



JAN 28 2004

Stephen Cunliffe  
President  
Nestlé Prepared Foods Company  
20 Inverness Place East  
Englewood, Colorado 80112-1114

Re: Nutrient Content Claim Petition to Expand the Definition for "Lean"

Dear Mr. Cunliffe:

This letter acknowledges receipt on January 13, 2004, by the Food and Drug Administration (FDA) of your petition to amend the definition for the nutrient content claim "lean". This petition was submitted pursuant to Section 403(r)(4)(A)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(4)(A)(i)).

Your petition is currently undergoing initial FDA review. In accordance with Section 403(r)(4)(A)(i) of the act (21 U.S.C. 343(r)(4)(A)(i)) and 21 CFR 101.69(m), within 100 days of receipt of a petition, the petition will either be filed for comprehensive review or denied. A denial may be either by FDA action within the 100-day period, which ends on April 22, 2004 or by a lack of action by FDA within the initial 100-day period in which case the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner.

If you have any questions please feel free to contact Connie Henry of the Nutrition Programs and Labeling Staff at (301) 436-1450.

Sincerely yours,

Constance Henry  
Nutrition Programs and Labeling Staff  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

cc: Steven B. Steinborn  
Counsel to Nestlé Prepared Foods Company  
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555 Thirteenth Street, NW  
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2004P-0183

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