HETERO LABS LIMITED
"Hetero Corporate", 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad - 500 018, Telangana, INDIA.
Tel : 91-40-23704923/24/25, Fax : 91-40-23704926, 23714250
E-mail : contact@heterodrugs.com URL : http//www.heterodrugs.com
CIN: U24110TG1989PLC009723

June 19, 2019

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20552

Citizen Petition

Product: Mexiletine Hydrochloride capsules 150 mg, 200 mg and 250 mg

Dear Sir/ Madam:

We intend to submit a Citizen Petition as per the 21 § C.F.R. 10.30 and in accordance with the regulations of 21 § C.F.R. 314.161, to request that the Commissioner of the Food and Drug Administration to determine whether the Reference listed drug Mexitil® (Mexiletine Hydrochloride); NDA# 018873 by Boehringer Ingelheim Pharmaceuticals, Inc. has been voluntarily withdrawn for safety or effectiveness reasons as outlined below.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether the drug product Mexitil® (Mexiletine Hydrochloride) has been voluntarily withdrawn from sale for safety or efficacy reasons.

The petitioner believes that the Boehringer Ingelheim Pharmaceuticals, Mexitil® (Mexiletine Hydrochloride); NDA# 018873 was not withdrawn for the reasons of safety and efficacy.

After a review of publicly available information, including searches on the Internet using common search engines, such as Google and Yahoo, it appears that Boehringer Ingelheim Pharmaceuticals, Inc. did not withdraw the Mexitil® (Mexiletine Hydrochloride); NDA# 018873 for safety or effectiveness reasons. In particular, we note the following research results:

- There are no published state or federal court decisions relating to product liability arising out of the use of the Mexitil® (Mexiletine Hydrochloride); NDA# 018873.

Hetero requests the Commissioner of the Food and Drug Administration to make a determination that the discontinued formulation Boehringer Ingelheim Pharmaceuticals, Inc., Mexitil® (Mexiletine Hydrochloride) was not discontinued for safety and efficacy reasons.

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B. Statement of Grounds:

The Food and Drug Administration maintains a list of drug products that are eligible for submission as abbreviated new drug applications in the Approved Drug Products with Therapeutic Equivalence Evaluations ("The Orange Book"). The Mexitil® (Mexiletine Hydrochloride); NDA# 018873 is currently listed in the Discontinued Section of the electronic Orange Book on FDA's website. According to the Preface to the Orange Book, a drug product in the Discontinued Section as to which a determination has already been made that withdrawal was not for safety or effectiveness reasons will include the following statement after its product strength: "Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons." There is no such annotation for Mexitil® (Mexiletine Hydrochloride); NDA# 018873 (**Refer Attachment I**). The petitioner asks the FDA to determine that the NDA holder, Boehringer Ingelheim Pharmaceuticals, Inc., voluntarily withdrew the Mexitil® (Mexiletine Hydrochloride); NDA# 018873 from sale for reasons other than safety or effectiveness.

After a review of publicly available information, including searches on the Internet using common search engines, such as Google and Yahoo, it appears that Boehringer Ingelheim Pharmaceuticals, Inc. did not withdraw the Mexitil® (Mexiletine Hydrochloride); NDA# 018873 for safety or effectiveness reasons. In particular, we note the following research results:

- There are no published state or federal court decisions relating to product liability arising out of the use of the Mexitil® (Mexiletine Hydrochloride); NDA# 018873.

Under FDA regulations, drugs are withdrawn from the market if the Agency withdraws or suspends approval of the drug application for the reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 C.F.R. § 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 § C.F.R. 314.161(a)(l)).

The available information suggests that the Mexitil® (Mexiletine Hydrochloride); NDA# 018873 was not withdrawn for safety or effectiveness reasons. Rather, it appears that Boehringer Ingelheim Pharmaceuticals, Inc. withdrew Mexitil® (Mexiletine Hydrochloride); NDA# 018873 for voluntary reasons unrelated to the product's safety or effectiveness. The Petitioner, therefore, requests that the FDA determine that Boehringer Ingelheim Pharmaceuticals, Inc. voluntary withdrawal of Mexitil® (Mexiletine Hydrochloride); NDA# 018873 from sale was for reasons other than safety or effectiveness in order to enable action on an ANDA referring to Mexitil® (Mexiletine Hydrochloride); NDA# 018873 product as the Reference Listed Drug. It also requests that the Agency publish a notice of its determination in the Federal Register and to appropriately annotate the Orange Book.

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Should the NDA holder recommence marketing its Mexitil® (Mexiletine Hydrochloride); NDA# 018873 after the submission of this petition and prior to an FDA response, and there is an evidence that the product is available in the marketplace, the petitioner will consider this petition.

C. Environmental Impact:

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 C.F.R. § 25.31.

D. Economic Impact:

Pursuant to 21 C.F.R. § 10.30(b), economic impact information is submitted only when requested by the Commissioner. This information will be promptly provided, if so requested.

E. Certification:

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petition which is unfavorable to the petition.

Sincerely,

Soma Raju, Ph.D.
Vice President - Regulatory Affairs

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Office of Generic Drugs (HFD-600)
Center for Drug Evaluation and Research
Food and Drug Administration
Central Document Room, 5901B
Ammendale Road, Beltsville, MD 20705

April 03, 2019 **US AGENT LETTER OF AUTHORIZATION**

Reference: US Agent Letter of Authorization

Dear Sir/Madam,

This letter will serve to advise your office that we have appointed the following person as Hetero U.S. Agent.

Dr. Soma Raju, Vice President - Regulatory Affairs
Hetero USA, Inc.,
1035 Centennial Avenue,
Piscataway, NJ 08854
Telephone: 732-529-0423
Fax: 732-562-8854
E-Mail: somaraju@heterousa.com

As our U.S. Agent, Dr. Soma Raju is authorized to submit and receive all correspondence on administrative or scientific matters pertaining to our ANDA submissions.

Sincerely

G. Sangeetha,
Associate Vice President - Regulatory Affairs,
Hetero Labs Limited.