

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

WASHINGTON, D.C. 20204

July 19, 1966

Henry Blackburn, M. D. University of Minnesota Stadium Gate 27 Minneapolis, Minnesota 55455

Dear Dr. Blackburn:

This replies to your letter of June 10, 1966 about "Afrodex" distributed by the Bentex Pharmaceutical Company, Houston, Texas. We also received a copy of your letter of May 11, 1966 to the firm.

We very much appreciate receiving with your letter a copy of the reply to Scientific Associates, Inc., on behalf of Bentex Pharmaceuticals. Such information from public spirited citizens like yourself is often helpful in our enforcement of the Federal Food, Drug, and Cosmetic Act.

We are aware of "Afrodex," and we have serious reservations about its safety and effectiveness for the uses recommended in its labeling. We are considering its status under the law to determine what action is indicated.

Thank you for writing.

Sincerely yours,

Howard S. Spunger
Howard S. Spungen
Food and Days Officer

Food and Drug Officer

Bureau of Regulatory Compliance