LACHMAN CONSULTANT SERVICES, INC.
CONSULTANTS TO THE PHARMACEUTICAL AND ALLIED INDUSTRIES

1600 STEWART AVENUE
WESTBURY, NY 11590
(516) 222-6222 • FAX (516) 683-1887

March 16, 2001

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OVERNIGHT COURIER 3/16/01

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

RE: Docket Number 01P-0081/CP 1

Dear Sir or Madam:

Reference is made to docket number 01P-0081/CP 1, the citizen petition to declare that the drug product Midodrine Hydrochloride Tablets, 10 mg, is suitable for consideration in an ANDA. In the first sentence of the second paragraph of that original petition, it is noted that a typographical error was made regarding the proposed dosage strength under consideration. Specifically, we would like to correct the dosage strength in that sentence from "15 mg" to "10 mg", and have attached a replacement page reflecting the indicated correction.

Please accept the attached revised copy of the first page of the letter dated February 16, 2001, submitted in quadruplicate, as a replacement page for the one originally submitted.

Respectfully submitted,

Robert Pollock

Robert W. Pollock
Vice President
Lachman Consultant Services, Inc.
1600 Stewart Avenue, Suite 604
Westbury, NY 11590

RP/cc

Attachment: Replacement page dated February 16, 2001 for citizen petition regarding Midodrine Hydrochloride Tablets, 10 mg (Docket 01P-0081/CP 1).

cc: G. Davis (OGD), L. Lachman

84p1075

01P-0081

CR1

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February 16, 2001

OVERNIGHT COURIER 2/16/01

Dockets Management Branch
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 Midodrine Hydrochloride Tablets, 10 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 make a determination that Midodrine Hydrochloride Tablets, 10 mg is suitable for submission as an ANDA. The reference listed drug (RLD) product upon which this petition is based is ProAmatine® Tablets 2.5 mg and 5 mg, (see Attachment I, page 3-236 of the Approved Drug Products with Therapeutic Equivalence Evaluations, 20th Edition, "The Orange Book"). Therefore, the petitioner seeks a change in strength (from 2.5 mg and 5 mg tablets to include a 10 mg tablet) 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 new drug that differs in strength from a listed drug provided the FDA has approved a petition that proposed the filing of such an application. This petition involves a change in strength for the proposed drug from that of the listed drug. The RLD on which this petition is based is ProAmatine® Tablets manufactured by Nycomed Austria Gmbh for Roberts Laboratories, Inc. The RLD is marketed as a tablet dosage form containing 2.5 mg or 5 mg of midodrine hydrochloride. The proposed drug product represents the same dosage form and route of administration as the RLD, and differs only in strength (10 mg of midodrine hydrochloride).

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