



DEPARTMENT OF HEALTH & HUMAN SERVICES

**Public Health Service
Food and Drug Administration**

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

VIA FEDEX

WARNING LETTER

September 1, 1999

Our Reference: 2086799

Mark Yu, President
Maxplus International, Inc.
357 East Arrow Highway, Suite 205
San Dimas, CA 91773

Dear Mr. Yu:

On August 10, 1999, our inspection of a shipment of six boxes of ball pens, pencils, card holders and key chains pens offered into import into the United States by your firm under entry number 110-6020661-1 (I99-6020661-5) revealed the entry included laser pens (laser pointers). Such misrepresentation at the time of entry appears to be an attempt to circumvent FDA's statutory requirements for the Federal performance standard for laser products and is a violation of the Federal Food, Drug and Cosmetic Act (Act). Laser pointers are subject to the requirements of Title 21, Code of Federal Regulations (21 CFR), Sections 1040.10 and 1040.11

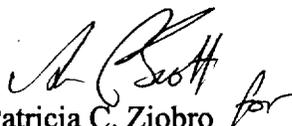
In addition, our examination of the laser pens included in the shipment revealed that the lasers were not in compliance with the Federal performance standard for laser products. The laser pens failed to have identification labels that provide the name and address of the manufacturer as well as the manufacturing date as required by 21 CFR 1010.3. The laser pens also failed to have permanently affixed warning labels as required by 21 CFR 1040.10(g)(2) and failed to have permanently affixed aperture labels as required by 21 CFR 1040.10(g)(5). Future entries may be detained if the products offered for import do not comply with applicable regulations.

Failure to prevent future violations may result in regulatory action, without further notice, such as seizure, injunction or detention without physical examination of future shipments.

It is your responsibility, as the importer, to ensure that imported product meets all requirements of the Act and the regulations promulgated thereunder.

Please notify this office in writing, within 15 days of receipt of this letter, of the specific steps you have taken to prevent recurrence of the noted violations. Your written reply should be addressed to the Food and Drug Administration, Attention: Mr. Russell A. Campbell, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, CA 94502.

Sincerely,


Patricia C. Ziobro *for*
Director
San Francisco District