



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT  
850 THIRD AVENUE  
BROOKLYN, NEW YORK 11232-1593

CABLE ADDRESS: NYFOODRUG

REGULATORY LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

SEP. 26 1988

Mr. Ronald Perelman, President  
Revlon, Inc.  
767 Fifth Avenue  
New York, NY 10153

Ref: 57-NYK-88

Dear Mr. Perelman:

This letter is in reference to "AGE - LESS ANTI-AGING DAILY FACE CAPSULES" and any other of your products that bear similar or related labeling statements. A review of this product labeling reveals what the Food and Drug Administration believes are drug claims.

The product is described in its labeling, which includes but is not limited to packaging, package insert, containers, and accompanying promotional brochures. This labeling bears statements such as the following:

"AGE - LESS ANTI-AGING DAILY FACE CAPSULES" ... "HELPS PREVENT THE VISIBLE SIGNS OF AGING. Your skin starts aging from the very first day it's exposed to the environment. But this skin aging can be controlled. AGE - LESS is a highly effective protective complex. It filters out damaging UV light rays, ... THE 'PILL' OF THE 90's...".

In summary, the aforementioned claims represent and suggest that the article is intended to affect the structure and function of the human body and that the product is adequate and effective for such uses as preventing the visible signs of aging, controlling skin aging, as an anti-aging 'pill', and other claims. Because of such claims, the product is regarded as a drug as defined in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (Act). Also, we are unaware of any substantial scientific evidence that demonstrates the safety and effectiveness of this article for its intended uses, nor are we aware that this drug is generally recognized as safe and effective for its intended uses. Therefore, the product is a new drug within the meaning of Section 201(p) of the Act. In conclusion, we regard the Revlon, Inc. product to be in serious violation of the Act as follows:

SECTION

BRIEF DESCRIPTION

- 505(a) The article "AGE - LESS ANTI-AGING DAILY FACE CAPSULES" is a new drug within the meaning of Section 201(p) of the Act, and no approval of an application filed pursuant to Section 505(b) is effective for such drug.
- 502(f)(1) The article is misbranded in that its labeling fails to bear adequate directions for use.

The agency has not reviewed your entire product line; therefore, the violative product described above is not all inclusive. It is your responsibility to ensure that all of your products are the subject of approved new drug applications as appropriate and that the products are properly labeled for their intended uses.

We request that you take prompt action to correct these violations. If such action is not taken, the Food and Drug Administration is prepared to take appropriate regulatory sanctions such as seizure or injunction (21 U.S.C. 332 and 334). Please advise us within ten (10) days as to the specific actions you have taken or intend to take, including measures to prevent the recurrence of the violations, and an explanation of any potential delays in correcting the violations that may occur. Your reply should be directed to Mr. Ira Flaum, Compliance Officer, at the above address.

Sincerely yours,

  
JOSEPH J. FALINE  
District Director  
Food and Drug Administration

JJF:IF:af

- cc: HFR-NE1 w/cc approval memo
- cc: HFR-NE100 (2) w/cc approval memo
- cc: HFR-NE140
- cc: HFR-NE150 w/cc approval memo
- cc: HFR-NE1500 w/cc approval memo
- cc: HFD-304 (Health Fraud Staff)
- cc: HFI-35
- cc: HFA-224
- cc: EF (Revlon, Inc.)
- cc: Legal File w/orig. approval memo
- cc: circ./chrono
- cc: IF