



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region *M1952N*

Telephone (973) 526-6009

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

May 19, 1998

WARNING LETTER

CERTIFIED MAIL -
RETURN RECEIPT REQUESTED

Dr. Mohamed Desoky, President
Quality Formulations, Inc.
110 Pennsylvania Avenue
Paterson, New Jersey 07503

File No: 98-NWJ-24

Dear Dr. Desoky:

On September 4, 1997, an Investigator from the New Jersey District Office of the Food & Drug Administration conducted an inspection of your manufacturing facility located at 110 Pennsylvania Avenue, Paterson, New Jersey. It was determined that the products you manufacture and distribute are foods, as defined by Section 201 of the Food, Drug and Cosmetic Act (the Act) and are subject to regulations under Title 21 of the Code of Federal Regulations (CFR).

On October 15, 1997, physical samples and labeling were collected for your product, Complete Nutrition Supplement Peanut Butter Bar, and were analyzed by our laboratory. Analytic results revealed this product to be misbranded within the meaning of Section 403(a) of the Act, in that the actual iron content was not present at a level at least equal to the value declared on the label. Analysis revealed [redacted] percent of the Daily Value of iron present [redacted] percent in check analysis). The label declares the product contains 35 percent of the Daily Value for iron.

Review of the above-referenced product labeling, reveals that this product claims to be a "complete nutritional supplement". According to the ingredient statement, a source of iron is listed as an ingredient, presumably to provide the amount of iron declared on the label. Therefore, this product is also considered adulterated under Section 402(b)(1) of the Act, in that a valuable constituent, the mineral iron, has been omitted, in whole or in part. While the less than declared amount of iron does not present a health hazard, the product is promoted as a complete nutritional supplement and consumers may be relying upon it to meet their daily iron requirements.

RELEASE

REVIEWED BY Meride Noth 5/26/98
C.O. DATE

Quality Formulations, Inc.
Paterson, NJ 07503

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The aforementioned violations are not intended to be all-inclusive of labeling deficiencies. It is your responsibility to assure compliance with regulations governing dietary supplements. New regulations concerning labeling requirements for dietary supplements were published in the September 23, 1997 edition of the Federal Register, a copy of which is enclosed. These new labeling regulations become effective March 23, 1999 and will apply to all dietary supplements.

You should take prompt action to correct these deficiencies and review all product lines you manufacture and distribute to assure they are in conformance with labeling regulations. Failure to promptly correct these violations may result in regulatory actions being initiated by the agency without further notice. These actions may include seizure of illegal products and/or injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, as to the specific steps you have taken to correct the stated violations. If corrective actions cannot be completed within fifteen (15) working days, state the reasons for the delay and the timeframe within which the corrections will be implemented.

Your reply should be sent to the Food and Drug Administration, New Jersey District Office, 10 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 07054, Attn: Mercedes B. Mota, Compliance Officer.

Sincerely,



DOUGLAS I. ELLSWORTH
Director, New Jersey District

ATTACHMENT: Federal Register, Vol. 62, September 23, 1997, pgs 49826-49856