Clinical Memorandum: Approval of Resubmission 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 recommendations and conclusions regarding approvability. The major deficiency was that "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." This deficiency was conveyed to the Applicant in a Discipline Review Letter date May 4, 2020.

On May 11, 2020, the Applicant submitted an Information Amendment which included alternative drug substance testing facilities which have been recently inspected. After discussion, the review team agreed to a 3 month extension of the goal date. The extended user fee goal date is now August 12, 2020. This was conveyed to the Applicant in a letter dated May 12, 2020. The letter also requested that the Applicant:

> "…update your NDA by May 19, 2020 with the name(s) of facility(ies) that you plan on using to replace Lucid Laboratories. Additionally, include a statement that you plan to rely only on the data from the newly added facility(ies) for (b) (4) testing for the release of the drug substance."

On May 19, 2020, the Applicant submitted a Quality Module Information Amendment containing the requested information. Per the OPQ memorandum by Dr. Hamid Shafiei, dated June 5, 2020:

"The proposed two new drug substance testing facilities have been reviewed by the facilities reviewer, Dr. Aditi Thakur. Dr. Thakur has found the proposed new testing facilities adequate to support the approval of this application.

Also, on June 1, 2020, the Applicant submitted updated PI labeling and carton/container labels. The updated PI labeling, and carton/container labels have adequately addressed all CMC deficiencies that were noted during the second review cycle for this application.

Therefore, from the OPQ perspective, this NDA is now recommended for **approval** with the expiration dating period of **36 months**."

Therefore, I also recommend approval of NDA 206966 for Xeglyze lotion for the treatment of head lice infestation in patients 6 months of age and older.

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
06/05/2020 05:12:56 PM

GORDANA DIGLISIC
06/08/2020 11:24:13 AM