



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

d19186

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-61

July 1, 1998

Robert Edwards, President
Rain Forest Pharmaceuticals, Inc.
1173 Hillsboro Mile
Hillsboro Beach, Florida 33062

Dear Mr. Edwards:

During an inspection of your firm on February 24 & 27, 1998, Investigators Michelle Dunaway and Janneth Caycedo determined that your firm manufactures Insul-End, an herbal liquid and is promoting and distributing the products, Insul-End and Insul-End Plus tablets.

Labeling for these products state that the products are useful in the treatment of diabetes and diabetic complications, including the following claims:

- The package insert for Insul-End states, "... to lower the blood glucose in patients with insulin dependent (type I) and non-insulin dependent (type II) diabetes mellitus...".
- A newsletter titled "SAY GOODBYE TO DIABETES" contains claims that insulin dependent patients taking Insul-End were successfully weaned off the insulin.
- Literature entitled "INSUL-END PLUS" states the product should be taken in conjunction with Insul-End to increase insulin sensitivity and to prevent diabetic complications such as atherosclerosis and diabetic retinopathy.
- The labeled name of the products, Insul-End and Insul-End Plus, implies an intended use for the products to be used to end the use of Insulin.

Mr. Robert Edwards

Page 2

July 1, 1998

Based on the claims made in the labeling for these products, Insul-End and Insul-End Plus are drugs [Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)]. They are "new drugs" [Section 201(p) of the Act] because they are not generally recognized as safe and effective for treating diabetes and may not be legally marketed in the United States without approved New Drug Applications [Section 505(a) of the Act].

These drugs are also misbranded [Section 502(f)(1)] because their labeling fails to bear adequate directions for use and further implies that there is scientific evidence in support of these claims when in fact there is not [Section 502(a)]. Additionally, the product, "Insul-End" is misbranded [Section 502(b)] in that it fails to list a quantity of contents.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your firm. It is your responsibility to ensure that all drug products manufactured are in compliance with the Act and the CGMP regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct these violations.

The Agency has performed a Health Hazard Evaluation for your products and has concluded that this is a situation in which use of Insul-End and Insul-End Plus may cause temporary and medically reversible adverse health consequences.

Your response should include:

1. An estimate of the quantity of the drug manufactured or received within the past twelve (12) months.
2. An estimate of the size and frequency of shipments made by you in the past twelve (12) months.
3. An estimate of the amount of the drug that is in inventory under your control and your estimate of the amount in distribution channels outside your control.
4. The date of discontinuance in the event that you have already discontinued marketing this drug product.
5. Your intention with respect to the disposition of your inventories and outstanding stocks in trade channels.

Mr. Robert Edwards
Page 3
July 1, 1998

Your reply should be directed to Martin E. Katz, Compliance Officer, Florida District, Food and Drug Administration, 555 Winderley Place, Ste. 200, Maitland, Florida 32751, telephone no. (407) 475-4729.

Sincerely,

A handwritten signature in black ink, appearing to read "Douglas D. Tolen". The signature is written in a cursive style with a long horizontal stroke extending to the left.

Douglas D. Tolen
Director, Florida District