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DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEI: 3004531356

Food and Drug Administration
Baltimore District Office
6000 Metro Drive, Suite 101
Baltimore, MD 21215-3215
Telephone: (410) 779-5454

WARNING LETTER
04-BLT-21

May 10, 2004

CERTIFIED MAIL
RETURN RECEIPT REQEUSTED

Mr. Moonchan Park
Beauty Supply d/b/a Beauty World
6433 Marlboro Pike
District Heights, MD 20747

Dear Mr. Park:

On April 27, 2004, an investigator from the United States Food and Drug Administration (FDA) purchased plano (i.e., noncorrective) tinted contact lenses from your facility at 6433 Marlboro Pike, District Heights, Maryland 20747. After purchasing the lenses, the investigator conducted an inspection of your facility. Based upon this purchase and inspection, the investigator determined that your firm distributes plano tinted contact lenses directly to consumers without requiring any evidence of proper fitting or other eye care professional involvement. Moreover, our investigator determined that your lenses are distributed without labeling describing the risks associated with the wearing of such lenses. We have therefore determined that your contact lenses violate the Federal Food, Drug, and Cosmetic Act (the Act).

If your firm's contact lenses are intended solely to change the appearance of the normal eye in decorative fashion, they are cosmetics within the meaning of Section 201(i) of the Act [21 U.S.C. 321(i)]. Your distribution of these lenses without the involvement of a qualified eye care professional causes them to be adulterated under Section 601(a) [21 U.S.C. 361(a)]. That section provides that a cosmetic shall be deemed to be adulterated "if it bears or contains a poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or, under such conditions of use as are customary or usual." If your lenses are cosmetics, they are also misbranded under Section 602(a) [21 U.S.C. 362(a)], because their labeling fails to reveal material facts regarding the consequences that may result from use of the lenses under the labeled, customary, or usual conditions of use.

If you are marketing your contact lenses, in the manner described above, with claims that cause them to be devices within the meaning of Section 201(h) [21 U.S.C. 321(h)], then they are misbranded devices under Section 502(f)(1) [21 U.S.C. 352(f)(1)] because their labeling does not bear adequate directions

for use. If your contact lenses are devices, they are also misbranded under Section 502(a) [21 U.S.C. 352(a)] because, as noted, their labeling fails to reveal material facts regarding the consequences that may result from use of the lenses under the labeled, customary, or usual conditions of use.

This letter is not intended to identify all violations of the Act that apply to the marketing of your plano tinted contact lenses. Please refer to www.fda.gov for additional information regarding statutory requirements for marketing cosmetics and devices. It is your firm's responsibility to ensure that your plano tinted contact lenses are in compliance with the Act and FDA regulations.

You should take prompt action to correct these violations. Failure to do so may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or injunction.

We request that your firm respond to this letter within 15 working days of receipt describing the steps you are taking to remedy these violations and to prevent the occurrence of these or similar violations. Please direct your response to: Steven B. Barber, Compliance Officer, U.S. Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, MD 20723.

If you have any questions, please contact Mr. Barber at (410) 779-5134.

Sincerely yours,

/s/

Roberta F. Wagner
Acting District Director
Baltimore District Office