NDA 213330/S-003

GENERAL ADVICE

Hikma Pharmaceuticals USA Inc
Attention: Venkata Sai Tankashala
Associate Director, Regulatory Affairs
2 Esterbrook Lane
Cherry Hill, NJ 08003

Dear Mr. Sai Tankashala:

Please refer to your supplemental new drug application (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for labetalol injection.

We also refer to our approval letter dated March 18, 2022, which contained an error.

In the page 6 of 20 of the approval letter, the following sentence has inadvertently been deleted in the appended label:

2. Remove tip cap by twisting it off. (See Figure 2)

This General Advice letter acknowledges the error described above and incorporates the correction of the error. The effective approval date will remain March 18, 2022, the date of the original letter.

If you have any questions, please call Maryam Changi, Regulatory Project Manager, at (240) 402-2725.

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD.
Deputy Director for Safety
Division of Cardiology and Nephrology
Office of Cardiology, Hematology,
Endocrinology and
Nephrology
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information

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/

MARY R SOUTHWORTH
03/29/2022 08:17:50 AM