DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

JUL 23 1998

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 # 6859

Dear Mr. Gryziewicz:

This letter is in reference to Johnson & Johnson Consumer Companies, Inc.'s (J&J) August 2, 1997, and April 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 print advertisements identified as DD2786 and DD2869, and has determined that they are in violation of the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

Specifically,

- The headings, "Wrinkles?" and "Wrinkles and Fine Lines" are misleading because they are inconsistent with the approved product labeling. For example, the labeling for Renova states that this product is indicated as an adjunctive agent for the use in the mitigation of "fine wrinkles". The unqualified use of the term "wrinkles" implies a greater efficacy for Renova than is indicated.

- The claim that "Renova is unlike any other anti-aging or anti-wrinkle cream. It is a prescription cream that is proven to work" is misleading because it suggests a better outcome for Renova than for other products, in the absence of adequate and well-controlled clinical trials to support the claim. In addition, the claim is misleading because it implies that Renova has proven anti-aging and anti-wrinkling properties. This implication is contrary to the approved product labeling.

- The advertisements are misleading because they fail to adequately describe the approved indication for Renova. Specifically, they fail to adequately disclose:

- the components of the comprehensive skin care and sun avoidance program;
- that Renova is only indicated in patients who do not achieve palliation using comprehensive skin care and sun avoidance programs alone;
- that Renova is only indicated as an adjunctive agent.

- The claim, "Unlike over-the-counter wrinkle creams which simply exfoliate the surface layer of your skin, Renova works deep at the cellular level" is misleading because it suggests superiority to over-the-counter creams without substantial evidence. Furthermore, the statement that Renova works at the cellular level is not supported by substantial evidence. The exact mechanism and site of action for Renova are unknown. J&J has been notified by DDMAC in previous correspondences that these claims would be misleading.

- In the April 8, 1998 submission, the photographic presentations and captions are misleading because they fail to prominently disclose that not all patients achieve this level of improvement. For example, the disclaimer is presented in a footnote at the bottom of the page beneath the logo rather than in association with the photograph it modifies.

- The print advertisements would be misleading because they fail to disclose that a majority of patients will lose most mitigating effects of Renova on fine wrinkles, hyperpigmentation, and tactile roughness of facial skin with discontinuation of a comprehensive skin care and sun avoidance program including Renova.

DDMAC requests that J&J take the following actions:

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

2. Provide to DDMAC, in writing, J&J's intent to comply with #1 above. Your response should be received by August 6, 1998.

If J&J has any questions or comments, please contact 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 the MACMIS ID 6859, in addition to the NDA number.

Sincerely,

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