



U.S. FOOD AND DRUG ADMINISTRATION

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

D1108B

Telephone: [718] 965-5300 [Ext 5301]

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

JAN 10 1997

Olga G. Cohen, President
Olga G. Marcus Cosmetics Inc.
345 Oser Avenue
Hauppauge, NY 11787

re: 30-NYK-97

Dear Ms. Cohen:

On October 24 and November 6, 1996 an FDA investigator from this office inspected your firm and collected labeling and records pertaining to "Rubie's Star Quality Glow Cream Makeup" which your firm manufacture

Our review of the labeling for and laboratory analysis of the "Rubie's Star Quality Glow Cream Makeup" and investigation reveals that the product contains zinc sulfide. The product is a cosmetic as defined at Section 201(l) of the Food, Drug And Cosmetic Act (the Act). The zinc sulfide is a color additive as defined in Section 201(t) of the Act. Since there is no color additive regulation allowing for the use of zinc sulfide as a colorant in cosmetic products, the glow cream makeup is adulterated under Section 601(e) of the Act. (That is, it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of Section 721(a) of the Act).

You should take prompt action to correct this deviation. Failure to promptly correct this deviation may result in regulatory action without further notice, such as seizure.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken or intend to take to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations and a timetable for correction.

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Your reply should be sent to the Food and Drug Administration, New York District Office, at the above address, Attention: William Friedrich, Compliance Officer.

Sincerely yours,



David Field
Acting District Director
New York District

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O: addressee
cc: HFR-NE1
cc: HFS-105 (Attn.: Allen R. Halper)
cc: HFS-607
cc: HFA-224
cc: HFI-35 (purged) *WJ Friedrich*
cc: HFC-210/DCMO(CFN 2437296)
cc: HFR-NE1
cc: HFR-NE100
cc: HFR-NE140
cc: HFR-NE150
cc: HFR-NE1500(Vitillo/Mooney)
cc: Warning letter file
cc: EP-~~XXXXXXXXXXXXXXXXXXXX~~ Olga G. Marcus Cosmetics, Inc.)
cc: circ/chrono
cc: Wf_{olgaqm.itr}