



8820 01 JUN 21 2002

TO: Jennie Butler
FROM: Bob Goldstein
DATE: June 18th 2001
RE: Labeling

Dockets Management Branch, Food and Drug Administration
Department of Health and Human Services, Room 10-61, 5630 Fishers Lane
Rockville, MD 20857

CITIZEN PETITION

The undersigned submits this petition under Section 341 Definitions and standards for food; US Code: Title 21, to request the Commissioner of Food and Drugs to issue a definition for the term "stone ground" as applied to wheat flour.

The undersigned requests the Commissioner to define the term as follows:

Stone ground whole wheat flour, stone 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 (80%) of the particle size reduction, that when tested by the method prescribed in paragraph (c)(2) of this section, not less than 90 percent passes through a 2.36 mm (No. 8) sieve and not less than 50 percent passes through a 850 μ m (No. 20) sieve. The proportions of the natural constituents of such wheat, other than moisture, remain unaltered. To compensate for any natural deficiency of enzymes, malted wheat, malted wheat flour, malted barley flour, or any combination of two or more of these, may be used; but the quantity of malted barley flour so used is not more than 0.75 percent. It may contain harmless preparations of α -amylase obtained from *Aspergillus oryzae*, alone or in a safe and suitable carrier. The moisture content of whole wheat flour

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is not more than 15 percent. It may contain ascorbic acid in a quantity not to exceed **200** parts per million as a dough conditioner. Unless such addition conceals damage or inferiority or makes the stone ground whole wheat flour appear to be better or of greater value than it is, the optional bleaching ingredient azodicarbonamide (complying with the requirements of Sec. 172.806 of this chapter, including the quantitative limit of not more than 45 parts per million) or chlorine dioxide, or chlorine, or a mixture of nitrosyl chloride and chlorine, may be added in a quantity not more than sufficient for bleaching and artificial aging effects.

The undersigned makes this request upon learning that some "stone ground" flour is primarily milled upon conventional milling equipment and the product is being mislabeled. Citing US Code Title 21, Section 341, which compels the Secretary of Health and Human Services to establish standards of identity to promote honesty and fair dealing in the interest of consumers, we ask you to consider this issue in the same framework.

We can find no performance or nutritional basis for this petition, it stands solely on the merit of truth in labeling. As precedent, we wish to cite the "Truth in Poultry Labeling Law of 1994"; Boxer and Feinstein, as defining a term for a process which did not affect the nutritional or performance characteristics of the product, simply the method by which it was processed, which according to the authors, was misleading the consumer.

Additionally, the recent definition of the term "organic" and how it can be applied to labeling should be noted. The term is defining the level of a type of processing a good must receive in order to live up to the spirit of the law. Again, the functionality of the product is not impacted, however, the term defines how it has been processed.

Also please note the term "natural" when applied to vitamins as in the Food and Drug Act refers to products which perform and function the same as synthetic vitamins. However, to protect the consumer and maintain integrity in labeling, the vitamins are differentiated.



Finally, the phrase "made in America" defines the percentage of a good which must be manufactured or assembled in the US to carry this phrase on its label. Again, no effect or impact on the performance of the product, simply a matter of truth in labeling.

Thank you in advance for considering this issue. The undersigned certifies that, to the best of his knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition (per the outline)

I am inclosing the letter sent to the Dept. of Public Health for you review also.

Thank you for your time and hope to hear your comment's

Bob Goldstein

Bob Goldstein
V.P of Production for Hodgson Mill
1203 Niccum Ave.
Effingham Illinois. 62401

Phone 1-800-525-0177 ext. 242



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug
Administration

Chicago District
300 S. Riverside Plaza
Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

May 25, 2001

Bob Goldstein
Vice President, Production
Hodgson Mill
1203 Niccum Ave.
Effingham, IL 62401

Dear Mr. Goldstein,

In reply to your inquiry concerning product clarification on labeling for "stone ground" flour, I could not find any reference or definition for "stone ground" in the FD&C Act or the Code of Federal Regulations Title 21. While one could argue that product labeled as "stone ground" which was not processed in a traditional stone mill was misbranded per Section 403(a)(1); the feasibility of invoking legal sanction against a product would among other things be dependent on the court establishing a working definition of the term "stone ground."

You may consider petitioning the agency for a standard of identity for this product to be published in the Federal Register or request the agency adopt a means of handling the aforementioned situation with a Compliance Policy Guide.

I have enclosed a document called "HOW TO PETITION THE FDA" for your information. I hope this will be of some assistance to you.

Sincerely,

Mark G. Peterson, Investigator



To: Mark Peterson
Food and Drug Administration

FROM: Bob Goldstein
V.P. Production for Hodgson Mill

DATE: May 16, 2001

RE: Product clarification on Labeling

Tom,

I am writing to seek clarifying the term "stone ground". Traditionally, stone ground products describe whole grain reduced in particle size by the action of stone wheels grinding against each other. The grist may be sifted and passed through another size reduction to achieve a uniform particle size. Word has reached us that some products label themselves as stone ground, but are primarily processed by conventional mill practices with only a small portion of the milling actually being ground by stones or just touching the stone as it passes down the spout on its way to the finished processed bin. As you can imagine there is a significant cost advantage for conventional milling but it is confusing to the consumer about the type of processing in their purchased foods.

I believe this issue has merit to the 1995 Food Safety and Inspection Service final rule regarding the labeling of "fresh" poultry. This is not an issue of functionality or public safety but simply an issue of properly informing the consumer of the processing of food. We have conducted investigations and analysis into functionality of the stone ground flour that is available and can find no functional difference in the product. Simple experience indicates that conventional milling is being used to process the grain.

What I am seeking is a standard for the percentage of particle reduction, which must occur by the stone grinding action in order to label a product "stone ground". This would be very similar to the recent actions establishing levels for the term "organic". With growing concern over the safety of the food supply and truth, we in the food industry must keep things as forthright as possible. I trust you will give this request fair and prompt consideration.

Thank you.

Bob Goldstein

Dockets Management Branch, Food and Drug Administration
Department of Health and Human Services, Room 10-61, 5630 Fishers Lane
Rockville, MD 20857

CITIZEN PETITION

The undersigned submits this petition under Section 341 Definitions and standards for food; US Code: Title 21, to request the Commissioner of Food and Drugs to issue a definition for the term "stone ground" as applied to wheat flour.

A. Action Requested: The undersigned requests the Commissioner to define the term as follows:

Stone ground whole wheat flour, stone ground graham flour, stone ground 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 (80%) of the particle size reduction, that when tested by the method prescribed in paragraph (c)(2) of this section, not less than 90 percent passes through a 2.36 mm (No. 8) sieve and not less than 50 percent passes through a 850 μ m (No. 20) sieve. The proportions of the natural constituents of such wheat, other than moisture, remain unaltered. To compensate for any natural deficiency of enzymes, malted wheat, malted wheat flour, malted barley flour, or any combination of two or more of these, may be used; but the quantity of malted barley flour so used is not more than 0.75 percent. It may contain harmless preparations of α -amylase obtained from *Aspergillus oryzae*, alone or in a safe and suitable carrier. The moisture content of whole wheat flour is not more than 15 percent. It may contain ascorbic acid in a quantity not to exceed 200 parts per million as a dough conditioner. Unless such addition conceals damage or inferiority or makes the stone ground whole wheat flour appear to be better or of greater value than it is, the optional bleaching ingredient azodicarbonamide (complying with the requirements of Sec. 172.806 of this chapter, including the quantitative limit of not more than 45 parts per million) or chlorine dioxide, or chlorine, or a mixture of nitrosyl chloride and chlorine, may be added in a quantity not more than sufficient for bleaching and artificial aging effects.

B. Statement of Grounds: The undersigned makes this request upon learning that some "stone ground" flour is primarily milled upon conventional milling equipment and believes the product is being mislabeled. Citing US Code Title 21, Section 341, which compels the Secretary of Health and Human Services to

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establish standards of identity to promote honesty and fair dealing in the interest of consumers, we ask you to consider this issue in the same framework.

We can find no performance or nutritional basis for this petition, it stands solely on the merit of truth in labeling. As precedent, we wish to cite the "Truth in Poultry Labeling Law of 1994"; Boxer and Feinstein, as defining a term for a process which has no effect on the nutritional or performance characteristics of the product, simply the method by which it was processed, which according to the authors, was misleading the consumer.

Additionally, the recent definition of the term "organic" and how it is to be used in labeling should be cited. The term defines the level of a type of processing a good must receive in order to live up to the spirit of the law. Again, the functionality of the product is not impacted, however, the term defines how it has been processed.

Also please note the term "natural" when applied to vitamins as in the Food and Drug Act refers to products which perform and function the same as synthetic vitamins. However, to protect the consumer and maintain integrity in labeling, the vitamins are differentiated based on derivation.

Finally, the phrase "made in America" defines the percentage of a good which must be manufactured or assembled in the US to carry this phrase on its label. Again, no effect or impact on the performance of the product, simply an issue of truth in labeling.

C. Environmental Impact Statement: Citing 21 CFR Subpart C Section 25.32a, this petition is for the issuance of a food standard and therefore not subject to the requirement to file an Environmental Assessment or Environmental Impact Statement.

Thank you in advance for considering this issue. The undersigned certifies that, to the best of his knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Also please find enclosed the letter sent to the Department of Public Health for your review as well. Thank you for your time and consideration, we look forward to your reply.

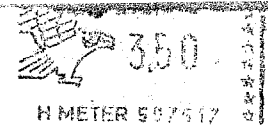
Sincerely,

AT
D. Butler

Bob Goldstein, V.P. of Production
Hodgson Mill
1203 Niccum Ave.
Effingham, IL 62401

217-347-0105 or 1-800-525-0177 Ext. 242

KUP CALL 1-800-222-1811



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2. PAYMENT METHOD

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3. ATTACH LABEL (if provided)

Remove label backing and adhere over customer address block area (white area).



HODGSON MILL, INC.
1203 Niccum Avenue
Effingham, Illinois 62401

TO:

Food and Drug Administration
Dockets Management Beach
Room 10-61 5630 Fisher Lane
Rockville, MD 20857

ATT

Jennie Butler