DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

September 17, 2020

Noor Araim
Acella Pharmaceuticals, LLC
1880 McFarland Parkway Suite 110
Alpharetta, GA 30005

Sent via email to: naraim@acellapharma.com

Dear Petitioner:

Your petition to the Food and Drug Administration requesting the Commissioner to make a determination regarding assigning a new Reference Standard (RS) for Meprobamate Tablets, 400 mg as the RLD has been discontinued and the current RS fromWatson is not available on the market was received by this office on 09/16/2020.

It was assigned docket number FDA-2020-P-1919. 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 and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2020.09.17 16:51:20 -04'00'

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