ASRS American Society of Retina Specialists

February 11, 2019

Division of Dockets Management (HFA-
305) Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2014-D-0779; Current Good Manufacturing Practice—Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act; Draft Guidance for Industry; Availability

To Whom It May Concern:

The American Society of Retina Specialists (ASRS) welcomes the opportunity to comment on the Revised Draft Guidance for Current Good Manufacturing Practice—Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act; Draft Guidance for Industry; Availability ("revised draft Guidance"). Specifically, we offer comments on the availability of office stock for our patients who present with an immediate need for treatment.

The ASRS is the largest retinal organization in the world, representing over 3,000 members and over 90 percent of retina specialists in the United States. Retina specialists are board certified ophthalmologists who have completed fellowship training in the medical and surgical treatment of retinal diseases. The mission of the ASRS is to provide a collegial and open forum for education, to advance the understanding and treatment of vitreoretinal diseases, and to enhance the ability of its members to provide the highest quality of patient care.

The ASRS agrees with the Food and Drug Administration's (FDA) goal of establishing regulations that ensure the safety and effectiveness of compounded drug products and we support requirements that assure that outsourcing facilities meet stringent safety and quality standards, in line with those imposed on drug manufacturing facilities, and that they pass FDA inspections. We have expressed to the agency concerns that these safety and quality standards create barriers to access to needed compounded drugs that are ordered in small quantities. Because a patient-specific prescription is required for physicians to obtain compounded drugs from 503A pharmacies, they must obtain such drugs from outsourcing facilities to ensure an adequate supply is on hand as ''office stock'' for patients who present with an immediate need. These drugs are often only needed in small quantities. We previously provided the following list of examples of compounded intravitreal antibiotics/antivirals/antifungals that are only available through 503A compounding pharmacies: acyclovir, amikacin, amphotericin, clindamycin, foscarnet, gancyclovir, and voriconazole. While intravitreal vancomycin and ceftazidime are currently available from 503B facilities for bacterial endophthalmitis, there are no 503B available agents for fungal or viral infections or in the event a patient is allergic to cephalosporins. The FDA notes that its revised draft Guidance strikes a balance to address comments and concerns expressed by stakeholders and it is intended to enable a broader range of production volumes, which the FDA in turn, believes would encourage additional compounders to register as outsourcing facilities. The FDA believes it addresses standards critical to reducing the risk of patient harm while balancing appropriate flexibility requested.

We thank the FDA for listening to stakeholders and are hopeful that more outsourcing facilities will emerge and produce a broader scope of drug products for hospitals and physicians. We have informed the agency that 503B outsourcing facilities are not willing to compound drugs in the quantity needed by retina practices to treat patients with emergent conditions due to costs involved with stability testing, and that its requirement for a patient specific prescription to obtain compounded drugs from a traditional compounding pharmacy creates obstacles to access, limiting office-stock, and placing those in need of emergency treatment in harm's way. The FDA acknowledged that a patient-specific prescription is not an effective way to obtain compounded treatments for patients experiencing a

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critical ophthalmic condition and indicated that it hoped to reduce the obstacles that physicians face in seeking office stock from outsourcing facilities.

Although the revised draft Guidance may reduce some obstacles and provide increased flexibility for outsourcing facilities, our preliminary feedback leaves us doubtful that the revised draft Guidance will significantly impact the current reality that 503B outsourcing facilities are not willing to compound drugs in small quantities. We remain concerned about both the economic disincentives for outsourcing facilities to prepare small batch compounds and our members' ability to access them in a timely and cost-effective manner.

An exception to the prescription requirement should be permitted to allow office stock of antibiotics, antifungal, antiviral medications and anti-proliferative agents used for ocular emergencies. As most of these medications are not produced by outsourcing facilities the only option is for the physician to order these from traditional compounders. For these reasons, we continue to view 503A compounding pharmacies as critical to filling this gap for retina specialists. **We strongly urge the FDA to prioritize the needs of patients with emergent conditions to provide an exception to allow 503As to compound emergency use drugs 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.**

ASRS sincerely appreciates the agency's efforts to implement the Drug Quality & Security Act in a safe and effective manner, its outreach to physicians and other stakeholders, and continued efforts to strike a fair balance. We look forward to further engagement with the agency at its upcoming public meeting in May on this important issue. Should you have any questions or wish to follow up with our organization please contact Jill Blim, ASRS Executive Vice President, at jill.blim@asrs.org.

Thank you for your consideration of our comments.

Sincerely,

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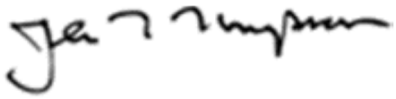

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