DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

DMF 030231

DMF ACKNOWLEDGEMENT

RANQ REMEDIES PVT. LTD.
ATTN: MR. SAMEER G. RANADIVE,
MANAGING DIRECTOR
D-14, KURKUMBH MIDC
KURKUMBH MS 413802, INDIA

Dear Mr. Sameer G. Ranadive,

The Food and Drug Administration acknowledges receipt of the following Drug Master File (DMF) submission:

DMF Number Assigned: 030231

Date of Submission: JANUARY 16, 2016

DMF Type: IV

Subject (Title): MICROCRYSTALLINE CELLULOSE (USP)

Holder: RANQ REMEDIES PVT. LTD.

Submitted by: RANQ REMEDIES PVT. LTD.

Agent: NONE

All subsequent correspondence to this DMF should be identified with the information as provided above. One original and one copy should be submitted to the following address.

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
Drug Master File Staff
5901-B Ammendale Road
Beltsville MD 20705-1266

Your DMF will be reviewed only in connection with a New Drug Application, Abbreviated New Drug Application, Investigational New Drug Application, Biological License Application, New Animal Drug Application, Abbreviated New Animal Drug Application, Investigational New Animal Drug Application, or DMF it is intended to support when a Letter of Authorization (LOA) is submitted to the DMF and a copy of the LOA is submitted in the application e.g., NDA, that references the DMF.

Currently, there is no requirement to submit or resubmit DMFs in any electronic format. However, beginning on May 5, 2017, new DMFs, as well as subsequent submissions to previously submitted

DMFs (i.e., amendments) must be submitted electronically, in the format specified by FDA in the eCTD guidance.[1] DMF submissions that are not submitted in eCTD format after this date may be subject to rejection. DMF holders whose DMFs are currently in paper form will not be required to resubmit their entire DMFs in eCTD format after May 5, 2017.

Electronic submissions that are 10GB or smaller in size must be submitted through the Electronic Submission Gateway (ESG). Most DMF submissions fall into this category, therefore submitters are advised to obtain ESG accounts at their earliest convenience. Submissions that are over 10GB may be submitted on physical media (such as compact disc) to the address above.[2]

At the same time, you have the option to convert your existing paper DMF into electronic format any time before May 5, 2017. If you decide to convert your paper DMF to electronic format, you may continue to use your existing DMF number. If your existing number is four-digits, e.g., 1234, you will need to pad left with zeroes to convert the DMF number to a 6-digit format, e.g., 001234 when you convert your DMF to electronic format. In addition, if you choose to resubmit a paper DMF in electronic format, and there are any changes in the content of the DMF as a result of the reformatting, e.g., addition of new or updated information, the cover letter for the submission must specify what areas of information have been updated.

You are responsible for compliance with 21 CFR314.420. See "The Guideline for Drug Master Files" http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/ucm073164.htm
You are required to submit all changes in information regarding the DMF (21 CFR 314.420(c)). In particular the FDA must be notified of any changes in the holder name or ownership and/or the agent and/or the name of the contact person.

The types of information to be submitted may be found at the DMF Web Site. See "**Submission of Amendments, Annual Reports, and Letters of Authorization.**

You are expected to:

- Adhere to the statement of commitment you have provided.
- Provide the following submissions to the DMF:
    a. Letters of Authorization (LOAs) granting permission to a third party (authorized party) to reference the DMF and for FDA to review the DMF. Listing an authorized party in the Annual Report (see below) is not sufficient to authorize that party to reference the DMF. Submission of a copy of the LOA to the authorized party without submitting the original LOA to the DMF is also not sufficient to authorize that party to reference the DMF.

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[1] Section 745A(a) of the Food, Drug, and Cosmetic Act. See "Guidance for Industry: Providing Regulatory Submissions in Electronic Format —Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications" at 3 (May 2015). http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM333969.pdf. [1]

[2] See FDA eCTD Web Page for further information. http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm.

b. Annual Reports to the DMF containing:
    i. Date(s) of the amendment(s) reporting changes since the last Annual Report or the original DMF filing date, whichever is most recent or a statement that no amendments have been submitted since the last Annual Report or the original DMF filing date, whichever is most recent.
    ii. A complete list of all parties authorized to make reference to the DMF, identifying by name, reference number, volume, date, and page number the information that each person is authorized to incorporate and the date of the LOA or a statement that there are no Authorized Parties.
    iii. A list of all parties whose authorization has been withdrawn, if applicable.

Submissions containing multiple types of information e.g. administrative changes, an annual report, or changes in technical information should specify the different types of information in the header in the cover letter.

If you submitted an LOA without the DMF number with the original submission, please resubmit the LOA with the DMF number.

If you have any questions, please email dmfquestion@cder.fda.gov

Sincerely,
{See appended electronic signature page}
Vathsala Selvam
Technical Information Specialist
Drug Master File
Immediate Office/Office of Pharmaceutical Quality
Center for Drug Evaluation and Research
Food and Drug Administration

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

CLAUDE THEOPHIN
02/02/2016