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Alliance for Pharmacy Compounding

March 16, 2021

Dockets Management Staff: Docket No. [FDA-2015-N-0030]
Food and Drug Administration 5630
Fishers Lane, Room 106
Rockville, MD 20852

RE: FDA "Notice to Compounders: Changes that affect compounding as of March 23, 2020" on transitioned biologics products.

To Whom it May Concern:

I write today in my role as President of the Alliance for Pharmacy Compounding (APC), formerly the International Academy of Compounding Pharmacists (IACP). APC is the voice for pharmacy compounding, representing compounding pharmacists and technicians in both 503A and 503B settings, as well as educators, students, researchers and suppliers. Compounding exists for patients and animals who are not served by traditional pharmaceutical manufacturers. Every day, APC members play a critical, often life-or-death role in patients' lives, creating essential medications unavailable elsewhere for a range of health conditions, including autism, oncology, dermatology, ophthalmology, pediatrics, women's health, animal health, and others.

APC is concerned about the potential negative impact to patients of FDA's statement in the notice to compounders that drugs transitioning to biologics will, as of March 23, 2020, no longer be eligible for the exemptions for compounded drugs under sections 503A and 503B of the Federal Food, Drug and Cosmetic Act (FDCA). This statement is inconsistent with our understanding of the law and with FDA's own previous guidance to industry (GFI) on this subject in the January 2018 (the Mixing/Repackaging Biologics GFI).

The 2018 guidance clarified for compounders that its provisions did not apply to drugs for which a marketing application can be or has been submitted under section 505 of the FDCA. This means that the transitioned products for which a marketing application has been filed under section 505 of the FDCA are still considered drugs for purposes of compounding by pharmacies and outsourcing facilities when all of the other provisions of 503A or 503B are met. For example, chorionic gonadotropin ("HCG") has a USP monograph and is not on the demonstrably difficult list and should therefore be eligible for compounding from bulk substances when the treating physician determines that there is no FDA approved product that meets that patient's individualized needs.

The March 2020 notice contradicts the Mixing/Repackaging biologics GFI, but more importantly, jeopardizes access to compounded medications for fertility patients, menopause patients, and others. In January of this year, APC joined the Outsourcing Facility Association (OFA) in requesting a listening session with the Center of Drug Evaluation and Research to discuss this issue and identify a solution that addresses FDA's concerns without eliminating the availability of these transitioned products compounded from bulk substances for the patients that need them. We reiterate that request and ask that you reconsider and rescind the March 23, 2020, notice until such time that FDA can work with stakeholders on a new GFI on this subject.

Please contact APC CEO Scott Brunner, CAE at scott@a4pc.org if you have questions. Thank you in advance for your consideration of these requests and we look forward to working with you on this important matter.

Michael Blaire, RPh, FIACP
President, Alliance for Pharmacy Compounding