AIMED ALLIANCE
Alliance for the Adoption of Innovations in Medicine

September 17, 2015

Johnny Young, M.A.
Director (Acting), Division of Filing Review
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Re: Docket # FDA-2015-N-2713 (Cyclosporine Ophthalmic Emulsion ANDAs)

Dear Mr. Young:

As an organization working to improve the development and utilization of novel, evidence-based medicines, the Alliance for the Adoption of Innovations in Medicine (Aimed Alliance) supports regulatory policies that expand access to innovative treatments for chronic diseases, such as Chronic Dry Eye, one of the most common ocular problems in the U.S. It is in this regard that Aimed Alliance respectfully submits these comments to express our concerns over what appears to be a departure from the U.S. Food and Drug Administration's (FDA) long-standing policies and practices regarding bioequivalence determinations for complex ophthalmic treatments.

Through the above-referenced docket, we became aware that the FDA may be moving forward to approve several abbreviated new drug applications (ANDAs) for the Chronic Dry Eye treatment cyclosporine ophthalmic emulsion based solely on laboratory tests to demonstrate bioequivalence. This is a disturbing development, especially because there is widespread consensus among ophthalmology specialists that all ophthalmic drugs used to treat dry eye must be thoroughly tested in the human eye to ensure their safety. Based on our research, this is because ophthalmic drugs in the form of suspensions and emulsions are complex and highly variable, making it difficult to confirm bioequivalence through laboratory testing alone. Furthermore, we have learned that locally acting ophthalmic drugs may not produce concentrations in the blood or plasma that can be measured through laboratory tests.

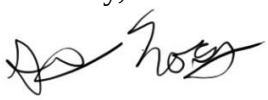
Aimed Alliance is also aware that when the FDA published draft guidance in 2013 to change the testing standards for generic versions of cyclosporine ophthalmic emulsions, the agency received numerous comments from patient advocacy organizations and the ophthalmology professional societies, all urging the FDA to maintain the current testing requirements. These comments urged the FDA to consult with independent scientists and eye care specialists about the clinical implications of modifying the current testing requirements before making a final decision. To our knowledge, the agency did not take this step or provide detail about existing scientific support to show bioequivalence determinations for generic cyclosporine ophthalmic emulsions can be based on in vitro data alone.

In light of these outstanding issues and the continued expressions of concern from ophthalmic professional societies and members of the patient community, we strongly encourage the FDA to refrain from considering or approving any ANDAs for cyclosporine ophthalmic emulsion at this

time. Further, we concur with the request that the FDA engage the ophthalmic scientific community and other stakeholders in the decision-making process so the validity of changing the testing standards is thoroughly vetted.

Thank you for your considering our views. If you have any questions or concerns, please contact me at sworthy@aimedalliance.org or (202) 559-0380.

Sincerely,



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