CARACO
PHARMACEUTICAL
LABORATORIES, LTD.

December 13, 2006

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

CITIZEN PETITION

Caraco Pharmaceutical Laboratories, Ltd (Caraco) submits this petition under Section 505 (j)(2)(c) of the Federal Food, Drug and Cosmetic Act, 21 CFR § 314.93 and in accordance with the procedural requirements set forth in 21 CFR § 10.30 to request the Commissioner of Food and Drugs to make a determination whether the Reference Listed Drug, Hydrochlorothiazide Tablets USP, 100 mg, the subject of ANDA 85-022, held by IVAX Pharmaceuticals Inc., was voluntarily discontinued from sale in the United States of America for reasons other than safety or effectiveness.

ACTION REQUESTED

Caraco Pharmaceutical Laboratories seeks a determination that the Reference Listed Drug, Hydrochlorothiazide Tablets USP, 100 mg, the subject of ANDA 85-022, held by IVAX Pharmaceuticals Inc., was voluntarily discontinued from sale in the United States of America for reasons other than safety or effectiveness.

STATEMENT OF GROUNDS

Caraco intends to submit an Abbreviated New Drug Application (ANDA) for the drug product, Hydrochlorothiazide Tablets USP, 12.5 mg. Per the CDER Office of Generic Drugs the "Basis of Submission" for the proposed ANDA must refer to the now discontinued RLD, Hydrochlorothiazide Tablets USP, 100 mg, the subject of ANDA 85-022, held by IVAX Pharmaceuticals Inc. Per the current "Electronic Orange Book", ANDA 85-002 was approved prior to January 1, 1982.

A citizen petition from Lachman Consultant Services (Docket 2005-0060/CP1) was approved April 8, 2005 for filing an ANDA for Hydrochlorothiazide Tablets, USP, 12.5 mg based on Hydrochlorothiazide Tablets USP, 100 mg from IVAX (ANDA 85-022). A FOI copy of the citizen petition approval letter is included here as an **Attachment**.

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According to the Code of Federal Regulations, when an ANDA makes reference to a discontinued label of a drug, FDA may still approve the ANDA upon determination that the formulation was riot withdrawn for reasons of safety or effectiveness (21 U.S.C. Section 355 (j)(6) and 21 CFR §§ 314.122 and 314.161).

Caraco is not aware of any documentation that establishes that the original formulation of the Hydrochlorothiazide Tablets USP, 100 mg from IVAX was discontinued for safety or efficacy reasons.

ENVIRONMENTAL IMPACT

Pursuant to 21 C.F.R. § 25.31(a), this petition qualifies for a categorical exclusion from the requirement for submission of an environmental assessment.

ECONOMIC IMPACT

According to 21 CFR § 10.30 (b), information on economic impact is to be submitted only when requested by the Commissioner following review of this petition.

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,

Derrick Mann
Director, Regulatory Affairs
Caraco Pharmaceutical Laboratories, Ltd.