

Food and Drug Administration, HHS

§ 101.70

(Date) _____
Name of petitioner _____
Post office address _____
Subject of the petition _____
Office of Nutritional Products, Labeling and
Dietary Supplements (HFS-800),
Food and Drug Administration,
Department of Health and Human Services,
Washington, DC 20204.

To Whom It May Concern:
The undersigned, _____ sub-
mits this petition under section 403(r)(4) of
the Federal Food, Drug, and Cosmetic Act
(the act) with respect to (statement of the
implied nutrient content claim and its pro-
posed use in a brand name).

Attached hereto and constituting a part of
this petition, are the following:

A. A statement identifying the implied nu-
trient content claim, the nutrient the claim
is intended to characterize, the cor-
responding term for characterizing the level
of such nutrient as defined by a regulation
under section 403(r)(2)(A)(i) of the act, and
the brand name of which the implied claim is
intended to be a part. The statement should
address why the use of the brandname as pro-
posed will not be misleading. It should ad-
dress in particular what information is re-
quired to accompany the claim or other ways
in which the claim meets the requirements
of sections 201(n) and 403(a) of the act. The
statement should provide examples of the
types of foods on which the brand name will
appear. It shall also include data showing
that the actual level of the nutrient in the
food qualifies the food to bear the cor-
responding term defined by regulation. Assay
methods used to determine the level of a
nutrient should meet the requirements
stated under petition format item C in para-
graph (k)(1) of this section.

B. A detailed explanation, supported by
any necessary data, of why use of the pro-
posed brand name is requested. This item
shall also state what nutritional benefit to
the public will derive from use of the brand
name as proposed. If the branded product is
intended for a specific group within the pop-
ulation, the analysis should specifically ad-
dress nutritional needs of such group and
should include scientific data sufficient for
such purpose.

C. The petitioner is required to submit ei-
ther a claim for categorical exclusion under
§ 25.30 or § 25.32 of this chapter or an environ-
mental assessment under § 25.40 of this chap-
ter.

Yours very truly,
Petitioner _____
By _____

(2) Within 15 days of receipt of the peti-
tion the petitioner will be notified by
letter of the date on which the petition
was received. Such notice will inform
the petitioner:

(i) That the petition is undergoing
agency review (in which case a docket
number will be assigned to the peti-
tion); or

(ii) That the petition is incomplete,
e.g., it lacks any of the data required
by this part, it presents such data in a
manner that is not readily understood,
or it has not been submitted in quadru-
plicate, in which case the petition will
be denied, and the petitioner will be
notified as to what respect the petition
is incomplete.

(3) FDA will publish a notice of the
petition in the FEDERAL REGISTER an-
nouncing its availability to the public
and seeking comment on the petition.
The petition shall be available to the
public to the extent provided under
paragraph (g) of this section. The no-
tice shall allow 30 days for comments.

(4) Within 100 days of the date of re-
ceipt of the petition that is accepted
for review (i.e., that has not been found
to be incomplete and subsequently re-
turned to the petitioner), FDA will:

(i) Notify the petitioner by letter of
the agency's decision to grant the peti-
tioner permission to use the proposed
brand name if such use is not mis-
leading, with any conditions or limita-
tions on such use specified; or

(ii) Deny the petition, in which case
the letter shall state the reasons there-
for. Failure of the petition to fully ad-
dress the requirements of this section
shall be grounds for denial of the peti-
tion. Should FDA not notify the peti-
tioner of his decision on the petition
within 100 days, the petition shall be
considered to be granted.

(5) As soon as practicable following
the granting of a petition, the Commis-
sioner of Food and Drugs will publish a
notice in the FEDERAL REGISTER in-
forming the public of such fact.

[58 FR 2413, Jan. 6, 1993; 58 FR 17343, Apr. 2,
1993, as amended at 58 FR 44033, Aug. 18, 1993;
62 FR 40598, July 29, 1997; 63 FR 26718, May 14,
1998; 63 FR 40024, July 27, 1998; 67 FR 9585,
Mar. 4, 2002; 69 FR 16481, Mar. 30, 2004]

**Subpart E—Specific Requirements
for Health Claims**

§ 101.70 Petitions for health claims.

(a) Any interested person may peti-
tion the Food and Drug Administration
(FDA) to issue a regulation regarding a

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health claim. An original and one copy of the petition shall be submitted, or the petitioner may submit an original and a computer readable disk containing the petition. Contents of the disk should be in a standard format, such as ASCII format. (Petitioners interested in submitting a disk should contact the Center for Food Safety and Applied Nutrition for details.) If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall state the petitioner's post office address to which any correspondence required by section 403 of the Federal Food, Drug, and Cosmetic Act may be sent.

(b) Pertinent information may be incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of FDA. Such information may include any findings, along with the basis of the findings, of an outside panel with expertise in the subject area. Any reference to published information shall be accompanied by reprints, or easily readable copies of such information.

(c) If nonclinical laboratory studies are included in a petition, the petition shall include, with respect to each nonclinical study contained in the petition, either a statement that the study has been conducted in compliance with the good laboratory practice regulations as set forth in part 58 of this chapter, or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(d) If clinical or other human investigations are included in a petition, the petition shall include a statement that they were either conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter, or were not subject to such requirements in accordance with §56.104 or §56.105, and a statement that they were conducted in compliance with the requirements for informed consent set forth in part 50 of this chapter.

(e) All data and information in a health claim petition are available for public disclosure after the notice of filing of petition is issued to the peti-

tioner, except that clinical investigation reports, adverse reaction reports, product experience reports, consumer complaints, and other similar data and information shall only be available after deletion of:

(1) Names and any information that would identify the person using the product.

(2) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(f) Petitions for a health claim shall include the following data and be submitted in the following form:

(Date) _____
Name of petitioner _____
Post office address _____
Subject of the petition _____
Food and Drug Administration,
Office of Nutritional Products, Labeling and
Dietary Supplements (HFS-800),
5100 Paint Branch Pkwy.,
College Park, MD 20740,

The undersigned, _____ submits this petition pursuant to section 403(r)(4) or 403(r)(5)(D) of the Federal Food, Drug, and Cosmetic Act with respect to (statement of the substance and its health claim).

Attached hereto, and constituting a part of this petition, are the following:

A. Preliminary requirements. A complete explanation of how the substance conforms to the requirements of §101.14(b) (21 CFR 101.14(b)). For petitions where the subject substance is a food ingredient or a component of a food ingredient, the petitioner should compile a comprehensive list of the specific ingredients that will be added to the food to supply the substance in the food bearing the health claim. For each such ingredient listed, the petitioner should state how the ingredient complies with the requirements of §101.14(b)(3)(ii), e.g., that its use is generally recognized as safe (GRAS), listed as a food additive, or authorized by a prior sanction issued by the agency, and what the basis is for the GRAS claim, the food additive status, or prior sanctioned status.

B. Summary of scientific data. The summary of scientific data provides the basis upon which authorizing a health claim can be justified as providing the health benefit. The summary must establish that, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), there is

significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

The summary shall state what public health benefit will derive from use of the claim as proposed. If the claim is intended for a specific group within the population, the summary shall specifically address nutritional needs of such group and shall include scientific data showing how the claim is likely to assist in meeting such needs.

The summary shall concentrate on the findings of appropriate review articles, National Institutes of Health consensus development conferences, and other appropriate resource materials. Issues addressed in the summary shall include answers to such questions as:

1. Is there an optimum level of the particular substance to be consumed beyond which no benefit would be expected?
2. Is there any level at which an adverse effect from the substance or from foods containing the substance occurs for any segment of the population?
3. Are there certain populations that must receive special consideration?
4. What other nutritional or health factors (both positive and negative) are important to consider when consuming the substance?

In addition, the summary of scientific data shall include a detailed analysis of the potential effect of the use of the proposed claim on food consumption, specifically any change due to significant alterations in eating habits and corresponding changes in nutrient intake resulting from such changes in food consumption. The latter item shall specifically address the effect on the intake of nutrients that have beneficial and negative consequences in the total diet.

If the claim is intended for a significant subpopulation within the general U.S. population, the analysis shall specifically address the dietary practices of such group, and shall include data sufficient to demonstrate that the dietary analysis is representative of such group (e.g., adolescents or the elderly).

If appropriate, the petition shall explain the prevalence of the disease or health-related condition in the U.S. population and the relevance of the claim in the context of the total daily diet.

Also, the summary shall demonstrate that the substance that is the subject of the proposed claim conforms to the definition of the term "substance" in §101.14(a)(2).

C. Analytical data that show the amount of the substance that is present in representative foods that would be candidates to bear the claim should be obtained from representative samples using methods from the AOAC INTERNATIONAL (AOAC), where available. If no AOAC method is available, the petitioner shall submit the assay method used and data establishing the validity of the

method for assaying the substance in food. The validation data should include a statistical analysis of the analytical and product variability.

D. Model health claim. One or more model health claims that represent label statements that may be used on a food label or in labeling for a food to characterize the relationship between the substance in a food to a disease or health-related condition that is justified by the summary of scientific data provided in section C of the petition. The model health claim shall include:

1. A brief capsulized statement of the relevant conclusions of the summary, and
2. A statement of how this substance helps the consumer to attain a total dietary pattern or goal associated with the health benefit that is provided.

E. The petition shall include the following attachments:

1. Copies of any computer literature searches done by the petitioner (e.g., Medline).
2. Copies of articles cited in the literature searches and other information as follows:
 - a. All information relied upon for the support of the health claim, including copies of publications or other information cited in review articles and used to perform meta-analyses.
 - b. All information concerning adverse consequences to any segment of the population (e.g., sensitivity to the substance).
 - c. All information pertaining to the U.S. population.

F. The petitioner is required to submit either a claim for categorical exclusion under §25.30 or §25.32 of this chapter or an environmental assessment under §25.40 of this chapter.

Yours very truly,
 Petitioner _____
 By _____
 (Indicate authority)

(g) The data specified under the several lettered headings should be submitted on separate pages or sets of pages, suitably identified. If such data have already been submitted with an earlier application from the petitioner or any other final petition, the present petition may incorporate it by specific reference to the earlier petition.

(h) The petition shall include a statement signed by the person responsible for the petition that, to the best of his/her knowledge, it is a representative and balanced submission that includes unfavorable information as well as favorable information, known to him/her to be pertinent to the evaluation of the proposed health claim.

(i) The petition shall be signed by the petitioner or by his/her attorney or agent, or (if a corporation) by an authorized official.

(j) *Agency action on the petition.* (1) Within 15 days of receipt of the petition, the petitioner will be notified by letter of the date on which the petition was received. Such notice will inform the petitioner that the petition is undergoing agency review and that the petitioner will subsequently be notified of the agency's decision to file for comprehensive review or deny the petition.

(2) Within 100 days of the date of receipt of the petition, FDA will notify the petitioner by letter that the petition has either been filed for comprehensive review or denied. The agency will deny a petition without reviewing the information contained in "B. Summary of Scientific Data" if the information in "A. Preliminary Requirements" is inadequate in explaining how the substance conforms to the requirements of §101.14(b). If the petition is denied, the notification will state the reasons therefor, including justification of the rejection of any report from an authoritative scientific body of the U.S. Government. If filed, the date of the notification letter becomes the date of filing for the purposes of this regulation. If FDA does not act within such 100 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner. A petition that has been denied, or has been deemed to be denied, without filing will not be made available to the public. A filed petition will be available to the public to the extent provided under paragraph (e) of this section.

(3) Within 90 days of the date of filing, FDA will by letter of notification to the petitioner:

(i) Deny the petition, or

(ii) Inform the petitioner that a proposed regulation to provide for the requested use of the health claim will be published in the FEDERAL REGISTER. If the petition is denied, the notification will state the reasons therefor, including justification for the rejection of any report from an authoritative scientific body of the U.S. Government. FDA will publish the proposal to amend the regulations to provide for

the requested use of the health claim in the FEDERAL REGISTER within 90 days of the date of filing. The proposal will also announce the availability of the petition for public review.

(iii) If FDA does not act within 90 days of the date of filing, the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner.

(4)(i) Within 270 of the date of publication of the proposal, FDA will publish a final rule that either authorizes use of the health claim or explains why the agency has decided not to authorize one.

(ii) For cause, FDA may extend, no more than twice, the period in which it will publish a final rule; each such extension will be for no more than 90 days. FDA will publish a notice of each extension in the FEDERAL REGISTER. The document will state the basis for the extension, the length of the extension, and the date by which the final rule will be published, which date shall be within 540 days of the date of receipt of the petition.

[58 FR 2534, Jan. 6, 1993; 58 FR 17097, Apr. 1, 1993, as amended at 59 FR 425, Jan. 4, 1994; 62 FR 28232, May 22, 1997; 62 FR 40599, July 29, 1997; 63 FR 26719, May 14, 1998; 63 FR 40024, July 27, 1998; 66 FR 56035, Nov. 6, 2001]

§ 101.71 Health claims: claims not authorized.

Health claims not authorized for foods in conventional food form or for dietary supplements of vitamins, minerals, herbs, or other similar substances:

(a) Dietary fiber and cardiovascular disease.

(b) Zinc and immune function in the elderly.

[58 FR 2534, Jan. 6, 1993, as amended at 58 FR 2548, 2578, 2620, 2639, 2664, 2714, Jan. 6, 1993; 58 FR 17100, Apr. 1, 1993; 59 FR 437, Jan. 4, 1994; 65 FR 58918, Oct. 3, 2000]

§ 101.72 Health claims: calcium and osteoporosis.

(a) *Relationship between calcium and osteoporosis.* An inadequate calcium intake contributes to low peak bone mass and has been identified as one of many risk factors in the development of osteoporosis. Peak bone mass is the