TO: State Boards of Pharmacy

FROM: Scott Brunner, CAE
Chief Executive Officer

Savannah Cunningham, PharmD
Director of Public Policy

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SUBJECT: *Applicability of USP reference in Food, Drug & Cosmetic Act*

Recently, as state boards of pharmacy have grappled with whether to adopt some or all provisions of the revised USP Chapters <795> and <797> and enforceability of USP <800> that became effective November 1, we have received inquiries regarding the reference to USP standards in the Food, Drug & Cosmetic Act. The gist of the question is whether Section 503A of the federal FD&C Act mandates that all compounding be done in compliance with the USP chapters and thus requires states to adopt applicable USP chapters in their entirety. It's a timely question regarding the context of the reference to USP standards in the FD&C Act. The purpose of this memo is to clarify what Section 503A of FD&C actually says on the matter.

As you may know, the Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing more than 600 compounding small businesses – including compounding pharmacists and technicians in both 503A and 503B settings – as well as prescribers, educators, researchers, and suppliers.

Excerpted below is the language of Section 503A that references USP. Please note that this section is addressing bulk drug substances, known as Active Pharmaceutical Ingredients (APIs). We have underlined that reference for context.

(b) Compounded drug

(1) Licensed pharmacist and licensed physician

A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician-

(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations-

(i) that-

(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or

(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c);

(ii) that are manufactured by an establishment that is registered under section 360 of this title (including a foreign establishment that is registered under section 360(i) of this title); and

(iii) that are accompanied by valid certificates of analysis for each bulk drug substance;

In short, this reference mandates that bulk drug substances used for compounding must comply with the USP compounding chapters' references to bulk drug substances. It does not mandate that all compounding must adhere to USP chapters, nor does it bind states to adopt USP compounding chapters in their entirety.

We hope this clarification is helpful to you. If APC may assist on this or any other issue related to pharmacy compounding, please contact us at savannah@a4pc.org.