DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

February 18, 2022

Michelle R. Ryder
Principal Consultant
Lachman Consulting Services, Inc.
1600 Stewart Ave., Suite 604
Westbury, NY 11590

Sent via email to: m.ryder@lachmanconsultants.com

Dear Petitioner:

Your submission requesting that the Commissioner of the Food and Drug Administration declare that the proposed drug product, Methylene Blue Injection, USP, 5 mg/1 mL is suitable for submission as an ANDA and the listed reference drug product (RLD), upon which this petition is based, is PROVAYBLUE (methylene blue) injection USP, for intravenous use, 50 mg/10 mL (5 mg/mL) and 10 mg/2 mL (5 mg/mL), held by PROVEPHARM SAS, NDA 204630 was received and processed under CFR 10.30 by this office on 02/18/2022.

It was assigned docket number FDA-2022-P-0200. Please refer to this docket number in future correspondence on this subject with the Agency.

Also, note that the acceptance of the suitability petition for filing is a procedural matter and in no way reflects the agency's decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2022.02.18 14:55:56 -05'00'

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