



DEPARTMENT OF HEALTH AND HUMAN SERVICES

HFA-308
Public Health Service

Food and Drug Administration
Rockville, MD

2862 02 JUL -9 A9:59

Mr. Bob Goldstein
Vice President
Hodgson Mill
1203 Niccum Avenue
Effingham, Illinois 62401

Re: Docket Number 01P-0290/CP 1

Dear Mr. Goldstein:

This letter responds to your citizen petition dated June 18, 2001, requesting that the Food and Drug Administration (FDA) establish a standard of identity for the term "stone ground" as applied to wheat flour. In your petition, you requested that FDA define the term as follows:

Stone ground whole wheat flour, ground graham flour, stone ground entire wheat flour is the food prepared by so grinding cleaned wheat, other than durum wheat and red durum wheat, using stone grinding wheels for more than eighty percent of the particle size reduction, that when tested by the method prescribed in paragraph (c)(2) of this section,

You stated that you were prompted to petition FDA to take this action because you are aware that some individuals are milling flour using conventional milling equipment and labeling the resultant product "stone ground." You also stated that it is your belief that labeling this conventionally milled flour as stone ground flour represents "mislabeling" of the conventionally milled flour.

You cited as grounds for your request Title 21 United States Code, section 341 (21 U.S.C. 341), which permits FDA to establish a standard of identity for a food to promote honesty and fair dealing in the interest of consumers. You also cited the Truth in Poultry Labeling Law of 1994, the definition of the term "organic," the phrase "made in America," and the use of the word "natural" to describe vitamins, as successful examples of truth in labeling which, you assert, have accomplished the goal that you desire from your petition. However, you did not provide any analytical data or other information to support your position that establishing a standard of identity for stone ground flour is necessary to promote honesty and fair dealing in the interest of consumers. See 21 U.S.C. 341; 21 CFR 130.5. For example, you did not provide any data to show what consumers understand the term "stone ground" to mean and to show that consumers are buying a product labeled "stone ground" that differs from their expectations. FDA also is unaware of any data or information indicating consumer confusion in this regard.

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In the absence of any substantiating data or other information, you have failed to demonstrate that your proposed standard for “stone ground” would promote honesty and fair dealing in the interest of consumers as required by 21 U.S.C. 341. Therefore under 21 CFR 10.30(e)(3), we are denying your petition. This denial is without prejudice to your future filing of a petition, supported by adequate data, demonstrating that the requirements of 21 U.S.C. 341 have been met.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Dennis E. Baker", with a long horizontal flourish extending to the right.

Dennis E. Baker
Associate Commissioner
for Regulatory Affairs