



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
New England District

g1005d

One Montvale Avenue  
Stoneham, Massachusetts 02180  
TEL: (781) 279-1675  
FAX: (781) 279-1742

March 8, 2001

**WARNING LETTER**

**NWE-09-01W**

**VIA FEDERAL EXPRESS**

Hillary J. Tounge  
Owner and President  
Downeast Pasta  
47B India Street  
Portland, ME 04101-4209

Dear Ms. Tounge:

On April 19, 2000 U.S. Food and Drug Administration (FDA) inspector Michael McPartlin collected under Sample Number 91091 samples of your firm's Downeast Pasta™ Macaroni Product Classic and Flavored. Review of the product labeling revealed that this product is *misbranded* within the meaning of Section 403(f) of the Act, in that information required by the Act to appear on the label or labeling is not placed thereon so that it is likely to be read under customary conditions of purchase. The following violation was noted:

- The list of ingredients for this product is printed on an interior label surface that is not visible to a purchaser under customary conditions of display for retail sale. A list of ingredients is information that is required by 21 CFR §101.2(b) to appear on the principal display panel or the information panel of the label of a packaged food. This is of particular concern, due to the fact that one of the listed ingredients is egg whites. This substance is known to be a potential allergen.

This product is also *misbranded* within the meaning of Section 403(q)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the labeling does not fully comply with

the nutritional labeling requirements, as specified in Title 21 Code of Federal Regulations (21 CFR) Part 101.9. The following significant violations were noted:

- The nutrition information for your product is not located on the labeling in accordance with 21 CFR § 101.9(i), which specifies that such information shall be in compliance with 21 CFR § 101.2. More precisely, 21 CFR § 101.2(b) states that all information required by § 101.9 to appear on the label of any package of food shall appear on the *principal display panel or on the information panel*, unless otherwise specified. Your product does not conform to §§ 101.9(i) and 101.2(b), the reason being that you have placed nutrition information (in the form of an aggregate nutrition panel containing information for 4 different types of pasta) on an interior label surface that is not visible to a purchaser under customary conditions of display for retail sale. Your product, as it is currently labeled, would have to be opened after it had been purchased in order for the nutrition information to be accessible.

You should take prompt action to correct these label deficiencies. Failure to do so may result in regulatory action being initiated by FDA without further notice. These include seizure and/or injunction. The above violations are not meant to be an all-inclusive list of deficiencies on your labels. Other label violations can subject foods to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable laws and regulations enforced by FDA.

As you review the labeling of any of your other products, you should consider the following additional comments with respect to the labeling of the Downeast Pasta™ Macaroni Product Classic and Flavored—

- The following graphic elements required under 21 CFR 101.9(d) are not in one of the specified formats—
  - 1) the heading “Nutrition Facts” must be set in a type size larger than all other print size in the nutrition label [reference: § 101.9(d)(2)]
  - 2) values expressing the content of saturated fat, dietary fiber, and sugars must be indented [reference: §§ 101.9(c)(2)(i), 101.9(c)(6)(i), and 101.9(c)(6)(ii)]
  - 3) nutrient information for vitamins and minerals (i.e., Vitamins A and C, Calcium, and iron) must be separated from information on other nutrients by a bar [reference: § 101.9(d)(8)]
- The ingredient list does not appear to be fully consistent with §§101.4(b)(2)(i) and 101.4(b)(2)(ii). It could be construed from the listing of flour as “Semolina/durham enriched flour” that *both* types of flour are present or that *only one or the other* type is present. In addition, “durum” (as opposed to durham) is the correct spelling for this type of wheat flour. Requirements pertaining to the labeling of and standards for wheat flours can be found at §§ 101.4(b)(15), 137.105, 137.220, and 137.320.

You should notify this office, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. Copies of revised labels should also be submitted. If corrective action cannot be completed within 15 working days, state the reason(s) for the delay and the time at which the corrections will be completed.

You should direct your reply to Mark Lookabaugh, Compliance Officer at One Montvale Avenue, Suite 4, Stoneham, MA 02180. If you have any questions concerning this matter, please contact Mr. Lookabaugh at **781.279.1675 x1718**.

Sincerely,



Gail T. Costello  
Director  
New England District Office