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1254 '06 JUL 28 P1:57

July 27, 2006

OVERNIGHT COURIER 07/27/06

Division of Dockets Management
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Citizen Petition

Dear Sir or Madam:

The undersigned submits this petition, in quadruplicate, pursuant to Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act, and in accordance with 21 CFR 10.30 on behalf of a client requesting the Commissioner of the Food and Drug Administration to declare that the drug product, Glycopyrrolate Tablets, USP 1.5 mg, is suitable for consideration in an abbreviated new drug application (ANDA).

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration declare that Glycopyrrolate Tablets, 1.5 mg, is suitable for submission as an ANDA. The listed reference drug product (RLD), upon which this petition is based, is Robinul® Forte (glycopyrrolate) Tablets, USP 2 mg, NDA 12-827 held by Sciele Pharmaceuticals. The petitioner also references Robinul® Tablets, 1 mg, in support of this petition. Therefore, the petitioner seeks a change in strength (from 2 mg to 1.5 mg) from that of the listed drug product.

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 strength from that of the listed drug provided the FDA has approved a petition that proposed filing such an application.

The RLD, Robinul® Forte Tablets by Sciele, Inc. is a tablet product containing 2 mg of Glycopyrrolate. See copy of the page from the current Electronic Edition of the *Approved Drug Products with Therapeutic Equivalence Evaluations* (Attachment 1). The proposed drug product also represents a tablet dosage form, but containing 1.5 mg of Glycopyrrolate. The petition is thus seeking a change in strength (from 2 mg to 1.5 mg) from that of the RLD. Please note that the proposed change in strength represents a dosage strength midway between the two currently approved 1 mg and 2 mg strengths of Glycopyrrolate.

The acceptability of the proposed 1.5 mg strength is contemplated in the labeling of the listed drug. The current dosing instructions in the approved labeling of the RLD are as follows:

> "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."
>
> The recommended initial dose of the 1 mg product "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."
>
> For the 2 mg product: "[T]he recommended dosage of Robinul® Forte for adults is one tablet two or three times daily at equally spaced intervals."

A 1.5 mg tablet would permit administration of an intermediate dose for those patients that may require greater than 1 mg, but less than 2 mg for relief of symptoms. Because this drug product is not without the potential for significant adverse reactions, the intermediate strength product would also give the health care practitioner greater flexibility in selecting the most appropriate dose for the patient while minimizing potential adverse events.

There are no proposed changes in labeling with the exception of the obvious changes in strength sought in this petition. The uses, indications, warnings and directions for use will remain the same as that of the RLD. Draft labeling for the proposed product is included in Attachment 2, and the RLD's approved labeling is provided in Attachment 3.

Therefore, the petitioner's request for the Commissioner to find that a change in strength from 2 mg to 1.5 mg, for Glycopyrrolate Tablets, USP 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.

Respectfully submitted,

Robert Pollock

Robert W. Pollock
Senior Vice President

RWP/pk

Attachments:
1. Approved Drug Products with Therapeutic Equivalence Evaluations, accessed 7/27/06
2. Draft Insert Labeling Proposed for Glycopyrrolate Tablets
3. Labeling for Robinul® Forte

cc: Leo Zadecky (OGD)

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