Baxter

March 29, 2019

Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir/Madam,

The undersigned, Baxter Healthcare Corporation (Baxter) submits this petition pursuant to section 505 (j) of the Federal Food, Drug, and Cosmetic (FD&C) Act, in accordance with the 21 CFR § 10.25(a) and § 10.30, and at the direction of the Office of Pharmaceutical Quality in response to Controlled Correspondence (00542), to request the Food and Drug Administration (FDA) to determine whether the Reference Listed Drug (RLD) CARDENE® (Nicardipine Hydrochloride Injection) 25 mg/10mL under the New Drug Application (NDA) 019734, was withdrawn for safety and/or effectiveness reasons and to designate an additional RLD.

A. Action Requested

The petitioner requests that FDA determine whether CHIESI USA Inc's RLD CARDENE® (Nicardipine Hydrochloride Injection) 25 mg/10mL approved under NDA 019734 was withdrawn for safety and/or effectiveness reasons and to designate an additional RLD.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products that are eligible for submission as an ANDA (abbreviated new drug application) in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book". As per the Orange Book CARDENE® 25 mg/10 mL (NDA 019734) by CHIESI

USA INC is the RLD and was approved by the FDA on January 30, 1992. However, CARDENE® 25 mg/10 mL is listed in the discontinued section (Attachment 1) of Orange Book without any determination as to whether a listed drug is withdrawn from sale for safety and/or effectiveness reasons.

Under current FDA regulations, drugs are withdrawn from the market if the Agency withdraws or suspends approval of the drug product application for reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (see 21 CFR §314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for safety and/or effectiveness reasons before an ANDA that refers to that listed drug may be approved (see 21 CFR 314.161(a)(1)).

The petitioner had also submitted a Controlled Correspondence (Attachment 2) to the Office of Generic Drugs (Office of Pharmaceutical Quality) requesting FDA's confirmation on the use of CARDENE® Premixed Injection for demonstration of pharmaceutical equivalence between CARDENE® 25mg/10 mL and Proposed Baxter Generic as CARDENE® 25mg/10 mL and all it's approved generics were listed as discontinued in the Orange Book.

In response, FDA advised to submit a Citizen Petition under 21 CFR 10.25(a) and 10.30 to the FDA requesting that the FDA determine whether the RLD CARDENE® (Nicardipine Hydrochloride Injection) 25 mg/10mL was withdrawn for safety and/or effectiveness reasons and to designate an additional RLD. The FDA further rreferenced the guidance – "*Referencing Approved drug products in ANDA submissions*" Section III.B.2 wherein if an RLD appears in the Discontinued Section and FDA has not yet made a determination whether the drug was withdrawn from sale for reasons of safety or effectiveness, the applicant must submit a citizen petition under 21 CFR 10.25(a) and 10.30 at the same time as the ANDA submission, seeking a determination whether the listed drug has been withdrawn from sale for safety or effectiveness reasons.

As CHIESI USA Inc's RLD Cardene® 25 mg/10 mL continues to be listed under the discontinued section of the Orange Book at the time of submission of this petition, the

petitioner requests that FDA determine whether CHIESI's decision to withdraw Cardene® 25 mg/10 mL from sale was for safety and/or effectiveness reasons and designate an additional RLD.

If the NDA holder reintroduces Cardene® 25 mg/10 mL to the commercial market after submission of this petition and prior to FDA's response, petitioner will at such time request the withdrawal of this petition.

C. Environmental Impact

The petitioner claims a categorical exclusion from the requirement of an environmental assessment or environmental impact statement pursuant to 21 CFR § 25.31.

D. Economic Impact

Pursuant to 21 CFR § 10.30(b), upon request by the Commissioner, the Petitioner will, submit an economic impact information.

E. Certification

The undersigned certifies that to the best of its knowledge, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the Petitioner which are unfavourable to the petition.

Sincerely,

Mitul

Digitally signed by Mitul
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