DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-921 S021/022/025
NDA 17-340 S032/033/036
NDA 17-522 S022/023/026
NDA 17-579 S018/020/023
NDA 17-955 S019/020/023
NDA 19-049 S007/008/011

Johnson & Johnson Consumer Companies, Inc.
Attention: Stephanie Davis
Manager, Regulatory Affairs
199 Grandview Avenue
Skillman, New Jersey 08558-9418

Dear Ms. Davis:

Please refer to the following supplemental new drug applications dated December 1, 1995 and received December 4, 1995:

NDA 16-921/S021, NDA 17-340/S032, NDA 17-522/S022, NDA 17-579/S018, NDA 17-955/S019 and NDA 19-049/S007; supplemental drug applications dated January 7, 1997 and received January 8, 1997:

NDA 16-921/S022, NDA 17-340/S033, NDA 17-522/S023, NDA 17-579/S020, NDA 17-955/S020 and NDA 19049/S008, and supplemental drug applications dated August 10, 2000 and received August 11, 2000:

NDA 16-921/S025, NDA 17-340/S036, NDA 17-522/S026, NDA 17-579/S023, NDA 17-955/S023 and NDA 19-049/S011 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Retin-A (tretinoin) Liquid, Retin-A (tretinoin) Cream, 0.1%, Retin-A (tretinoin) Cream, 0.05%, Retin-A (tretinoin) Gel, 0.025%, Retin-A (tretinoin) Gel, 0.01%, and Retin-A (tretinoin) Cream, 0.025%.

We also acknowledge receipt of correspondence dated May 3 and 14, and July 27, 2001; and February 12, and June 3 and 4, 2002, to NDA 16-921/S022, NDA 17-340/S033, NDA 17-522/S023, NDA 17579/S019, NDA 17955/S020, and NDA 19-049/S008.

In addition, we acknowledge receipt of correspondence dated June 3 and 4, 2002 to NDA 16-921/S021, NDA 17-340/S032, NDA 17-522/S022, NDA 17-579/S018, NDA 17-955/S019 and NDA 19-049/S007.

These supplemental new drug applications provide for a combined labeling for all Retin-A products, with the addition of a **WARNINGS** section in the package insert, as well as on the carton and container, that Retin-A Gels are flammable; and the addition of **"Pediatric Use"** and **"Geriatric Use"** subsection to the **PRECAUTIONS** Section in accordance with 21 CFR 201.57 (f)(9)(v) and 201.57(f)(10) respectively.

We have completed the review of these supplemental applications, 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, these supplemental applications are 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 supplements:

NDA 16-921/S021/022/025
NDA 17-340/S032/033/036
NDA 17-522/S022/023/026
NDA 17-579/S018/020/023
NDA 17-955/S019/020/023
NDA 19-049/S007/008/011".

Approval of these submissions 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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Markham Luke
6/10/02 11:40:52 AM
Acting for Dr. Jonathan Wilkin, Division Director, DDDDP