



TRANSMITTED BY FACSIMILE

George Latyszonek  
Director, Regulatory Affairs  
Johnson & Johnson Consumer Companies, Inc.  
199 Grandview Road  
Skillman, NJ 08558-9418

**RE: NDA 20-475**  
Retin-A Micro (tretinoin gel) microsphere, 0.1%  
MACMIS ID# 11125

Dear Mr. Latyszonek:

This letter objects to Johnson & Johnson Consumer Companies, Inc. (J&J) dissemination of promotional materials for Retin-A Micro (tretinoin gel) microsphere, 0.1% that are in violation of the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations. Specifically, as part of its routine monitoring program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has identified a 30-second direct-to-consumer (DTC) television broadcast advertisement (TV Ad) for Retin-A Micro entitled "Possible" that is misleading.

The TV ad fails to clearly communicate and minimizes the risk associated with the use of the product, while simultaneously overstating the efficacy of the product. The juxtaposition of these misleading claims results in an advertisement that dramatically misrepresents who should consider using the product and what they can realistically expect might result from use of this product. We are particularly concerned because this misleading advertisement targets adolescents.

Failure to Clearly Communicate Risk Information

The graphic and audio presentation of the TV ad fails to clearly communicate the following important risk information associated with Retin-A Micro treatment. The approved patient package insert (PPI) states, "The most common side effect with Retin-A Micro is skin irritation. This can include skin redness, burning, stinging, itching, dryness, and peeling. Some of these side effects may go away or bother you less after you have used Retin-A Micro for a few weeks." Furthermore, the PPI states, "Spend as little time as possible in the sun. Use a daily sunscreen with a SPF 15 rating or higher, sun protective clothing, and a wide brimmed hat to protect you from sunlight."

Specifically, the sequence involving the presentation of the most important risk information features two cheerful and happy teenagers who do not appear to be experiencing any skin irritation (i.e., redness, dryness, and peeling) from Retin-A Micro treatment. They are trying on earrings and using a camera with a flash to photograph each other. This sequence involves numerous scene changes and quick camera movements. Concurrently, subtitled SUPERS ("See our Ad in Teen People, Sunscreen is

recommended, and 1-877-72-MICRO”) appear in white lettering against a light-colored background as the risk information is being spoken in the audio at a fast pace, with poor audibility and articulation over competing music. Consequently, the totality of the poor clarity of the audio, the competing music, the poor contrast given to the SUPERS, the quick camera movements, and the distracting camera flashes interferes with and indeed undermines comprehension of the most important risk information. Therefore, the critical information describing the risks associated with Retin-A Micro therapy and precautionary measures a patient should take to minimize such risks are not adequately communicated. The totality of this misleading presentation suggests that Retin-A Micro is safer than has been demonstrated by substantial evidence or substantial clinical experience.

#### Minimization of Risk

In addition, during the audio presentation you claim, “Dryness, redness, or peeling may initially occur.” However, the claim lacks context from the PPI that these side effects may actually persist for several weeks. The PPI states, “Some of these side effects may go away or bother you less after you have used Retin-A Micro for a few weeks.” Therefore, the claim that these bothersome side effects may occur initially is misleading because “initially” does not adequately convey that consumers may experience irritation for at least several weeks.

#### Overstatement of Efficacy

The TV ad makes the following claims:

- “Clearer skin in two weeks?”
- “Clearer skin in 2 weeks is possible – with Retin-A Micro.”

The audio presentation of these claims in the TV ad is such that the articulation of the qualifying word “clearer” consistently sounds like “clear.” This presentation is misleading because it overstates the efficacy of Retin-A Micro by seeming to guarantee “clear skin.” This impression is reinforced by the visual image of teenaged girls with no apparent facial acne. This presentation is inconsistent with the approved product labeling (PI) for Retin-A Micro which describes a 45% and 32% mean percent reduction in total lesion counts compared to 23% and 16%, respectively, for Retin-A Micro and the vehicle gel.

#### Requested Action

J&J should immediately cease distribution of this broadcast ad, and all other promotional materials for Retin-A Micro that contain the same or similar claims or presentations. Please submit a written response to DDMAC, on or before December 17, 2002, describing your intent and plans to comply with the above. In its letter to DDMAC, J&J should include a list of promotional materials that were discontinued, and the discontinuation date.

J&J should direct its response to the undersigned by facsimile at 301-594-6771, or by written communication at the Division of Drug Marketing, Advertising and Communications, HFD-42, Room 8B-45, 5600 Fishers Lane, Rockville, MD 20857.

George Latyszonek  
Johnson & Johnson Consumer Companies, Inc.  
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DDMAC reminds you that only written communications are considered official. In all future correspondence regarding this particular matter, please refer to MACMIS ID# 11125 in addition to the NDA number.

Sincerely,

*{See appended electronic signature page}*

Rebecca Williams, Pharm.D.  
Regulatory Review Officer  
Division of Drug Marketing,  
Advertising, and Communications

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

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Rebecca Williams  
12/3/02 08:57:33 AM

CLIENT: [ ]  
 PRODUCT: Retin-A Micro  
 TITLE: Possible :30  
 DATE: 07/29/02



JESSICA: Clearer skin in 2 weeks? It's possible with



RETIN-A MICRO® It can start clearing up skin

SUPER: Oil Free Prescription only



in just 2 weeks

SUPER: 1-877-72-MICRO



With full results

SUPER: 1-877-72-MICRO



after 7

SUPER: 1-877-72-MICRO



RETIN-A MICRO®

SUPER: 1-877-72-MICRO



is the prescription acne

SUPER: 1-877-72-MICRO



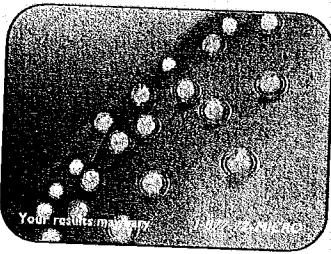
treatment you get from a

SUPER: 1-877-72-MICRO



doctor.

SUPER: 1-877-72-MICRO



It's the only one with microspheres packed with the medicine prescribed #1

SUPER: Your results may vary 1-877-72-MICRO



by dermatologists.

SUPER: See our ad in Teen People 1-877-72-MICRO



Dryness, redness or peeling may initially occur.

SUPER: See our ad in Teen People 1-877-72-MICRO



To prevent aggravating the skin, protect it from

SUPER: Sunscreen is recommended 1-877-72-MICRO



sun, tanning lights, extreme wind or cold.

SUPER: Sunscreen is recommended 1-877-72-MICRO



and harsh skincare products.

SUPER: Sunscreen is recommended 1-877-72-MICRO



So, see a dermatologist.

*SUPER: retinamicro.com*



Clearer skin

*SUPER: retinamicro.com*



in 2 weeks is possible --

*SUPER: retinamicro.com*



with RETIN-A MICRO®.

*SUPER: retinamicro.com*