June 21, 2018

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Senior Science Advisor for Compounding
Center for Drug Evaluation & Research
Food and Drug Administration
U.S. Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Dohm:

On behalf of the undersigned organizations, we would like to thank you for meeting with us on April 30, 2018, to discuss our concerns with the implementation of the compounding provisions of the Drug Quality and Security Act (DQSA) and its impact on the availability of compounded drug products. We also appreciate the opportunity to participate in the recent FDA compounding listening session. In response to these meetings, we are providing the agency the enclosed list of ophthalmic compounded and repackaged treatments that ophthalmologists are unable to access or have had difficulty accessing from 503B outsourcing facilities. In addition, we have also attached our input on bulk substances that we believe should be included on the 503B bulk substances list.

Many of these compounded and repackaged treatments are vital to treating patients suffering from ailments that threaten their vision, including dangerous bacterial or fungal infections in the eye. We also note that for a number of these treatments, there is no FDA-approved product. For others, the drug must be compounded in a specific concentration for ophthalmic use or in a preservative-free format. **We urge the FDA to allow physicians to obtain compounded drugs from 503A traditional compounding pharmacies without a patient-specific prescription to treat patients that present with emergent conditions.**

Ophthalmic Compounded Drug Access Concerns

Given the unique anatomy and physiology of the eye, many manufactured medications are not appropriate for use in treating conditions of the eye. Frequently, medications are not manufactured in dosage sizes appropriate for ophthalmic use and compounders repackage the product to meet physician and patient needs. In some cases, additional alterations are needed to compound a drug with the right composition for use in the eye, such as changes to the drug's concentration or removing the preservative from the drug. The lack of readily available, direct-from-manufacturer ophthalmic medications for many eye conditions has resulted in a significant number of ophthalmologists relying on compounding pharmacies to fill the gaps and provide critical, sight-saving drugs for physicians and patients.

Since the FDA released its initial draft guidance, "Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act," our organizations have expressed concerns related to patient safety and physician access to drugs for office-use. The FDA's requirement for a physician to have a patient-specific prescription to obtain compounded medications from a 503A compounding pharmacy poses significant safety concerns for patients with emergent conditions that need immediate treatment. The FDA acknowledged in its guidance that a patient-specific prescription is not an effective way to obtain compounded treatments for patients experiencing a critical ophthalmic condition. Physicians

have the alternative to obtain compounded medications from a 503B outsourcing facility; however, there are many barriers in securing drugs from these facilities.

Our organizations have been told by 503B outsourcing facilities that they are not willing to compound drugs in the quantity needed by ophthalmology practices to treat patients with emergent conditions due to costs involved with testing. Our organizations are concerned about both the willingness of outsourcing facilities to prepare these types of small batch compounds and our doctors' ability to access them in a timely and cost-effective manner. Ophthalmologists across the country see patients with ocular conditions that have the potential to cause significant vision impairment and even blindness, in a matter of hours, if there is no immediate treatment. This is especially true in rural areas, where access to medication and healthcare is already at risk. Thus, it is vital that ophthalmologists have assured and timely access to necessary compounded medications to treat patients with emergent conditions. **For these reasons, we view 503A compounding pharmacies as critical to filling this gap for our specialty. At a minimum, we strongly urge the FDA to prioritize the needs of patients with emergent conditions to allow compounding in small quantities for office-use without a patient-specific prescription. This would ensure physician have access to important compounded medications to treat patients with emergent ocular conditions.**

Concerns & Recommendations Regarding 503B Outsourcing Facility Product Report

Our organizations appreciate the FDA's work to release the outsourcing facility product report and attempt to provide transparency on the availability of certain compounded and repackaged drug products from 503B outsourcing facilities. From our review, several ophthalmic drugs are missing from the list of available drugs or are not being produced in the correct concentration or route of administration needed by an ophthalmologist. Additionally, many of the ophthalmic drugs in the product report are being made by a single facility. This raises additional concerns for ophthalmology, as the dependence on a single facility leaves physicians and patients vulnerable to supply interruptions should a facility's production encounter technical difficulties or become impacted by a natural disaster. We would urge the agency to continue to identify and implement improvements to the outsourcing facility product report. The agency should consider ways to include more real-time information, detailing contact information for facilities, pricing, and other information that would improve awareness and timely acquisition of available products.

Bulk Substances for Inclusion on the 503B Bulks List

In response to FDA's draft guidance, "Evaluation of Bulk Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act," our organizations wish to reiterate that many of the compounded drugs ophthalmology utilizes must be compounded from bulk substances. This is due to our reliance on different concentrations and preservative-free formulations required for certain patients. To ensure ophthalmologists are able to secure necessary compounded treatments for their patients, we compiled an initial list of bulk drug substances, found in appendix B, that should be included on the 503B Bulks List and explanations for their inclusions. Our organizations understand that the agency is aware that clinical needs, and the consideration of those needs, are a critical part of the successful implementation of this policy. We urge the agency to engage with our organizations to ensure that implementation of this policy does not threaten access to important and sight-saving treatment options for ophthalmology patients.

Closing Remarks

Our organizations appreciate your efforts to implement the Drug Quality & Security Act and we look forward to future engagement on these important issues. Should you have any questions or wish to schedule a meeting with our organizations, please contact Scott Haber at the American Academy of Ophthalmology at shaber@aaodc.org or 202-737-6662.

Sincerely,

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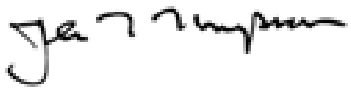

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