



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region *g1784d*

Telephone (973) 526-6010

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

September 5, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Joseph Unanue
President
Goya Foods, Inc.
100 Seaview Drive
Secaucus, New Jersey 07096

File No.: 01-NWJ-36

Dear Mr. Unanue:

On January 11, 2001, our investigators visited your firm at 100 Seaview Drive, Secaucus, NJ. During the visit, they collected samples of Enriched Coarse Corn Meal (lot 03540013) and Enriched Rice Flour (lot 03500011). Our analysis revealed that the products are considered adulterated and misbranded according to Sections 402(b)(1) and 403(a)(1) of the Federal Food, Drug & Cosmetic Act (the Act). The Enriched Corn Meal product is also adulterated according to Section 403(g) of the Act because it does not conform to the established standard of identity.

Specifically, our analysis found that the products contained significantly less than the labeled amount of folic acid. The standard of identity for Enriched Corn Meal as specified in Title 21, Code of Federal Regulations (21CFR), Section 137.260, requires that it contain "not less than 0.7 mg. and not more than 1.0 mg. of folic acid" per pound. Our analysis of the Enriched Corn Meal found that it contained only 13.9% of the label declaration (17.8% of declared on check). This equates to 0.137 mg/lb of folic acid (0.176 mg/lb check).

Our analysis of the Enriched Rice Flour found that this product also contains significantly less than the declared amount of folic acid. Specifically, our analysis found that it contained only 16.1% of the declared amount (18.7 % on check analysis).

The above violations concern certain new labeling requirements and are not meant to be an all-inclusive list of deficiencies on your label or at your facility. Other label violations can subject the food 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 and manufactured in accordance with all applicable regulations.

Goya Foods, Inc.
Secaucus, NJ 07096

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Please notify this office within 15 working days of receipt of this letter outlining the specific steps you have taken to correct the violations noted above and to prevent their recurrence. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time needed to complete the correction. Please submit your response to: U.S. Food & Drug Administration, 10 Waterview Boulevard, 3rd Floor, Parsippany, New Jersey 07054, Attn: Sarah A. Della Fave, Compliance Officer.

Sincerely,

Edward H. Wilkins, for
Douglas I. Ellsworth
District Director
New Jersey District