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Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

September 10, 2001

WARNING LETTER
CHI-49-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Janusz Kopytek, Owner
Delta Imports, Inc.
11962 Oak Creek Parkway
Building B, Unit F
Huntley, Illinois 60142

Dear Mr. Kopytek:

Your facility imported entries 791-1502557-3 on 12/8/00, 791-1503311-4 on 2/26/01, 791-1503826-1 on 5/1/01, 791-1503853-5 on 5/2/01, 791-1503969-9 on 5/14/01, 554-9413306-3 on 5/24/01, and 554-9417932-2 on 8/3/01. For each of the above entries, there was product detained, refused entry, or otherwise not released for sale in the U.S. because of apparent violations of the Federal Food, Drug, and Cosmetic Act. When our inspector, John E. Verbeten, visited your facility, he found articles had been distributed without an FDA release.

This is a violation of Title 21, Code of Federal Regulations, Part 1.90 (21 CFR 1.90) (copy enclosed), which requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or a "Release Notice" from FDA.

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 products meet all requirements of the Federal Food, Drug, and Cosmetic Act, and the regulations promulgated thereunder.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the violation. In addition, you should inform Customs and FDA if and when redelivery is accomplished.

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Your reply should be addressed to Food and Drug Administration, attention: Dorothy S. Stanback, Compliance Officer, at the above address.

Sincerely,

\s\
Raymond V. Mlecko
District Director