Dear Dr. Enas:

Please refer to your supplemental new drug application dated December 18, 1998, received December 21, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Humulin® 70/30 (70% human insulin isophane suspension and 30% human insulin injection, [rDNA origin]).

This “Changes Being Effected” supplemental new drug application provides for new insulin vial label bearing a bar code which makes an audible announcement when used with a device (b)-------------------------------------------------------. The barcode is to aid sight-impaired patients with diabetes in identifying their insulin.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) for immediate container submitted on December 18, 1998.

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, HF-2
    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.
If you have any questions, call Julie Rhee, Regulatory Project Manager, at (301) 827-6424.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
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/

---------------------
David Orloff
11/1/02 05:11:56 PM