DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

WARNING LETTER

Food and Drug Administration
Rockville MD 20857

Mr. Michael Krassnof
President
PDK Labs, Inc.
145 Ricefield Lane
Hauppauge, New York 11788-2007

FEB 24 1997

Ref: 97-HFD-312-01

Dear Mr. Krassnof:

This is in reference to "MaxAlert" tablets distributed by your firm. Each tablet contains the combination of 25 mg ephedrine hydrochloride and 100 mg guaifenesin. The "statement of identity" and "indications" portions of the label state that the product is a bronchodilator and an expectorant."

The trade name of your product, "MaxAlert," suggests that the product is intended for stimulant uses by implying that the product will increase the consumer's alertness. The only OTC ingredient the FDA considers generally recognized as safe and effective as a stimulant is caffeine (Title 21 Code of Federal Regulations part 338). Because "MaxAlert" is intended for stimulant purposes, it is subject to these final regulations on OTC stimulant drug products. Since neither ephedrine hydrochloride nor guaifenesin are generally recognized as safe and effective for stimulant indications, "MaxAlert" does not meet the final regulations on OTC stimulant drug products. We, therefore, consider "MaxAlert" to be a "new drug" (section 201(p) of the Federal Food, Drug, and Cosmetic Act (the Act)), which may not be legally marketed in the United States as it is not the subject of an approved New Drug Application (section 505).

We continue to receive reports that ephedrine is being used for stimulant and recreational use. The FDA believes that there are serious health risks inherent in the promotion of ephedrine for stimulant use. The trade name "MaxAlert" implies that the product may be intended for recreational use which leads to misuse and abuse. Significant adverse reactions linked to the use of "MaxAlert" as a stimulant drug have been reported. It is our position that the trade name "MaxAlert" must be changed in order to ensure that the product is not intended/promoted for stimulant use.

We request that you take action immediately to correct these violations. Failure to do so may result in regulatory action without further notice. This action may include seizure and/or injunction.

Please respond to this office in writing within fifteen (15) working days of receipt of this letter. Your response should describe the specific actions you will take, or have taken, to correct the violations. Your response should also include an explanation of each step being taken to prevent recurrence of similar violations. If corrective action cannot be completed

within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed. Your reply should be addressed to the Food and Drug Administration, Division of Labeling and Nonprescription Drug Compliance (HFD-310), 5600 Fishers Lane, Rockville, MD 20857, Attention: Robert A. Eshelman, Compliance Officer.

If you choose to correct the trade name violation noted above, and continue to market the combination product as a bronchodilator and expectorant, you will need to revise the formulation. The acceptable dosage for guaifenesin as an expectorant is 200 mg to 400 mg every 4 hours (21 CFR 341). Additionally, you must ensure that the labeling conforms with the requirements of 21 CFR 341 in all respects.

Sincerely yours,

Bradford W. Williams
Director
Division of Labeling and
Nonprescription Drug Compliance
Office of Compliance
Center for Drug Evaluation and Research