August 16, 2022

VIA ELECTRONIC SUBMISSION

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

SUITABILITY PETITION

Dear Sir or Madam:

The undersigned hereby submits this petition pursuant to Section 505(J)(2)(C) of the Federal Food, Drug, and Cosmetic Act ("FDC Act"), and 21 C.F.R. § 314.93, and in accordance with 21 C.F.R. § 10.20 and 21 C.F.R. § 10.30, requesting the Commissioner of the Food and Drug Administration to declare that the drug product, Glycopyrrolate Oral Film, in strengths of 1 mg, 1.5 mg and 2 mg are suitable for consideration as an abbreviated new drug application (ANDA).

A. Action Requested

The Petitioner requests that the Commissioner of the Food and Drugs Administration to declare that Glycopyrrolate Oral Film, in strengths of 1 mg, 1.5 mg and 2 mg are suitable for submission as an ANDA.

The reference-listed drug product (RLD), upon which this petition is based, is Robinul and Robinul Forte (Glycopyrrolate) Tablets 1 mg & 2 mg approved under NDA012827 currently held by Casper Pharma as designated in the Orange Book (see copy of the page from the current Electronic Edition of the Approved Drug Products with Therapeutic Equivalence Evaluations (Attachment 1)).

The current reference standard product (RS) is Glycopyrrolate tablets 1 mg and 2 mg, ANDA 040653 currently held by PAR Pharmaceuticals as designated in the Orange Book (see copy of the page from the current Electronic Edition of the Approved Drug Products with Therapeutic Equivalence Evaluations (Attachment 2)).

Further, 1.5 mg film refers to Glycopyrrolate tablets ANDA 091522 which was approved to LGM Pharma Solutions Llc by FDA on March 12, 2012. This approval was based on ANDA suitability petition number 2006-P-0300, which referenced the same RLD as cited in this petition. Therefore, the petitioner seeks only a change in dosage form from conventional tablets to oral films, from that of the listed drug products currently approved.

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B. Statement of Grounds

The Federal Food, Drug, and Cosmetic Act provides for the submission of an Abbreviated New Drug Application for a drug product that differs in dosage form from that of the listed drug provided that FDA has approved a petition declaring that the proposed changed product does not raise any questions of safety or effectiveness. This Petition requests to submit an ANDA for a change in the dosage form.

The RLD, Robinul Forte and Robinul (Glycopyrrolate) Tablets by Casper are conventional tablet products containing 2 mg or 1 mg of Glycopyrrolate in each tablet. As noted above, there is also a 1.5 mg Glycopyrrolate tablet approved that referenced the same RLD, but was approved based on an ANDA suitability petition. The proposed drug product will be an oral film dosage form, containing 1 mg, 1.5 mg, or 2 mg of Glycopyrrolate. This petition is thus seeking a change in dosage form to an oral film from that of the RLD, a conventional oral tablet dosage form.

The petitioner would like to bring to the agency's notice that the agency has previously approved many suitability petitions for many products, which requested for a change in the dosage form.

The proposed product will contain the same dosing schedule as that of the RLD and the only difference will be that the Oral film product will be recommended to be dissolved in the mouth prior to swallowing. The current dosing instructions in the approved labelling of the RLD are as follows:

Dosage and Administration:

- The dosage of Robinul® or Robinul® Forte should be adjusted to the needs of the individual patient to assure symptomatic control with a minimum of adverse reactions. The presently recommended maximum daily dosage of Glycopyrrolate is 8 mg.

- Robinul (Glycopyrrolate, 1 mg) tablets. The recommended initial dosage of Robinul for adults is one tablet three times daily (in the morning, early afternoon, and at bedtime). Some patients may require two tablets at bedtime to assure overnight control of symptoms . For maintenance, a dosage of one tablet twice a day is frequently adequate.

- Robinul Forte (Glycopyrrolate, 2 mg) tablets. The recommended dosage of Robinul Forte for adults is one tablet two or three times daily at equally spaced intervals.

- Robinul tablets are not recommended for use in pediatric patients under the age of 12 years.

The proposed oral film would provide for ease of administration for those patients that have difficulty in swallowing conventional tablets, or may have dysphagia. The product could also be taken without water, which may also provide patients greater ease or convenience over traditional tablets. Further Oral films provide additional advantages over tablets as no risk of chocking, better Taste masking, improved patient compliance.

There are no proposed changes in labelling with the exception of the obvious changes in dosage form sought in this petition, which would encompass directions of use of the oral film. Such a label change is permitted in accordance with the regulations based on an approval of an ANDA suitability petition for a permitted change. The uses, indications, warnings and directions for use will remain the same as that of the RLD. Draft labelling for the proposed product is included in Attachment 3, the RLD's approved labelling is provided in Attachment 4 and the RS's approved labelling is provided in Attachment 5.

Therefore, the petitioner's request for the Commissioner to find that a change in dosage form from an oral film should raise no questions of safety or effectiveness, and the Agency should approve the petition.

Pediatric Waiver Request

In September 2007, Congress reauthorized the Pediatric Research Equity Act of 2003 (PREA) that amended the Federal Food, Drug, and Cosmetic Act to provide the Agency authority to require drug firms to study drugs in pediatric patients, if the Agency concludes that such study would provide beneficial health data for that patient population . The Act specifically requires that a request for a new dosage form is subject to a pediatric evaluation. The act also provides for a waiver from such requirement if the drug :
(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients ; and
(II) is not likely to be used in a substantial number of pediatric patients.

The proposed product will contain labelling that permits dosing for all ages of pediatric patients for whom the drug is indicated (down to 12 years of age). While the RLD labelling contains information stating that "Since there is no adequate experience in pediatric patients who have received this drug, safety and efficacy in pediatric patients have not been established. " However, since this product is indicated for peptic ulcer and since peptic ulcer is rarely seen in patients younger than their second decade of life, and because there are other products available for the treatment of this condition in younger patients, Glycopyrrolate is not likely to be used in a substantial number of pediatric patients. Based on this information, it is believed that it is not likely that this product would , nor should be used in a younger age group than described in the labelling.

The petitioner hereby requests that a full waiver from the conduct of pediatric studies be granted for this petition to permit a subsequent ANDA filing, as the proposed drug product, an oral film dosage form, containing 1 mg, 1.5 mg, or 2 mg of Glycopyrrolate, is not likely to be used in a substantial number of pediatric patients.

C. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR 25.31 from the requirement to submit an environmental assessment.

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D. Economic Impact Statement

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.

Sincerely,

Michael Eastep
Director Project Management & US Representative

Attachments:

1. Approved Drug Products with Therapeutic Equivalence Evaluations of RLD, Electronic Orange Book listing, accessed Sep 19, 2020
2. Approved Drug Products with Therapeutic Equivalence Evaluations of RS, Electronic Orange Book listing, accessed Sep 19, 2020
3. Draft insert labelling for proposed product
4. Approved labelling for reference-listed drug, Robinul and Robinul Forte (Glycopyrrolate) Tablets by Casper.
5. Approved labelling for reference standard Glycopyrrolate Tablets 1 mg and 2 mg by Par Pharmaceutical Inc(ANDA 040653)

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