



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

g3760d

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (714) 798-7600

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

W/L 09-03

November 19, 2002

Mr. Cary D. Ferguson, President
Klaire Laboratories, Inc.,
140 Marine View Avenue, Suite 110
Solana Beach, CA 92075

Dear Mr. Ferguson:

This letter is written in reference to inspection of your facility conducted by our investigators on May 9 and 13, 2002 and the marketing of SerenAid™ by your firm. SerenAid's labeling suggests that it is useful in improving conditions of autism in children. Specifically, statements which appear on your websites such as www.Klaire.com, www.Serenaid.com and www.Serenaid.org, and the SerenAid™ product sheet characterize this product as a drug within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act ("the Act").

Specific examples from the website links and product sheet which associate the product SerenAid with the treatment of autism include the following:

- (a) the "Latest News" link (http://www.klaire.com/latest_news.php) contains the statement, "'SERENAID' is so unique because it breaks down Exorphin peptides which are produced from ingesting DAIRY (milk) and GLUTEN (wheat) products. In AUTISTIC CHILDREN this can create Opiate like reactions and affect their neurological and behavioral patterns. 'SERENAID' contains a special enzyme that is lacking in these children and helps decrease or completely stop the production of these Exophrin peptides. Clinical research has shown the favorable results..."
- (b) the "SerenAid – caps" product link (http://www.klaire.com/product_details.php?product_id=38) describes "A 12 week pilot study was conducted with the assistance of the Autism Research Institute" that produced "moderate to great improvement" in one or more criteria, including eye

Mr. Cary Ferguson

Page 2

contact, socialization, attention, mood, hyperactivity, stimming, comprehension, speech, sound, sensitivity, digestion, sleep, and perseveration.

(c) the single page, dual sided product profile sheet shipped with orders contains the statements "several clinicians have observed a significant correlation between symptoms of autistic spectrum disorders and an impaired ability to adequately digest wheat and dairy protein;" "the causal relationship between certain digestive disorders and the cognitive and sensory disturbances common to autistic spectrum disorder has been further established by reported success in reducing symptoms with the implementation of a wheat and dairy free diet;" and "no toxicity has been demonstrated with even large doses."

These claims evidence that this product is intended for use as a drug as defined in section 201(g) (1) (B) of the Act. It is also a new drug under section 201(p) of the Act and may not be legally marketed in the United States without an approved New Drug Application (section 505(a) of the Act)). This drug is also misbranded (section 502(f) (1) of the Act) because the labeling fails to bear adequate directions for use. In addition, the labeling is false and misleading because it suggests that the product is safe and effective for its intended use when, in fact, this has not been established (section 502(a) of the Act).

This letter is not intended to be an all-inclusive review of your Internet websites, labeling, or products. Moreover, the violations of the Act described above are not intended to be an all-inclusive list of violations concerning your firm and its products. It is your responsibility to ensure adherence to requirement of the Act and its implementing regulations.

You should take prompt action to correct these violations. Failure to promptly correct them may result in regulatory action such as seizure and/or injunction being initiated by FDA.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct this violative situation. 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.

This matter has been assigned to Compliance Officer MaryLynn Datoc. Please feel free to contact her at telephone number 949-798-7628 for any specific questions you may have. Your written reply should be addressed to:

Mr. Cary Ferguson
Page 3

Thomas L. Sawyer, Director, Compliance Branch
US Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, California 92612-2445

Sincerely,

A handwritten signature in black ink, appearing to read 'M.L.T.' with a flourish at the end.

fw Alonza E. Cruse
District Director