DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 021-108/S001

Johnson & Johnson Consumer Companies, Inc.
Attention: Kathleen Wille, Ph.D.
Manager, Regulatory Affairs
199 Grandview Avenue
Skillman, New Jersey 08558-9418

Dear Dr. Wille:

Please refer to your supplemental new drug application S001 dated September 6, 2000, received September 7, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Renova (tretinoin cream) Cream, 0.02%.

We also acknowledge receipt of correspondence dated November 27, 2000, March 13, and December 6, 2001.

This supplemental new drug application provides for a modification of the numbers in the ADVERSE REACTIONS section.

We have completed the review of this supplemental application, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, this supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling text. Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Provide Regulatory Submissions in Electronic Format – NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submission should be designated "FPL for approved supplement NDA 21-108/S001".

Approval of this submission by the FDA is not required before the labeling is used.
If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, 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 Kalyani Bhatt, Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic and Dental Drug Products,
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure