Acella
PHARMACEUTICALS, LLC

September 16, 2020

Acella Pharmaceuticals, LLC (Acella) submits this Citizen Petition in accordance with 21 CFR 10.25(a), 10.30, and 314.161 requesting the Commissioner of the Food and Drug Administration to determine a new Reference Standard (RS).

A. Action Requested

Acella requests 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 from Watson is not available on the market.

B. Statement of Grounds

Acella wishes to resume manufacture of Meprobamate Tablets, 400 mg under approved ANDA 084153. Due to this ANDA being off the market since 2009 and was last manufactured in 1986, there is no dissolution profile that can be found in the ANDA documents. There are also no pre-change samples on which to run the dissolution profile. The listed RS in the Orange Book is by Watson Labs (ANDA 083308) which is not available on the market. Because there is no Reference Standard or Reference Listed Drug available to run a dissolution profile against, Acella is filing this Citizen Petition in accordance with 21 CFR 10.25(a) and 10.30 to request that the FDA select a different listed manufacturer as an RS.

Pursuant to 21 CFR 10.25(a) and 10.30, we are requesting the Commissioner to determine a new RS.

C. Environmental Impact

Pursuant to 21 CFR 25.20, the petitioner hereby claims a categorical exclusion from the requirement of preparing and submitting an environmental assessment (EA) as provided for in 21 CFR 25.31(a) and to Acella's knowledge, no extraordinary circumstances exist.

The classes of actions listed in 21 CFR 25.31(a) are categorically excluded from the requirement to prepare an EA or an Environmental Impact Statement (EIS):

> Agency action on an NDA, abbreviated application, application for marketing approval of a biologic product, or a supplement to such applications, or actions on an OTC monograph, if the action does not increase the use of the active moiety.

In accordance with the FDA guidance for industry, Environmental Assessment of Human Drug and Biologics Applications, July 1998, Attachment A, approval of an abbreviated application is not considered to result in increased use of an active moiety already approved by the agency. The present application is an abbreviated application based on FDA's prior approval of the RLD, Meprobamate Tablets 400 mg, Application No. 009698, held by Medpointe Pharmaceuticals Medpoint Healthcare, Inc.

D. Economic Impact

This section is not applicable.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which to be unfavorable to the petition.

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