July 26, 2016

Robert M. Califf, M.D., Commissioner
Food and Drug Administration
U.S. Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Access to Quinacrine

Dear Commissioner Califf,

As patient advocates, physicians, and pharmacists, we are writing concerning access to quinacrine hydrochloride for patients with lupus and dermatomyositis as well as other autoimmune diseases. We are disappointed that the FDA Pharmacy Compounding Advisory Committee (PCAC) voted to recommend not including quinacrine on the section 503A bulk drug substances list despite its history of being used safely and effectively for these conditions. Using the suggested expanded access pathway to obtain this medication will not allow for timely treatment. We would like to meet with you and your compounding team to discuss the impact of this decision on patients and how to provide them with medically necessary and appropriate treatment.

At the meeting in March, the PCAC voted to recommend not including quinacrine hydrochloride on the section 503A bulk drug substances list. Unfortunately, the PCAC did not find that the importance of access to this safe and effective drug for patients with serious autoimmune conditions, including lupus and dermatomyositis, outweighed the potential risks associated with treatments for conditions that are no longer current. The PCAC recommendation was consistent with the recommendation from the FDA’s Office of New Drugs, Division of Bone, Reproductive, and Urologic Products, and Division of Anti-Infective Products, which are associated with medical specialties that do not currently use the medication. This was not consistent with the approval recommendation of the Division of Pulmonary, Allergy, and Rheumatology Products, which reviewed quinacrine for the only indications for which it is currently used in the U.S.
We look forward to continuing this conversation about access to quinacrine, and would like to schedule a meeting between you, other FDA staff, and the undersigned groups. If you have any questions about this request, please contact Natasha Pattanshetti, Regulatory Policy Manager for the American Academy of Dermatology Association at npattanshetti@aad.org or (202) 712-2618.

Sincerely,

American Academy of Dermatology Association
American College of Rheumatology
International Academy of Compounding Pharmacists
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Lupus Research Alliance
National Community Pharmacists Association
Professional Compounding Centers of America