



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

*Mason*  
Food and Drug Administration  
Denver District Office  
Bldg. 20-Denver Federal Center  
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6<sup>th</sup> Avenue & Kipling Street  
Denver, Colorado 80225-0087  
Telephone: 303-236-3000  
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March 15, 2000

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Sam Naimo, President  
Genesist, Inc.  
d.b.a. Solstice Vitamins Inc.  
982 Stuyvesant Avenue  
Union, New Jersey 07083

Ref #: DEN-00-22

Dear Mr. Naimo:

During an inspection of your firm, Genesist, Inc., located at 1321 South Grant Street, Longmont, Colorado on December 21- 22, 1999, Consumer Safety Officer Eric S. Myskowski determined that your firm repacks and labels amino acid supplements. These products are dietary supplements within the meaning of Section 201(ff) of the Food, Drug and Cosmetic Act (the Act).

Our review of your labeling reveals your products are misbranded within the meaning of section 403(j) of the Act, in that they purport to be for special dietary use and their labels fail to bear information concerning their vitamin, mineral or other properties as regulation prescribes as necessary to fully inform purchasers as to their value for such use. Specifically, the labeling fails to bear "Supplement Facts" nutrition labeling in accordance with the requirements of Title 21 Code of Federal Regulations, Part 101.36(e) [21 CFR 101.36 (a) and (e)] unless an exemption has been filed and approved by FDA as provided by paragraph (h) of this section. A review of our records has determined your firm has no labeling exemption on file.

For your information, labeling and Internet advertising for your products, Virusine and Meno-ease were also reviewed. Virusine is promoted in Internet advertisements to be a "unique amino acid formulation designed to reduce viruses (colds, flu, etc.) by inhibiting viral growth with Hydroxy-Lysine and labeled, " Suggested Use: Upon onset of cold/flu symptoms, take 4 capsules every hour for four hours, for four days, or as directed by your physician." Meno-Ease is promoted in Internet advertisements and on the product labeling to be a "unique combination

formulated to alleviate depression, tension, water retention and other discomforts associated with the menstrual cycle.”

These statements and claims suggest these products are intended to treat, cure, mitigate or prevent disease. These claims suggest these products are intended for use as a drug within the meaning of section 201(g)(1)(B) of the Act, and thus would be subject to regulation as drugs under provisions of the Act.

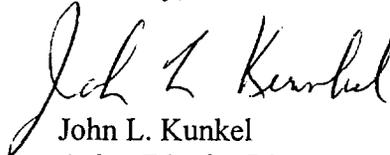
You should review all of your labeling and statements to ensure they meet the nutritional labeling requirements of 21 CFR 101.36 (copy enclosed). Additional information may be obtained at FDA's Internet Website, [www.fda.gov](http://www.fda.gov), under the Center for Food Safety and Applied Nutrition.

The above identification of violations is not intended to be an all-inclusive list of deficiencies on your labels. It is your responsibility to assure that all of your products are labeled in accordance with the laws and regulations enforced by FDA. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible action includes seizure and/or injunction.

The above violations include nutrition labeling violations that concern certain new labeling requirements and are not intended to be an all-inclusive list of deficiencies on your labeling. Other label violations could subject these dietary supplements to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA.

Please advise this office, in writing, within fifteen (15) working days after receipt of this letter, of the specific actions you have taken to correct the violations. Your response should include: (1) each step that has or will be taken to completely correct the current violations and prevent the recurrence of similar violations; (2) the time when correction will be completed; (3) any reason why the corrective action is not completed within the response time; and (4) any documentation necessary to indicate correction has been achieved. Your response should be directed to Steven C. Madzo, Acting Compliance Officer, at the above address.

Sincerely,



John L. Kunkel  
Acting District Director

Enclosure:  
21 CFR 101.36

cc:  
Ms. Cheryl E. Johnson  
Account Manager  
Genesist Inc.  
1321 South Grant Street  
Longmont, Colorado 80521