DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 18 1998

TRANSMITTED VIA FACSIMILE

Lewis Gryziewicz
Manager, Regulatory Affairs
Johnson & Johnson Consumer Companies, Inc.
199 Grandview Road
Skillman, NJ 08558-9418

RE: NDA 19-963
Renova (tretinoin emollient cream) 0.05%
Macmis # 6960

Dear Mr. Gryziewicz:

This letter is in reference to Johnson & Johnson Consumer Companies, Inc.'s (J&J) July 8,1998, submission under cover of FDA Form-2253 for Renova (tretinoin emollient cream) 0.05% to the Division of Drug Marketing, Advertising, and Communications' (DDMAC). As part of DDMAC's routine monitoring of prescription drug advertising, DDMAC has reviewed a Renova advertisement identified as DD2977, and has determined that it is in violation of the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

- J&J has identified this material as a reminder advertisement. Reminder advertisements may disclose the name of the product but may not include written, printed, or graphic matter that contains any representation or suggestion relating to the advertised drug product. However, the combination of the graphic of a woman sunning herself on the beach, the statement "Because she didn't know then," and the product name, in juxtaposition with the request to "Visit us at www.wrinklereport.com" make a representation about the use of Renova, making it a full product advertisement. Thus, as a full product advertisement, it is lacking in fair balance because it fails to present any information associated with Renova's use relating to side effects and contraindications of the drug with a prominence and readability reasonably comparable with the presentation of information relating to effectiveness of the drug.

- Moreover, the approved product labeling for Renova specifically states that Renova does not repair sun damaged skin. However, this advertisement, through J&J's choice of graphic (a woman on the beach) promotes Renova for repairing sun damaged skin, an unapproved use.

DDMAC requests that J&J take the following actions:

1. Immediately discontinue the use of this and all other promotional materials for Renova that contain the same or similar violations.

2. Provide to DDMAC, in writing, J&J's intent to comply with #1 above. Your response should be received by September 1, 1998.

J&J should direct its response to the undersigned by facsimile (301) 594-6771, or by written communication at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, 5600 Fishers Lane, HFD-40, Rm. 17B-20, Rockville, MD 20857.

In all future correspondence regarding this matter, please refer to MACMIS ID 6960, in addition to the NDA number.

Sincerely,

/S/

Jean E. Raymond, P.A.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications