

Food and Drug Administration
Rockville MD 20857

CERTIFIED MAIL

AUG 16 1999

• RETURN RECEIPT REQUESTED

WARNING LETTER

Ref. # 99-HFD-310-06

Mr. []
Discovery Experimental & Development, Inc.
D.b.a. Astak
29949 S. R. 54 West
Wesley Chapel, Florida 33543

Dear Mr. []

This letter is in reference to your firm's manufacture and distribution of "Liquid Deprenyl Citrate." The labeling claims it to be "effective on: depression, learning, cognitive & motor functions, sense of well being, senile dementia, increasing energy, pain reduction, abolishing ulcer formation, hormone release, inhibiting toxic free radicals, sex drive dysfunction, revival of dying brain cells, Parkinson's Disease, Alzheimer's Disease, increasing life span, multiple sclerosis, ALS (Lou Gehrig's Disease), Blepharospasms, high blood pressure, stroke induced paralysis & mental dysfunction." Such claims cause the product to be a drug [(section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act))] and a "new drug" [section 201(p) of the Act]. Therefore, it may not be legally marketed in this country without an approved New Drug Application [section 505(a) of the Act].

This drug is also misbranded because its labeling fails to bear adequate directions for use [section 502(f)(1) of the Act]. Its labeling is also false and misleading, since it suggests that this product is safe and effective for its intended use when this has not been established and further that it is manufactured in and distributed from Mexico, when this is not the case. We would also point out that the FDA does not permit the personal importation of drugs when 1) they are promoted to persons residing in the United States; and 2) they pose an unreasonable risk to public health [section 502(a) of the Act].

You have reportedly exported this unapproved product to the United Kingdom. As provided in section 802(b)(1)(A) et seq, unapproved drugs may be exported from the United States only under certain limited conditions. We are asked to monitor the export of products through a simple notification process, whereby your firm provides a simple notification to FDA of your export of this product if clause (i) or (ii) of section (b)(1)(A), which, in fact, applies to the United Kingdom. Thus, if this product is approved in the UK, you have failed, at the minimum, to comply with section 802(g) of the Act.

This letter is not intended to be an all-inclusive review of labeling and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

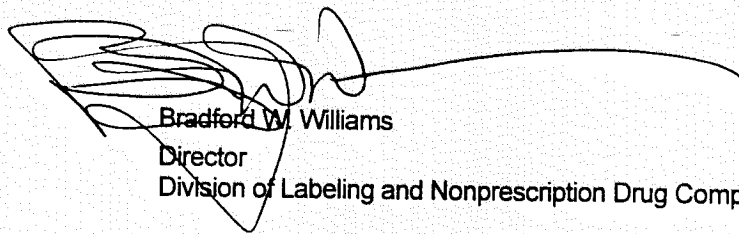
August 16, 1999

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be implemented.

Your reply should be addressed to the following:

Donald L. Leggett
Compliance Safety Officer, HFD-316
Division of Labeling and Nonprescription Drug Compliance
Office of Compliance
Center for Drug Research and Evaluation

Sincerely,

A handwritten signature in black ink, appearing to read "Bradford W. Williams", with a long horizontal flourish extending to the right.

Bradford W. Williams
Director
Division of Labeling and Nonprescription Drug Compliance