



October 17, 2002

WARNING LETTER
SJN-03-02

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Guillermo Marrero Rivera
President
Drogueria Central
Rd. #2, Km. 19.5
Pepsi Industrial Park
Toa Baja, PR 00959

Dear Mr. Marrero Rivera:

From consumer complaint information received by the Food and Drug Administration (FDA), and from an FDA inspection from August 13 to 16, 2002, of your drug warehouse and distribution facility located at the above address, FDA has learned that you are distributing over-the-counter (OTC) drug products in violation of Title 21, Code of Federal Regulations, Part 201 – Labeling (21 C.F.R. Part 201).

Specifically, your firm has distributed Extra Strength Tylenol® products bearing labels and labeling in Spanish only to a New York, NY distributor for sale in the United States. This is in violation of 21 C.F.R. § 201.15(c)(1), which provides that all words, statements, and other information required by or under authority of the Act to appear on the label or in the labeling of a drug must appear in the English language. There is an exception in the regulation for products distributed solely in Puerto Rico or in a United States Territory where the predominant language is one other than English, but you distributed the product from Puerto Rico to the contiguous United States, where the exemption does not apply. In legal terms, this violation causes your drugs to be misbranded within the meaning of Section 502(c) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 352(c).

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Please take prompt action to correct this violation. Failure to do so may result in FDA taking action against you (e.g., product seizure or injunction) without further informal notice. In addition, please notify FDA, in writing and within 15 working days of receipt of this letter, of the specific steps you have taken to correct the violation. Please include in your response an explanation of each step being taken to prevent the recurrence of the violation or similar violations. Your reply should be sent to the Food and Drug Administration, San Juan District Office, 466 Fernandez Juncos Ave., San Juan, Puerto Rico 00906-2332, Attention: Mary L. Mason, Compliance Officer.

Sincerely,



Evelyn Bonnin
Acting District Director