



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

September 30, 2020

Lee H. Rosebush
Outsourcing Facilities Association
1050 Connecticut Ave., NW
Suite 1100
Washington, DC 20036-5403

Sent via email to: lrosebush@bakerlaw.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to issue a regulation defining the term “clinical need” under section 503B(a)(2)(A)(i) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 353b(a)(2)(A)(i) (hereinafter “FD&C Act”) and in full accordance with the definition requested herein, establish the list of bulk drug substances for which there is a clinical need (503B Bulks List) within the next 180 days was received by this office on 09/30/2020.

It was assigned docket number FDA-2020-P-2028. 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 Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)