



NDA 11-145/S-093

NDA 11-870/S-037

Merck & Co., Inc.
Attention: Mr. Kenneth A. Kramer
Sumneytown Pike
P.O. Box 4, BLA-20
West Point, PA 19486

Dear Mr. Kramer:

Please refer to your electronic supplemental new drug applications dated June 30, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

NDA 11-145/S-093 Diuril™ (chlorothiazide) 250 & 500 mg Tablets
NDA 11-870/S-037 Diuril™ (chlorothiazide) 250 mg/ 5 mL Suspension

We acknowledge receipt of your submissions dated January 7 and May 25, 2005. Your submissions of May 25, 2005 constituted a complete response to our November 29, 2004 action letter.

These supplemental new drug applications provide for final printed labeling (FPL) deleting all references to the tablet formulation throughout the package insert, adding the liquid volumes that correspond to the adult dosages described in the DOSAGE AND ADMINISTRATION section, and including a Geriatric Use subsection under PRECAUTIONS (approved in supplemental NDA 11-145/S-090 and 11-870/S-036 on September 2004).

We have completed our review of these electronic supplemental new drug applications, as amended, and they are approved, effective on the date of this letter, for use as recommended in the FPL submitted on May 25, 2005.

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

NDA 11-145/S-093

NDA 11-870/S-037

Page 2

If you have any questions, please call:

Mr. Daryl Allis
Regulatory Health Project Manager
301-594-5332

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Acting Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Norman Stockbridge
8/10/05 06:52:59 AM