



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDEX

WARNING LETTER

September 1, 1999

Our Reference: 2086715

Riley Stoops, President
Elite Distributing Co., Inc., dba Edco
3401 Fujita Street
Torrance, CA 90505

Dear Mr. Stoops:

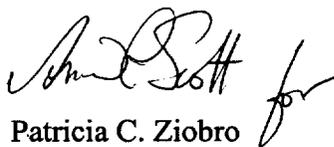
On July 7, 1999 our inspector collected a sample of Disney © brand sunglasses that were offered for import into the United States by your firm on June 24, 1999 under entry number 110-6019138-3. Sunglasses are medical devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The Food and Drug Administration's testing revealed that these sunglasses do not have impact resistant lenses as required by Title 21, Code of Federal Regulations Section 801.410. The sunglasses are adulterated within the meaning of Section 501(c) of the Act, in that, the quality of the sunglasses fall below that which it purports or is represented to possess. In addition, the sunglasses are misbranded under Section 502(a) of the Act, in that, the labeling is false and misleading. The entry documentation included certification that misrepresented the sunglasses as having impact resistant lenses. Such misrepresentation at the time of entry appears to be an attempt to circumvent FDA's statutory requirement for impact resistant lenses and is a violation of the Act and may violate other provisions of law, such as Title 19 United States Code (U.S.C.) 1592 and 18 U.S.C. 542.

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of future shipments. It is your responsibility, as the importer, to ensure that imported product meets all requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

Within 15 working days of receipt of this letter, notify this office in writing of the specific steps you have taken to correct the violation, including an explanation of each action being taken to prevent recurrence of the violation. Your written reply should be addressed to Food and Drug Administration, Attention: Mr. Russell A. Campbell, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, CA 94502.

Sincerely,

A handwritten signature in black ink, appearing to read "Patricia C. Ziobro" with a stylized flourish at the end.

Patricia C. Ziobro
Director
San Francisco District