

Clinical Memorandum: Resubmission of NDA 206966

On September 14, 2015, the Applicant (Dr. Reddy's Laboratories, SA) submitted NDA 206966 for Xeglyze (abametapir) lotion, 0.74% for the treatment of head lice infestation in patients 6 months of age and older. On August 30, 2016, the Agency issued a Complete Response Letter because of deficiencies discovered during an inspection of Dr. Reddy's Lab Ltd. CTO Unit VI (FEI 3002949085) manufacturing facility.

On November 12, 2019, the Applicant resubmitted NDA 206966. The resubmission included a new site as an alternative drug substance manufacturing facility, additional drug product information and stability data, and updated manufacturing process and facilities information. The resubmission contained no new clinical information. On April 23, 2020, the Office of Pharmaceutical Quality (OPQ) issued an Integrated Quality Assessment. On May 4, 2020, the OPQ issued a memorandum with final final recommendations and conclusions regarding approvability:

"At the time of the review of the resubmission of this NDA, the Office (of) Pharmaceutical manufacturing Assessment had made a recommendation of "Withhold" for the drug substance manufacturing facility, Dr. Reddy's Lab Ltd. CTO Unit VI (FEI 3002949085). As of April 30, the status for this manufacturing facility has been changed to "Compliant". However, the following deficiencies still exist:

- 1) The required preapproval inspection of the drug substance testing facility, (b) (4) is still pending due to travel restrictions associated with the COVID-19 pandemic, and OPMA has made a final recommendation of (b) (4) for the facility.
- 2) The resolution of the currently pending CMC labels/labeling issues have been deferred to (the) next review cycle.

Therefore, from the OPQ perspective, this NDA is recommended for **Complete Response** per 21 CFR 314.125(b)(6),(13) until the above issues are satisfactorily resolved."

I concur with the recommendations and conclusion from OPQ recommending a Complete Response to the resubmission of NDA 206966.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

KEVIN L CLARK
05/05/2020 02:48:14 PM

GORDANA DIGLISIC
05/05/2020 05:49:55 PM