



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

98-PHI-29

August 27, 1998

Dr. Stuart A. Fine
Chairman & Chief Medical Officer
Akesis Pharmaceuticals, Inc.
Sainte Claire Plaza, Suite 3000
1121 Boyce Road
Pittsburgh, PA 15241

Dear Dr. Fine:

This letter is written in reference to your firm's marketing and distribution of the product Diabetes Pro Health, DPH, Pro Health Pak. This product was ordered from your firm and received by the purchaser on August 11, 1998. Our review of labeling for Pro Health Pak finds that it makes therapeutic claims which cause the product to be a drug [section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act)]. Labeling is not limited to the immediate product container but includes all promotional literature which you distribute in connection with your product.

Objectionable claims for Diabetes Pro Health, DPH, Pro Health Pak include the following:

References to the disease diabetes, including use of the brand name, "Diabetes Pro Health," which results in prominent displays of the disease name, Diabetes, on the label of the immediate product container and in the product brochure (labeling). Prominence in this context refers not only to size but may also refer to either the placement or the frequency of use of the disease name, Diabetes.

References to Type I and Type II [diabetes].

Statements such as: "formulated to meet the nutritional needs of adults with diabetes and pre-diabetes," "an important addition to your total diabetes management/prevention program," "improve the quality of life for those with or at high risk of developing diabetes," "effective and inexpensive intervention/prevention for diabetes," "Regular blood glucose monitoring is recommended when using this product," "preventing, or even minimizing its [diabetes] long-term complications, e.g. nerve damage, eye, kidney and premature cardiovascular disease," and "prevent the complications of diabetes."

Additional objectionable claims are found in the Diabetes Pro Health, DPH, Pro Health Pak brochure, which explains how and why Pro Health Pak and the individual product ingredients will treat or prevent either diabetes itself, or disease complications that are associated with diabetes. Further, the prominent use of the disease name, diabetes, as well as other references to diabetes, such as Type I and Type II, create a context wherein statements such as, "Supports insulin function" and "Supports glucose metabolism," cannot be separated from the disease and also represent disease claims. Diabetes Pro

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Health, DPH, Pro Health Pak is thus a "new drug" [section 201(p) of the Act] and therefore, 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 the conditions for which it is offered [section 502(f)(1) of the Act], and its labeling is false and misleading since it suggests that this product is safe and effective for its intended uses when, in fact, this has not been established [section 502(a) of the Act].

This drug is further misbranded in that its labeling makes the false and misleading statement that Willow Bark is "a natural and superior source of aspirin." We are not aware of any evidence that Willow Bark is equivalent to or a superior source of the drug, aspirin [section 502(a) of the Act].

We are also aware that the claims found in the product brochure are found in your firm's Internet web site.

This letter is not intended to be an all-inclusive review of all 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 do so 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.

Please notify this office in writing within fifteen (15) working days after the 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 identify and make corrections 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 within which the corrections will be completed. Please provide any documentation necessary to indicate correction has been achieved.

Your reply should be sent to the attention of Lynn S. Bonner, Compliance Officer, at the address noted above.

Sincerely,



W. Charles Becoat
Acting District Director
Philadelphia District

CC: Pennsylvania State Department of Health
132 Kline Plaza, Suite A
Harrisburg, PA 17104
Attention: Robert E. Bastian, Director
Division of Primary Care and Home Health Services

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