the term "'essentially a copy of a commercially available drug product' does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug." Sec. 502(A)(b)(2).

The guidance states that if pharmacies and outsourcing facilities "plan to rely on" the prescriber's determination to show that the drugs they are compounding are not essentially copies of approved drugs, then the prescription must state how the compounded drug is different from a commercially available product and how that change makes a clinical difference for that patient. FDA is not authorized to inspect records of traditional compounding pharmacies, including prescriptions. Although the guidance clearly intends that pharmacies will demonstrate compliance with this rule by maintaining the appropriate documentation on prescriptions, the guidance does not address the fact that the FDCA specifically limits FDA's authority to inspect their records. The guidance does not describe any other means FDA contemplates using to assess compliance with this provision other than reviewing prescriptions. It seems that FDA expects pharmacies will "voluntarily" choose to show their prescriptions in order to demonstrate compliance.

With respect to compounding in traditional 503A pharmacies, FDA will consider a compounded drug to be essentially a copy of a commercially available drug product if:

- The compounded drug product has the same active pharmaceutical ingredient(s) as the commercially available drug product;
- The API(s) have the same, similar, or an easily substitutable dosage strength; and
- The commercially available drug product can be used by the same route of administration as prescribed for the compounded drug

With respect to compounding in outsourcing facilities, FDA will consider a compounded drug to be essentially a copy of a commercially available drug product if:

- The compounded drug product has the same active pharmaceutical ingredient(s) as the commercially available drug product;
- The compounded drug product has the same dosage form and dosage strength;
- The commercially available drug product can be used by the same route of administration as prescribed for the compounded drug; and
- The compounded drug has the same excipients as the commercially available approved drug.

The guidance pertaining to outsourcing facilities also sets out how they may demonstrate that the drugs they compound for office use are not essentially copies of commercially available drugs. The outsourcing facility must obtain a statement from the practitioner that specifies the change between the compounded drug product and the commercially available product and why the change produces a clinical difference, and which further states that the compounded drug will only be dispensed to patients for whom the change makes a clinical difference.

The FDA intends to address in separate guidance or rulemaking how these policies apply to hospital and health system pharmacies.

LINKS:

Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry (1/18/18)
https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM510154.pdf

Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry (1/18/18)
https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM510153.pdf

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