FDA's GFI #256

FDA has finalized Guidance for Industry #256,
Compounding Animal Drugs from Bulk Drug Substances,
and it will be enforced beginning April 1, 2023.

The guidance will impact the availability of compounded medications for office use and add new requirements for writing prescriptions for compounded medications.

Laura,
Pharmacist Quality Manager,
with Bo

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Three things you need to know about GFI #256:

1

The FDA has established lists that define which preparations compounded using Bulk Drug Substances (BDS) will be available for office use.

- Medications on FDA's list of office stock drugs and medications under review **may be ordered for office use or prescriptions.**
- Medications that have been reviewed and not listed **may be prescribed for patients**, but are *not* available for office use.

Easily filter for office use availablility at WedgewoodPharmacy.com as of April 1, 2023.

2

For medications compounded from bulk for individual patients, you *may* be required to supply a clinical difference supported by a **medical rationale for why the compounded medication is needed** instead of an FDA-approved drug.

Examples:

- *Patient has an allergy, food sensitivity, or aversion to commercial product.*
- *Commercial product would reduce compliance and/or is not effective for achieving medical outcome.*
- *Commercially available dosage form is unachievable or unsafe for patient.*
- *Commercial product is not available and/or unable to source.*

Wedgewood Pharmacy's digital prescription tools include a list of these as of April 1, 2023.

3

You will be required to report adverse events and product defects to FDA using form 1932a.

Easily access this form on our GFI resources page below!

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