

Food and Drug Administration Rockville MD 20857

July 1, 2013

FILE COPY

Christine Miller, Pharm.D Associate Director Lachman Consultant Services, Inc. 1600 Stewart Avenue Westbury, NY 11590

Dear Dr. Miller:

Your petition to the Food and Drug Administration requesting to declare that the drug products, Dapsone, 50 mg, is suitable for submission as an ANDA, was received by this office on 07/01/2013. It was assigned docket number FDA-2013-P-0800/CP1, and it was filed on 07/01/2013. 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,

Gloria Ortega

Administrative Proceedings Officer Division of Dockets Management

FDA/Office of the Executive Secretariat (OES)