DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

November 27, 2019

Allison Fulton
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2099 Pennsylvania Avenue, NW, Suite 100
Washington, D.C. 20006-6801

Sent via email to: afulton@sheppardmullin.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requiring that any ANDA (or supplement to an ANDA) for Penicillamine capsules be approved only if the bioequivalence study supporting such approval uses a bioanalytical method that introduces a stabilizing agent to minimize the degradation of free Penicillamine post sample collection and includes steps to measure Penicillamine from Penicillamine-copper complex was received by this office on 11/25/2019.

It was assigned docket number FDA-2019-P-5571. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Digitally signed by Dynna Bigby
Date: 2019.11.27 12:16:42 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of Operations (OO)