DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-750/S-018

Organon Inc.
Attention: Maria I. Penaherrera
Regulatory Associate, Regulatory Affairs Department
375 Mt. Pleasant Avenue
West Orange, NJ 07052

Dear Ms. Penaherrera:

Please refer to your supplemental new drug application dated August 21, 2002, received August 22, 2002, submitted under 505(b) of the Federal Food, Drug, and Cosmetic Act for Cortrosyn® (cosyntropin) for Injection.

This supplemental new drug application provides to market this product without the saline diluent, and for labeling changes to the **DESCRIPTION, PRECAUTIONS, DOSAGE AND ADMINISTRATION,** and **HOW SUPPLIED** sections of the package insert. In addition, changes to the carton and vial labels have also been proposed.

We acknowledge receipt of your submission dated September 26, 2002.

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in draft labeling text.

The final printed labeling (FPL) must be identical to the draft labeling for the package insert, immediate container and carton labels submitted on August 21, 2002.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavyweight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 16-750/S-018." Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Ms. Jena Weber, Regulatory Project Manager, at 301-827-6422.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation ODE 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

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