U.S. FOOD & DRUG ADMINISTRATION

ANDA 086841

TRANSFER OF OWNERSHIP

Everest Life Sciences LLC
8 Sheller Drive
Monroe, NJ 08831
Attention: Mallikarjuna Desireddy

Dear Mallikarjuna Desireddy:

We acknowledge receipt of your communication on November 21, 2022, submitted as required by the provisions of 21 CFR 314.72(a) for notifying the Food and Drug Administration of the change of ownership of the following abbreviated new drug application (ANDA):

Name of Drug Product:	Dapsone Tablets, 25 mg
Name of New Owner:	Everest Life Sciences LLC
Name of Former Owner:	Jacobus Pharmaceutical Company, Inc.

Your correspondence notes that the date that the change in ownership is effective on November 21, 2022. Under 21 CFR 314.72(b), the new owner shall advise us about any change in the conditions of the approved application.

We request that you notify your suppliers and contractors who have Drug Master Files (DMFs) referenced by your application of the change in ownership so that they can submit new letters of authorization to their DMFs.

We remind you that you must comply with the requirements for an approved ANDA in 21 CFR 314.80 and 21 CFR 314.81. In addition, you are responsible for any correspondence that is outstanding as of the effective date of the transfer.

If the drug that is the subject of an ANDA requires a risk evaluation and mitigation strategy (REMS), the change in ownership must also be reflected in the approved REMS and submitted as described below. Because the change is made to the REMS supporting document, it is not considered a REMS revision.

1. Submit the updated REMS supporting document to the application or communicate with the DMF holder to submit the updated REMS supporting document to the DMF as follows:

ANDA or DMF ######
General Correspondence—REMS Supporting Document

2. Submit a redline (using Track Changes) version and a clean version of the revised REMS supporting document with the new corporate name and address to reflect the change in ownership of the application.

3. Follow the procedures outlined in the guidance for industry *Use of a Drug Master File for Shared System REMS Submissions*[1] and the Technical Conformance Guide for Shared System REMS Drug Master File Submissions.[2]

4. If the approved REMS contains a Medication Guide, you must also revise the Medication Guide to reflect the change in ownership. As described in the guidance for industry *Risk Evaluation and Mitigation Strategies: Modifications and Revisions*, a REMS change of this kind is considered a REMS revision. Submit the revised Medication Guide as a REMS revision as described in the guidance, prominently identifying the submission with the following wording in bold capital letters at the top of the first page of the submission:

   ANDA ######
   REMS REVISION

5. You should also describe this REMS revision in the next annual report.

The communication you submitted will be retained as part of your application.

If you have any questions, contact CAPT Aaron Sigler, Deputy Director, Division of Project Management at (240) 402-8786.

Sincerely,

{See appended electronic signature page}

Honghong La
Division of Project Management
Office of Regulatory Operations
Office of Generic Drugs

---

[1] We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

[2] The Technical Conformance Guide for Shared REMS Drug Master File Submissions is available on the eCTD Resources web page at https://www.fda.gov/drugs/developmentapprovalprocess/formssubmissionrequirements/electronicsubmissions/ucm535180.htm#Technical_Conformance_Guide.

Honghong La

Digitally signed by Honghong La
Date: 12/12/2022 03:32:18PM
GUID: 58e556a800220dea4c79ba6ff28bcac5