Prescription Requirement Under Section 503A of the FD&C Act

Inter-governmental Working Meeting on Drug Compounding
September 20, 2016

Sara Rothman
CDER, Compliance

Overview

- Applicable language in the Federal Food, Drug, and Cosmetic Act (FD&C Act)
- Why is the prescription requirement important?
- FDA's draft guidance concerning the prescription requirement in section 503A
- Topics for discussion

Prescription Requirement under Section 503A

Section 503A(a)

Certain requirements of the FD&C Act "shall not apply to a drug product if the drug product is compounded ***for an identified individual patient based on the receipt of a valid prescription order*** or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient." Section 503A(a) of the FD&C Act) (emphasis added).

Prescription Requirement under Section 503A Cont.

Sections 503A(a)(1) and 503A(a)(2)

Under section 503A(a), the compounding must either be:

- "on the prescription order for such individual patient" (section 503A(a)(1)); OR
- "in limited quantities before the receipt of a valid prescription order for such individual patient" if:
  - The compounding is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the human drug product; and
  - The orders have been generated solely within an established relationship between the licensed pharmacist or licensed physician and either such patient for whom the prescription order will be provided or the physician or other licensed practitioner who will write such prescription order.

Section 503A(a)(2).

Congressional Intent

"It is the intent of the conferees to ensure continued availability of compounded drug products as a component of ***individualized therapy***, while limiting the scope of compounding so as to prevent manufacturing under the guise of compounding. Section 503A establishes parameters under which compounding is appropriate and lawful. The conditions set forth in Section 503A should be used by the state boards of pharmacy and medicine for proper regulation of pharmacy compounding in addition to existing state-specific regulations."

Joint Explanatory Statement of the Committee of Conference (1997) (emphasis added).

Patient-Specific and Non-Patient Specific Compounding Under Section 503B

Section 503B states that "[a]n outsourcing facility may or may not obtain prescriptions for identified individual patients." Section 503B(d)(4)(C)) of the FD&C Act.

Why is the Prescription Requirement in Section 503A Important?

- Entities that compound drugs in accordance with section 503A generally do not:
  - Obtain FDA approval of their compounded drugs
  - Comply with current good manufacturing practice requirements
  - Report adverse events to FDA
  - Label compounded drugs with warnings or adequate directions for use
  - Register with FDA
- FDA does not know of most of the compounders in the United States that seek to operate under section 503A, and generally does not routinely inspect them.

Why is the Prescription Requirement in Section 503A Important? (Cont.)

The prescription requirement is intended to:

- Ensure that compounding under section 503A is based on individual patient need.
- Serve as a clear boundary between:
  - **Compounding pharmacists and physicians** who are primarily subject to state oversight (although some federal requirements continue to apply, e.g., no insanitary conditions), and
  - **Conventional manufacturers** and **outsourcing facilities**, which are primarily subject to FDA oversight

Failure to enforce the prescription requirement in section 503A would undermine the incentive for compounders to elect to register as outsourcing facilities and increase the likelihood of another outbreak like the 2012 fungal meningitis outbreak.

FDA Draft Guidance:
Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act

- When compounding under section 503A can occur:
  - After the receipt of a valid patient-specific prescription (section 503A(a)(1)), or
  - In limited quantities before the receipt of a valid patient-specific prescription (section 503A(a)(2))
    - Proposed policy related to "limited quantities": any 30-day supply within the last year

- When a compounded drug can be distributed:
  - 503A compounders: after the receipt of a valid patient-specific prescription (section 503A(a))
  - Outsourcing facilities: with or without first receiving a patient-specific prescriptions (section 503B(d)(4)(C))

Language in the draft guidance:

> [F]or each drug compounded under section 503A, the compounder must obtain a patient-specific prescription order. We therefore understand that the compounder can fill a prescription for compounded drugs under section 503A only pursuant to such a patient-specific prescription. We recognize that some state boards of pharmacy may authorize the writing of prescriptions that do not include individual patient names. Such prescriptions, however, do not meet the requirement of a patient-specific prescription in section 503A. Under section 503B, outsourcing facilities can fill such prescriptions if they meet the requirements of applicable state and Federal laws.

FDA Draft Guidance:
Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Examples of public comments:

- **Section 503A includes a prescription requirement, and it is important to enforce the statutory requirement**
  - Public health objectives
  - Support outsourcing facility category
  - Clear lines of accountability
- **Section 503A does not include a prescription requirement, or FDA should not enforce the prescription requirement in section 503A**
  - Contrary to Congressional intent
  - Inconsistent with the statutory language in section 503A
  - Conflict with state laws allowing office stock
- **Access concerns**
  - Concern that outsourcing facilities may not produce certain drugs that are needed for office stock
- **Proposed policy of 30-day supply for anticipatory compounding is too lenient**
  - A 30-day supply could include a very large quantity of drugs.
  - Suggest a cap at a certain number of units (e.g., 500 units)
- **Proposed policy of 30-day supply for anticipatory compounding is too stringent**
  - Safer and more efficient, cost-effective to compound drugs in larger batches

Topics for Discussion

- Are states that allow non-patient specific compounding for office stock (by entities other than outsourcing facilities) considering amending their laws to mirror the federal prescription requirements?
  - If so, what, if any, challenges are you facing?
  - If not, why?
- Concerns expressed by stakeholders:
  - Access
  - Drug quality
  - Undermining outsourcing facilities and the DQSA
  - FDA/State primary regulatory oversight
  - Defining and enforcing limits