



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

January 23, 2020

John H. Fuson
Crowell & Moring, LLP
1001 Pennsylvania Avenue N.W.
Washington, DC 20004-2595

Sent via email to: jfusion@crowell.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that the agency refrain from finalizing the memorandum of understanding (“MOU”) under section 503A(b)(3)(B)(i) or taking any regulatory action against compounders based on section 503A(b)(3)(B)(ii) that relies on a definition of “distribution” that includes “dispensing” was received by this office on 01/22/2020.

It was assigned docket number FDA-2020-P-0368. 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
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)