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January 29, 2007

OVERNIGHT COURIER 1/29/07

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

Re: Docket #2006P-0510
Correction

Citizen Petition Correction

Dear Sir or Madam:

The undersigned submitted the above referenced petition in quadruplicate, on December 12, 2006 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 Propoxyphene Hydrochloride, 65 mg and Acetaminophen, 325 mg Tablets is suitable for consideration in an abbreviated new drug application (ANDA). We noticed that there was an inadvertent typographical error on the strength of the Reference-Listed Drug (RLD) cited in the Action Requested section of the petition. The RLD strength was incorrectly cited as 65 mg / 325 mg and should have been 65 mg / 650 mg. The revised Action Requested section is provided below for your convenience.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration declare that a Propoxyphene Hydrochloride, 65 mg and Acetaminophen, 325 mg Tablet is suitable for submission as an ANDA. The reference-listed drug product (RLD), upon which this petition is based, is Wygesic® (Propoxyphene Hydrochloride and Acetaminophen), 65 mg / **650** mg Tablets, ANDA 84-999, currently held by Leitner Pharmaceuticals as designated in the Orange Book. Therefore, the petitioner seeks a change in strength of the Acetaminophen component (from 650 mg to 325 mg) from that of the listed drug product.

We apologize for any inconvenience this may have caused.

Respectfully submitted,

Robert Pollock

Robert W. Pollock
Senior Vice President

RWP/pk

cc: C. Kiester, OGD

A43P7029

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