DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

9292d

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER

September 16, 2003

VIA FEDERAL EXPRESS

Mr. Brian Cohen
President
BWild Incorporated
2357 Bedford Avenue
Bellmore, New York 11710

Dear Mr. Cohen:

On August 20 and 26, 2003, an investigator from the United States Food and Drug Administration (FDA) inspected your facility at 2357 Bedford Avenue, Bellmore, NY 11710. Our investigator determined that your firm distributes plano tinted contact lenses, intended solely to change the appearance of the normal eye in decorative fashion, 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 any instructions regarding proper insertion, removal, cleaning, or handling of the lenses, and without any labeling describing the risks associated with the wear of the lenses. Based on the inspectional findings, FDA has determined that your contact lenses violate the Federal Food, Drug, and Cosmetic Act (the Act).

Because 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 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 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." Your lenses are also misbranded under 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.

In addition, if you market, in the manner described above, contact lenses with claims that cause them to be "devices" within the meaning of 21 U.S.C. § 321(h), then they are misbranded under 21 U.S.C. § 352(f)(1) because their labeling does not bear adequate directions for use.

This letter is not intended to identify all violations of the Act that apply to the marketing of your plano tinted contact lenses. It is your firm's responsibility to ensure that these products 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:

Ronald Swann, Branch Chief
Dental, ENT, and Ophthalmic Devices Branch (HFZ-331)
Office of Compliance
Center for Devices and Radiological Health
2098 Gaither Road
Rockville, MD 20850

If you have any questions, please contact Mr. Swann at 301-594-4613 x105.

Sincerely yours,

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health