



0454 '03 JUN 28 10:19

**Date:** January 20, 2003

**To:** Alayson L. Saben

**From:** Bob Goldstein

**RE: Petition for Reconsideration  
Docket # 01P-0290/CP 1**

Based on conversations and correspondence with the Regulatory Affairs department of the FDA, we respectfully petition for reconsideration of establishing a standard of identity for the term stone ground used in labeling. Using the guidelines of 21 CFR 10.33, following are the grounds on which we would like you to reconsider:

**Decision Involved:** "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". From correspondence with Mr. Dennis E. Baker, Associate Commissioner for Regulatory Affairs, Department of Health and Human Services, FDA.

**Action Requested:** Review the consumer survey information in response to the observation by Mr. Baker above.

**Statement of Grounds:**

Based on the deficiency in the petition noted by Mr. Baker, a consumer survey was conducted to support the claim. In a survey of 567 respondents, over 86% consider a flour or meal labeled as "Stone Ground" to have been primarily or solely processed on grinding stones as opposed to conventional milling equipment. Additionally, 68.8% of respondents consider the stone grinding process to give less refinement to the flour or meal they are purchasing and 71.8% of respondents seek foods with lower levels of refinement. Finally, 94.5 % of respondents believe that the level of refinement affects the value of the product.

01P-0290

PRC1



The survey demonstrates that the consumers select foodstuffs based on the method of processing and consider the effects of processing as part of the value in the foodstuff. Truthful labeling is the means to communicate this information to the consumer. Therefore, we respectfully submit this request for re-consideration of the petition for a standard of identity for stone ground.

Thank you,

A handwritten signature in black ink, appearing to read "Bob Goldstein", written in a cursive style.

**Bob Goldstein**  
**1203 Niccum Ave.**  
**Effingham IL 62401**  
**217-347-0105**



January 20, 2003

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 <greek-m>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 <greek-a>-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 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 is 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 and Environmental Assessment or Environment 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,

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

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



**To: Alayson L. Saben**

**From: Bob Goldstein**

**Date: January 20, 2003**

**RE: Response on letter from FDA**

**Alayson**

**Enclosed is a copy of correspondence we have sent to the FDA in the past year. Included is a response from Dennis E Baker returned back to Hodgson . Mill. Please look over all the Information including the Pictures and analytical data sent out to there customers which includes the Term; (Stone Ground).**

**There is individual survey information available if needed.**

**I was asked to send you this information along with the survey material to resubmit Our petition to establish a Standard of Identity for the Term (Stone Ground).**

**I would like to here your thoughts on this matter.**

**My Phone # is 1-800-525-0177**

**Thanks**

**Bob Goldstein  
V.P. production  
Hodgson Mill**

# Result Summary

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## 1. Hodgson Mill Stone Ground Survey

1. Do you purchase or consume wheat flour or corn flour/meal?			Response Percent	Response Total
Yes			93.63%	529
No			6.73%	38
<b>Total Respondents</b>				567
Skipped				0

2. Have you ever heard of the term "stone ground"?			Response Percent	Response Total
Yes			99.82%	564
No			0.53%	3
<b>Total Respondents</b>				567
Skipped				0

3. Would you consider stone ground flour/meal and flour/meal conventionally milled on steel roller or hammer mills to have received the same level of refinement?			Response Percent	Response Total
Yes			31.5%	178
No			68.85%	389
<b>Total Respondents</b>				567
Skipped				0

4. When you hear the term "stone ground" flour/meal, do you consider the flour/meal to be:			Response Percent	Response Total
Processed from whole grain to flour/meal using grinding stones only.			52.92%	299
Processed from whole grain to flour/meal primarily using grinding stones.			33.81%	191
Processed from whole grain to flour/meal using grinding stones only to "scuff" the			8.85%	50

outer seed coat.			
Passing the whole grain through a room containing grinding stones.		4.78%	27
<b>Total Respondents</b>			567
Skipped			0

**5. If purchasing a product labeled as "stone ground," would you expect it to have been processed:**

		Response Percent	Response Total
Using a conventional milling system to process the grain		6.73%	38
Using grinding stones to process the grain		93.63%	529
<b>Total Respondents</b>			567
Skipped			0

**6. Do you seek food products with higher or lower levels of refinement?**

		Response Percent	Response Total
Higher		28.5%	161
Lower		71.86%	406
<b>Total Respondents</b>			567
Skipped			0

**7. Do you believe the level of refinement has an effect on the value of the product?**

		Response Percent	Response Total
Yes		94.51%	534
No		5.84%	33
<b>Total Respondents</b>			567
Skipped			0

**8. Your Email Address:**

		Response Percent	Response Total
<b>View</b>		100%	567
<b>Total Respondents</b>			567
Skipped			0

**9. First Name:**

		Response Percent	Response Total
<b>View</b>		100%	567



		<b>Total Respondents</b>	567
		Skipped	0
<b>10. Last Name:</b>			
		<b>Response Percent</b>	<b>Response Total</b>
<b>View</b>		100%	566
		<b>Total Respondents</b>	566
		Skipped	0
<b>11. Mailing Address:</b>			
		<b>Response Percent</b>	<b>Response Total</b>
<b>View</b>		100%	566
		<b>Total Respondents</b>	566
		Skipped	0
<b>12. City:</b>			
		<b>Response Percent</b>	<b>Response Total</b>
<b>View</b>		100%	565
		<b>Total Respondents</b>	565
		Skipped	0
<b>13. State:</b>			
		<b>Response Percent</b>	<b>Response Total</b>
<b>View</b>		100%	567
		<b>Total Respondents</b>	567
		Skipped	0
<b>14. Zip or Postal Code:</b>			
		<b>Response Percent</b>	<b>Response Total</b>
<b>View</b>		100%	567
		<b>Total Respondents</b>	567
		Skipped	1

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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,

A handwritten signature in black ink, appearing to read "Mark G. Peterson", is written over a horizontal line.

Mark G. Peterson, Investigator

25 June, 2001

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

#### CITIZEN PETITION

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

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**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

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 is 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.

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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,

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

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



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



Food and Drug Administration  
Rockville MD 20857

*Response  
DEC 31st 2001*

July 02, 2001

Bob Goldstein  
Hodgson Mill  
1203 Niccum Avenue  
Effingham, IL 62401

Dear Mr. Goldstein:

Your petition requesting the Food and Drug Administration to define the term "stone ground" for wheat flour was received by this office on 06/29/01. It was assigned docket number 01P-0290/CP 1 and it was filed on 07/02/01. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Jennie C. Butler  
Dockets Management Branch

*Takis 180 DAY'S*

*Jennie Butler*

*1-301-827-6860*



TO: Jennie Butler  
FROM: Bob Goldstein  
DATE: June 18<sup>th</sup> 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

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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



DEC 17 2001

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

Re: Docket Number 01P-0290/CP 1

Dear Mr. Goldstein:

This letter is in response to your citizen petition dated June 18, 2001, which was received and filed on June 29, 2001, under Docket Number 01P-0290/CP1. You requested that the Food and Drug Administration amend its current regulations to establish a standard of identity for the term "stone ground" as applied to wheat flour.

In accordance with 21 CFR 10.30(e)(2), this letter is to advise you that we have not been able to reach a decision on your petition within the first 180 days of its receipt because of other agency priorities and limited availability of resources. The Center for Food Safety and Applied Nutrition (CFSAN) is in the process of finalizing priorities for 2002 to make the most efficient use of available resources, i.e., "CFSAN Program Priorities." While the Center's priorities are focused on food safety, and now, after the September 11 terrorist attacks, with counter-terrorism, it is unlikely that your petition will be placed on CFSAN's 2002 Program Priorities. However, we are committed to making progress in other areas, such as labeling, and hope to address your petition as our resources allow.

Sincerely yours,

A handwritten signature in cursive script that reads "Christine Taylor".

Christine Lewis Taylor, Ph.D.  
Director  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition



Copy sent again

1-24-02

Dear Mr. Harrison:

I am writing to follow up our phone conversation of Monday 17 December regarding the issue of "stone-ground" flour and seeking enforcement of the Truth in Labeling Act. As I stated then, we believe the term is currently being used on flour products that are merely brought into proximity of the millstones while actually being processed on conventional milling equipment. Our contention is that if a product is labeled "stone-ground," it must be primarily processed on millstones. For example, the *Encarta World English Dictionary* defines stone-ground as, "ground in the traditional way with millstones rather than with metal rollers".

In our experience, consumers typically pay a premium for what is represented as a product processed by this specific, well-defined method. If the product is processed no differently than the discount flour, bread, or retail mix on the adjacent shelf, the label is false, and the consumer has not received value for his investment. As you would expect, the flour so labeled goes into many consumer goods and the impact downstream in the consumer market is substantial. We believe the consumer is entitled to a truthful label.

Ms. Geraldine June, Team Leader for Conventional Foods Team, Division of Standards and Labeling Regulations, Office of Natural Products and Labeling and Dietary Supplements of the Food and Drug Administration, asked us to contact your department regarding this matter. We have filed a petition with FDA to create a Standard of Identity for the term Stone Ground but due to the tragedy of 11 September their office is overwhelmed with agri-terrorism issues. Ms. June advised us that this issue may be resolved through enforcement of existing statutes. We have agreed to keep the petition in place but dormant while exploring this opportunity to enforce the Truth in Labeling Act. Hence we seek your help. I believe Ms. Martha Roberts of the Florida Department of Agriculture has also been in contact with you, as they are seeing a disturbing increase in label misrepresentation and have offered support for this cause, since they regard this trend as one that needs correction.

Please find enclosed the materials you requested: 1) a copy of the original petition to FDA, and 2) packaging from the flour with names of the manufacturers. We believe that the facilities producing the flour in question are: ConAgra, 145 W. Broadway, Alton, IL 62002 tel: 618-463-4411; Bay State Milling, 55 Franklin St., Winona, MN 55987 tel: 507-452-1770; and Cargill Inc., 15407 McGinty Rd., Wayzata, MN 55391 tel: 952-742-7575 (corporate offices). To aid the investigation, I offer the name of Dr. Jeff Gwartz, Assistant Professor, Department of Grain Science, Kansas State University, Manhattan, KS, Tel: 785-532-5320 as a technical resource. Dr. Gwartz may be able to provide technical guidance to differentiate between the equipment needed to conventionally process whole wheat flour and that needed for processing stone ground whole wheat flour. Dr. Gwartz's expertise comes from many years in academia and industry; he will be able to provide a neutral opinion for you.

Please let us know if we can be of service in any manner. Thank you for your help. I have been assured this matter will be treated in utmost confidence, and I trust that confidence will be maintained. We look forward to your response.

Sincerely,

A handwritten signature in black ink, appearing to read "Bob Soldat". The signature is written in a cursive style with a long horizontal flourish extending to the right.

ATT

Gerodine

June

From BM Solent

1-800-525-0177

Faxed & she called back

6-24-02.

3:15



Fared  
624-02  
3:42 PM

Include clause of confidentiality

Food and Drug Administration  
300 South Riverside Plaza  
Suite 550 South  
Chicago Illinois  
60606

ATT

Dear Mr. Harrison:

← Geraldine June

I am writing to follow up our phone conversation of Monday 17 December regarding the issue of defining the term "Stone Ground" for flour, either by publishing a Standard of Identity or Truth in Labeling enforcement. As we discussed, we believe the term is currently being used on products that are merely brought into proximity of the stone milling wheel and then processed on conventional milling equipment. While studies have not indicated a nutritional or performance difference, consumers typically pay a premium for what is represented as a product processed in the old fashioned method when indeed it is processed no differently than the discount flour, bread, or retail mix on the adjacent grocer's shelf. As you would expect, the raw flour so labeled goes into many consumer goods and the impact downstream in the consumer market is substantial. We believe the consumer deserves better information.

Ms. Geraldine June, Team Leader for Conventional Foods Team, Division of Standards and Labeling Regulations, Office of Natural Products and Labeling and Dietary Supplements of the Food and Drug Administration, asked us to contact your department regarding this matter. We have filed a petition with FDA to create a Standard of Identity for the term Stone Ground but due to the tragedy of 11 September their office is overwhelmed with agri-terrorism issues. Ms. June advised us that this issue may be resolved through enforcement of current statutes. We have agreed to keep the petition in place but dormant while exploring this opportunity to clarify the term and enforce the Truth in Labeling Act. Hence we seek your help and guidance. I believe Ms. Martha Roberts of the Florida Department of Agriculture has also been in contact with you as they are seeing a disturbing increase in label misrepresentation and have offered support for this cause feeling it has merit.



Please find enclosed the materials we discussed: a copy of the original petition to FDA and packaging from the suspect flour with names of the manufacturers. We believe that the facilities themselves are located in ConAgra, 145 W. Broadway, Alton, IL 62002 tel: 618-463-4411; Bay State Milling, 55 Franklin St., Winona, MN 55987 tel: 507-452-1770; and Cargill Inc., 15407 McGinty Rd., Wayzata, MN 55391 tel: 952-742-7575 (corporate offices). Additionally, to aid the investigation, I would like to offer the name of Dr. Jeff Gwartz, Assistant Professor, Department of Grain Science, Kansas State University, Manhattan, KS, Tel: 785-532-5320 as a technical resource. Dr. Gwartz may be able to provide technical guidance to differentiate the equipment needed to conventionally process whole wheat flour and that needed for processing stone ground whole wheat flour. Dr. Gwartz's expertise comes from many years in academia and industry and can provide a neutral opinion for you.

Please let us know if we can be of service in any manner. Thank you for your consideration of this matter, I look forward to your response.

Sincerely,

Bob Goldstein  
V. P. Production





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.~~

Rick -  
Do you want to keep  
this, John & I have talked.

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,



Dennis E. Baker  
Associate Commissioner  
for Regulatory Affairs

301-827-301

signature #

John  
Rozzilli

301-827-7

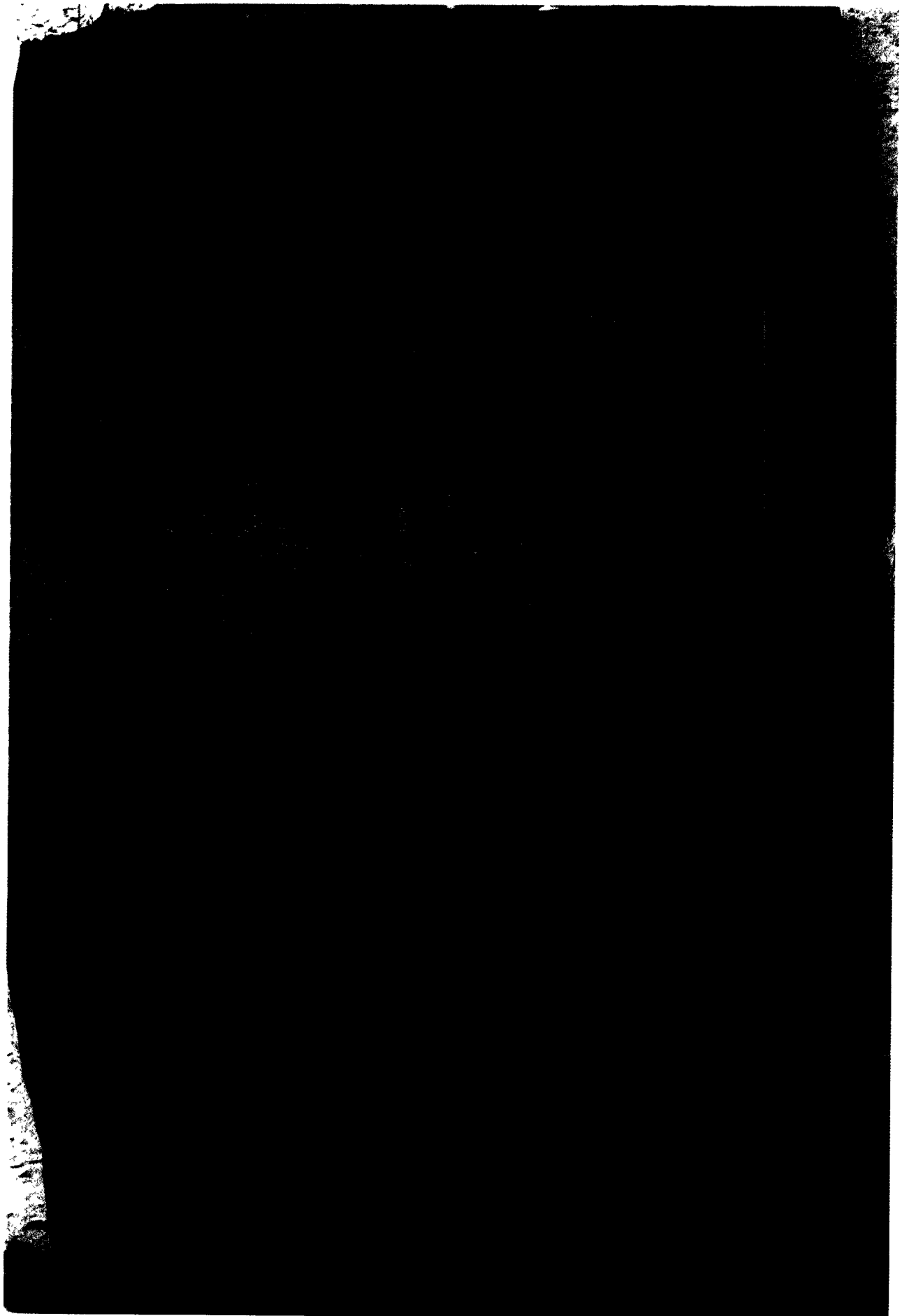
5600 Fingers Lane

HCC-1 Room -- 70

John Taylor

Rockville MD

20051





# BAY STATE MILLING COMPANY

P.O.Box 188, Winona, MN 55987 Phone (507) 452-1770 Fax (507) 452-0247

## Certificate Of Analysis

Reported on 14% Moisture Basis

MAR-21-01

**COPY TO:**  
ATTN: SANDY  
CHICAGO SWEETENERS  
FAX: 1 (847) 299-1669

**CUSTOMER (45460) :**  
CHICAGO SWEETENERS  
C/O OAKLEY WHSE  
2234 W 43RD ST  
CHICAGO, IL 60609

**ORDER NO. : 29313**  
**CUST. P.O. : 75293**  
**CAR/TRUCK NO: LTC(RTL)U36587**  
**DATE SHIPPED : MAR-20-01**

### Analytical Results

#### 815500 WINONA UNBRO (50LB)

DATE CODE W031901  
LABORATORY NO. 13314

Moisture 14.0  
Ash .51  
Protein 12.7  
Modified Amylograph 240

Absorption 64.3  
Peak 7.5  
MTI 30  
Stability 13.0

#### 710000 WINGOLD BAKERS (100#)

DATE CODE W031901  
LABORATORY NO. 13307

Moisture 13.7  
Ash .44  
Protein 12.2  
Modified Amylograph 235

Absorption 63.4  
Peak 6.5  
MTI 25  
Stability 14.0

*Office - Terry Stelloic*

*Produced AT Winner.*

#### 691000 WHOLE WHEAT FINE (50LB)

DATE CODES W031501 W031901  
LABORATORY NO. 13152 13304

Moisture 13.0  
Ash 1.62  
Protein 14.6

13.4  
1.60  
14.5

17

THE BREAD BOOKS

# PROGRESSIVE BAKER

WHOLE WHEAT FLOUR

THE BREAD BOOKS  
WHOLE WHEAT FLOUR



THE BREAD BOOKS  
WHOLE WHEAT FLOUR



# PRODUCT SPECIFICATION

**CARGILL FOODS**  
**FLOUR MILLING DIVISION**  
Mankato Flour Mills  
200 N RIVERFRONT DRIVE  
MANKATO MN 56001  
Phone (507) 388-1679

Spec Code: MK0113  
Prepared by: Deanna Konkol  
Revision Date: 09/01/01

**Product Name:** PROGRESSIVE BAKER STONE GROUND FINE WHOLE WHEAT

**Product Description:** This product is prepared by grinding cleaned hard wheat, other than durum wheat and red durum wheat that, when tested by the prescribed method [C.F.R. Title 21, Part 137.200 (c) (2)], not less than 90 percent will pass through a 2.36 mm (No. 8) sieve and not less than 50 percent will pass through a 850 um (No. 20) sieve. The proportions of the natural constituents of such wheat, other than moisture, remain unaltered. This product is prepared, processed, and packaged under modern sanitary conditions in accordance with the FDA, and will comply with all FDA regulations as amended.

**Ingredient Declaration** Wheat Flour

**Analytical Specification:**

Standard

Moisture % 13.0 max.  
Ash % 1.8 max.  
Protein % 14.0 min.

**Granulation:**

18W 0.2% max.  
30W 2.5% max.  
40W 4.0-15.0%  
70W 45.0% max.  
Pan 45.0% min.

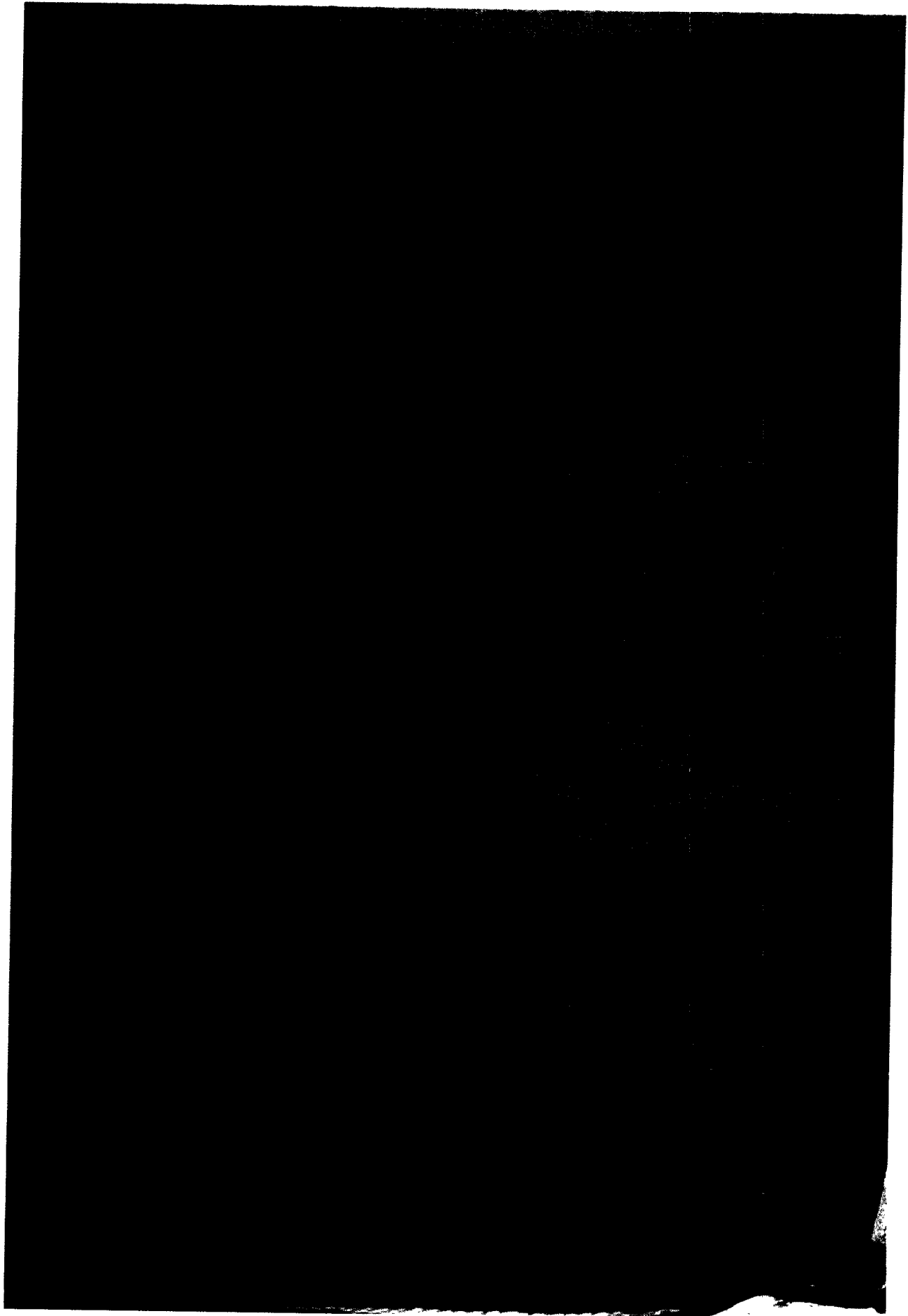
1 Minute/Rotap with knocker

**Extraneous Matter:** This product is in compliance with current regulatory requirements and does not exceed the defect action levels established by the U.S. Food and Drug Administration.

**Kosher Status:** Kashruth certification by "Union of Orthodox Jewish Congregations of America"

**Optimum Storage & Handling** Product should be kept stored in a clean dry place that is well ventilated. Product should be used within six months and kept at 70 degrees or less at low humidity.

**Crop Year:** This specification is pertinent to the current crop year characteristics and must be reviewed and updated with each new crop year.





# CERTIFICATE OF ANALYSIS

To: HODGSON Mills  
1203 Niccum Ave  
EPPINGHAM IL 62407

Date Shipped: 4-24-01  
Brand: WHOLEWHEAT MEDIUM  
Car or Truck: 501B BAG  
Mill: ALTON

### ANALYSIS (14% Moisture Basis)

Moisture: 12.2 %  
Ash: 1.62 %  
Protein: 14.2 %  
Falling No: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

### GRANULATION

On US #20: 6.9 %  
On US #30: \_\_\_\_\_ %  
On US #40: 18.1 %  
On US #60: 19.7 %  
On US #80: 58.2 %  
On US #100: \_\_\_\_\_ %  
Thru US #100: 58.9 %  
41.2 %

Signed: Big Helen

WE GROW WITH FOOD

\*\* TOTAL PAGE 01 \*\*

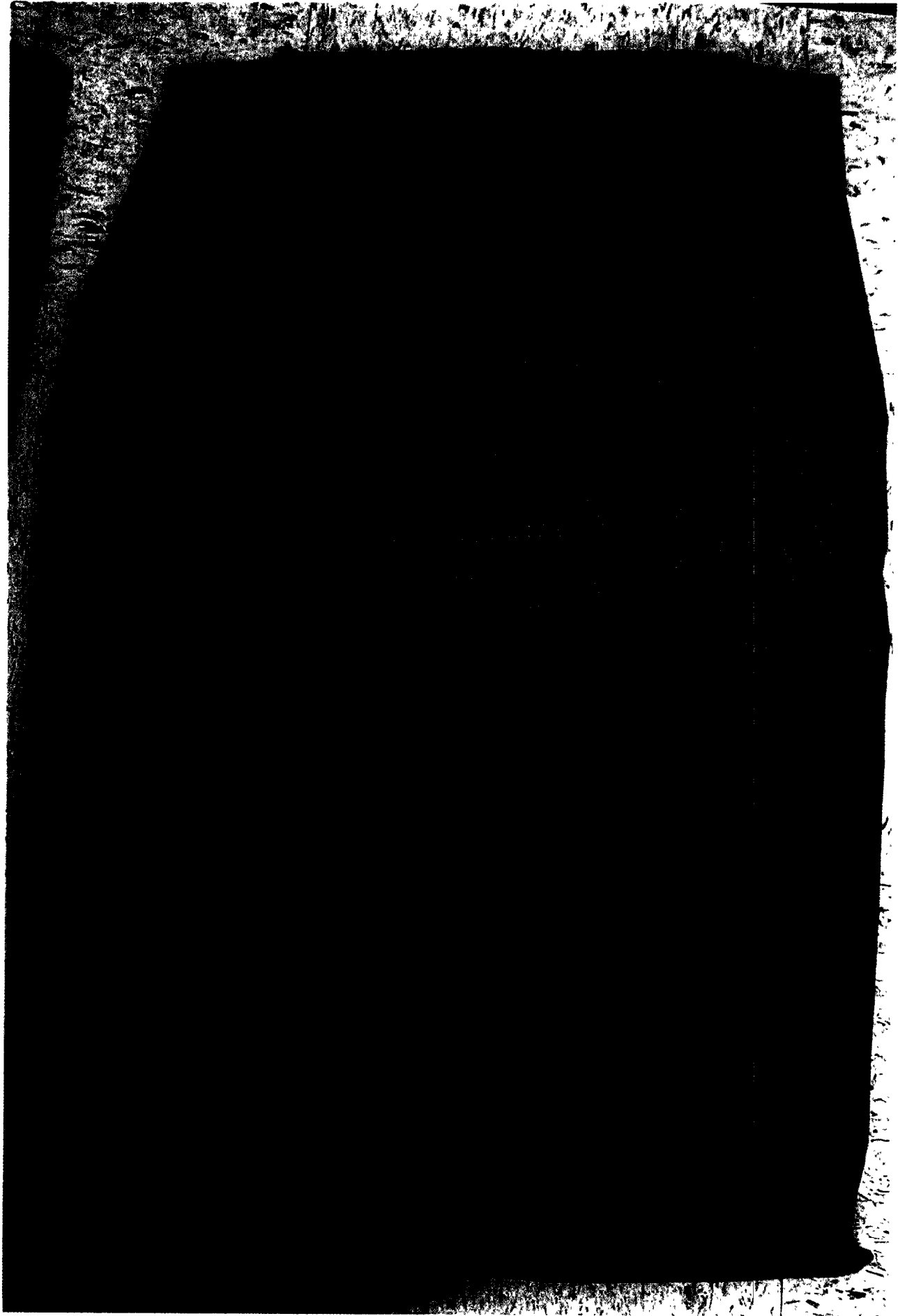
PS-1142 (1-00)

Handwritten notes: *Bag To*, *samples sent*, *F.D.A.*

**STARLIX**  
(nateglinide) 120 mg LC

Post-It® Fax Note	7671	Date	4-25	# of pages	2
To	BOB GOLDSTEIN	From	JAN		
Co./Dept	HODGSON	Co.	CONNELL		
Phone #		Phone #			
Fax #	217 247-0198	Fax #			





01/22/03	13:01	CONNEL PURCHASING → HODGSON EFFINGH	NO. 081	001
		913 491 9610		
01/22/2003	12:18	ADM MILLING CO → 16305799123	NO. 692	001
01/22/2003	12:06	ADM MILLING → 4919610	NO. 623	003



ADM MILLING COMPANY MINNEAPOLIS MILL 333 MAIN ST. SE MINNEAPOLIS, MN 55414-2107 TELEPHONE 612-407-1000

**ADM MILLING FLOUR SPECIFICATION**

**ADM STONEGROUND WHOLE WHEAT MEDIUM  
P.C 3890**

**CHEMICAL & PHYSICAL PROPERTIES**

<b>MOISTURE</b>	<b>14.00% MAXIMUM</b>
<b>ASH</b>	<b>1.70% MAXIMUM</b>
<b>PROTEIN</b>	<b>14.00% MINIMUM</b>

**GRANULATION**

ON USBS#20 - .75+/- .25  
 ON USBS#40 - 11.0+/- 1.0  
 ON USBS#60 - 25.5+/- 1.5  
 ON USBS#100 - 24.0+/- 1.5  
 THRU - 38.5+/- 1.5

<b>INGREDIENTS:</b>	<b>HARD SPRING WHEAT</b>
<b>PACKAGING:</b>	<b>50/100 LB. MULTIWALL BAGS</b>

**FOR INFORMATION AND PRICING**

Post-It® Fax Note	7871	Date	1/22/03	# of pages	1
To	Jan / BOB G.	From	Kent Lyman		
Co./Dept.	Connell	Co.	ADM		
Phone #		Phone #	913-491-9400		
Fax #	630-579-9123	Fax #	913-491-9610		