



Food and Drug Administration  
Minneapolis District  
240 Hennepin Avenue  
Minneapolis MN 55401-1999  
Telephone: 612-334-4100

**PURGED** *ERH*

September 4, 1997

cc: HFI-35/FOI Staff  
DWA

**WARNING LETTER**

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

Refer to MIN 97 - 59

William L. Rush  
President/CEO  
Nutrition Medical  
9850 - 51st Avenue North  
Minneapolis, Minnesota 55442

Dear Mr. Rush:

The Food and Drug Administration recently collected a sample of L-Elemental Pediatric lot number EXP OCT.G28763166 manufactured by your firm. FDA analysis of these samples revealed that the product contains selenium at 4.2 mcg (56% of declared) and 4.14 mcg (55.2% of declared) per 1.7-oz. packet by original and check analysis, respectively. This causes your product to be adulterated within the meaning of Section 402(b)(1) of the Federal Food, Drug and Cosmetic Act in that a valuable constituent, selenium, has been in whole or in part omitted or abstracted from the product.

The product is also misbranded under Section 403(a)(1) in that it falsely represents the amount of selenium on the product's label.

We request that you notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct this violation, including any corrective action you take with respect to any other products containing less than the declared amount of a nutrient. Failure to promptly

Page Two

William L. Rush  
September 4, 1997

correct this deviation may result in regulatory action without further notice. This may include seizure and/or injunction.

Your reply should be directed to Compliance Officer Judy E. Heisick at the address indicated on the letterhead.

Sincerely,



James A. Rahto  
Director  
Minneapolis District

JEH/ccl