PHARMOBEDIENT

April 10, 2024

Division of Dockets Management
U.S. Food and Drug Administration
Department of Health and Human Services
Room 1061, l-IFA-305
5630 Fishers Lane
Rockville, MD 20852

ANDA Suitability Petition for Carbinoxamine Maleate Tablets 2 mg

Dear Sir/Madam,

The undersigned submits this Suitability Petition pursuant to section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act ("FDC Act") and in accordance with 21 C.F.R. § 10.20, 10.30 and 314.93, to request that the Commissioner of the U.S. Food and Drug Administration ("FDA") declare that the drug product, Carbinoxamine Maleate Tablets, 2 mg is suitable for submission in an Abbreviated New Drug Application ("ANDA") .

A. Action Requested:

The Suitability Petition requests that the FDA determine and declare that Carbinoxamine Maleate Tablets, 2 mg is suitable for submission in an Abbreviated New DrugApplication (ANDA). This Suitability Petition pursuant to Section 505(j)(2)(C) of the FDC Act and 21C.F.R. §314.93, is the appropriate mechanism for securing FDA authorization to submit an ANDA for a drug product that differs in dosage strength (from 4 mg to 2 mg) from the Reference Listed Drug (RLD).

The Reference Listed Drug (RLD) upon which this petition is based is CLISTIN (CARBINOXAMINE MALEATE) Tablets from Ortho Mcneil Pharmaceutical Inc which FDA approved prior to Jan 1, 1982 under NDA # N008915. CLISTIN is discontinued and **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**.

Reference Standard (RS) drug listed is # A040442 of Genus Lifesciences Inc and is marketed in 4 mg strength tablet as identified in the Orange Book. The relevant copy of the pages from the current Electronic Edition of the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) for CLISTIN is provided as **Attachment 1**.

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Approval of this Suitability Petition would allow the sponsor to submit Carbinoxamine Maleate Tablets, 2 mg as an ANDA.

B. Statement of Grounds:

The FDC Act Section 505(j)(2)(C)(iii) and 21C.F.R. §314.93, provides for the submission of an Abbreviated New Drug Application for a drug product that has a different dosage strength from theRLD product provided that the FDA has approved a suitability petition proposing such anapplication.

Carbinoxamine maleate Tablets, 4 mg, the RS for the proposed drug product, containing 4 mg of Carbinoxamine maleate, is a histamine-H_1 receptor blocking agent for the symptomatic treatment of:

- Seasonal and perennial allergic rhinitis
- Vasomotor rhinitis
- Allergic conjunctivitis due to inhalant allergens and foods
- Mild, uncomplicated allergic skin manifestations of urticaria and angioedema
- Dermatographism
- As therapy for anaphylactic reactions adjunctive to epinephrine and other standard measures after the acute manifestations have been controlled
- Amelioration of the severity of allergic reactions to blood or plasma

Dosing recommendations in the RS package insert are as follows:

- Usual Adult Dosage:
  1 or 2 tablets (4 to 8 mg) 3 to 4 times daily
- Usual Child's Dosage:
  Six to eleven years – ½ to 1 tablet (2 to 4 mg) 3 to 4 times daily
- Children 2 to 5 years
  0.2 to 0.4 mg/kg/day divided into 3 to 4 daily doses

A copy of the most recent labeling for RS under ANDA # 040442 (Revised Sep 23, 2022) is provided as **Attachment 2**.

The proposed drug products also contain Carbinoxamine Maleate in a tablet dosage form, but in 2 mg (unscored) strength. The proposed change in strength is consistent with the dosing instruction for the RLD. Moreover, the availability of a new 2 mg (unscored) tablet strength will provide a prescribing physician with a greater degree of flexibility in achieving proper dosing for a specific

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patient's needs. The proposed changes in strength from that of the RLD do not raise questions of safety or efficacy for the proposed drug product.

Table 1 presents the comparison between approved marketed and proposed drug product.

Table 1 - Comparison of Approved Drug Products to Proposed Drug Product

Product Name	Reference Standard (RS) and RLD Drug Products	Carbinoxamine maleate Tablets by Pharmobedient Pharmaceuticals, LLC
Drug Substance	Carbinoxamine maleate, USP	
Dosage Strengths	RLD: 4 mg RS: 4 mg	2 mg
Dosage Form	Tablets (Scored)	Tablets (Unscored)
Route of Administration	Oral	
Indication	• Seasonal and perennial allergic rhinitis • Vasomotor rhinitis • Allergic conjunctivitis due to inhalant allergens and foods • Mild, uncomplicated allergic skin manifestations of urticaria and angioedema • Dermatographism • As therapy for anaphylactic reactions adjunctive to epinephrine and other standard measures after the acute manifestations have been controlled • Amelioration of the severity of allergic reactions to blood or plasma	

Note: - *Formulation development of tablet will be done to meet all the quality and regulatory requirement.*

The proposed labeling for Pharmobedient's Carbinoxamine maleate tablets is provided as **Attachment 3;** with the changes annotated in track changes from the FDA approved labeling of the Immediate Release Tablets. The only differences between the two products' labeling are those related to the *product strength*.

Considering the formulation release properties and the desired bioequivalence to the RS formulation, the bioavailability of the 2 mg dosage strength of tablets shall be studied against the

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4 mg dosage strength of Genus's Carbinoxamine maleate Tablets, 4 mg as this is specified as the reference standard (RS) against which in vitro bioequivalence must be established. Thus, within the scope of the proposed ANDA approach, the drug product tablets shall demonstrate comparable dissolution profiles to RS required by the Office of Generic Drug (OGD) Product-Specific Guidance for Generic Drug Development for bioequivalencestudies of Carbinoxamine maleate tablets, as provided in **Attachment 4**.

Therefore, the petitioner's request for the Commissioner to find that a change in dosage strength of 2 mg should raise no questions of safety or effectiveness, and the Agency should approve the petition.

C. Environmental Impact
The petitioner claims a categorical exclusion under 21 CFR 25.31.

D. Economic Impact
The petitioner does not believe that this is applicable in this case, but will agree to provide such an analysis, if requested by the Agency.

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 petitioner, which are unfavorable to the petition.

During the course of the review of this Suitability Petition, if there are any questions or comments, please do not hesitate to contact undersigned.

Sincerely,

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