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Alliance for Pharmacy Compounding

August 28, 2023

Submitted electronically via regulations.gov

Documents Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2023-D-0939

To Whom it May Concern:

The Alliance for Pharmacy Compounding (APC) appreciates the opportunity to provide input to the Food and Drug Administration (FDA) on the Draft Guidance for Industry (GFI) released in June 2023 entitled "Prohibition on Wholesaling Under 503B of the Federal Food, Drug, and Cosmetic Act" ("the Draft GFI").

APC is the voice for pharmacy compounding, representing more than 600 compounding pharmacies and facilities, including compounding pharmacists and technicians in both 503A and 503B settings, as well as prescribers, educators, researchers, and suppliers.

APC is generally supportive of the Draft GFI, which provides some long-needed clarification to the prohibition against "wholesaling" by outsourcing facilities found in section 503B(a)(8) of the Food Drug and Cosmetic Act, included in amendments made to the FDCA ten years ago as part of the Drug Quality and Security Act of 2023. APC supports provisions in the Draft GFI that address sales or transfers from outsourcing facilities to state-licensed pharmacies and physicians and intracompany transfers as consistent with congressional intent and the plain language of the statute that these activities are authorized under the law and do not run afoul on the prohibition on wholesaling.

However, we seek further clarification on the following:

- Clarification of the terms "sold or transferred" as they relate to the use of common carriers and third-party logistics providers is necessary. Specifically, we ask that any final GFI address this uncertainty by clarifying that the term "sold" as it relates to the prohibition on wholesaling requires a passing of title from seller to buyer and does not include the marketing services of a third-party marketing firm or website operator. This is consistent with the provision in the Draft GFI stating that a group purchasing organization (GPO) working for a health system to facilitate the purchase of compounded drugs based on pricing and availability does not take title to the drugs and therefore does not own the drug, triggering the statutory prohibition on wholesaling.
- Laws and regulations that have been adopted by several states pursuant to the 2013 change in federal law creating 503B outsourcing facilities may not be consistent with the Draft GFI's interpretation of the statutory prohibition on wholesaling. Those state laws and regulations may limit the uptake and

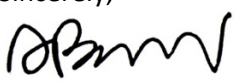
effectiveness of the 503B-to-503A model allowed in the GFI in those states. We urge that FDA increase communications with state boards of pharmacy as this Draft GFI moves to final form.

- Clarification is needed as to whether 503A compounding pharmacies are allowed to manipulate and repackage drugs purchased from 503B facilities into smaller units for convenience of dispensing directly to patients. We urge that the FDA to specifically allow this in a final GFI.
- Clarification is needed as to whether it is acceptable for 503A compounding pharmacies to replace or alter a label in order to incorporate legally required content and disclosures for patient-specific prescriptions is necessary as well. We urge the FDA to allow 503A pharmacies to relabel drugs for dispensing in a final GFI, and we urge the agency to provide guidelines for such re-labeling.
- Consistent with GFI 256 and federal law, a final GFI should clearly state that a 503A compounding pharmacy should be able to dispense medication obtained from a 503B to veterinary hospitals for office stock if those medications are on CVM's "listed" or "under review" list, enabling faster access to medications FDA has determined are not commercially available and are needed for urgent and emergency use in non-foodstock animals.
- Finally, clarification is needed on the acceptability of 503B outsourcing facilities preparing drugs that are listed on the 503A bulks list in federal regulation (which is officially titled "Bulk drug substances that can be used to compound drug products in accordance with section 503A of the Federal Food, Drug, and Cosmetic Act") and which are destined to be dispensed by a 503A, but which are not listed on the 503B bulks list. Permitting this would create more efficiency within the system, and we urge the FDA to allow this in a final GFI.

Again, we appreciate the opportunity to comment on this Draft GFI, and we support the necessity of addressing the prohibition against "wholesaling" by outsourcing facilities found in section 503B(a)(8) of the Food Drug and Cosmetic Act. We look forward to the clarification of these points in a final GFI.

Please contact me at Scott@A4PC.org with questions.

Sincerely,



Scott Brunner, CAE
Chief Executive Officer