ATTACHMENT-34

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

November 29, 1993

Mr. Randal P. Schumacher
Senior Vice President
The Jefferson Group
1341 G Street, N.W.
Suite 1100
Washington, DC 20005

Dear Mr. Schumacher:

This is in response to your letter of November 19, 1993, concerning a product functioning as an anticaking agent when used in the manufacture of shredded cheese. There are four ingredients in the product, rice flour, microcrystalline cellulose, bacterial cultures, and annatto extract. You cited 21 CFR 170.6, Opinion letters on food additive status as a basis for requesting an informal opinion letter from us on the GRAS status of this product.

First of all, § 170.6 in paragraph (b) states that since enactment of the Food Additives Amendment, FDA has given opinions as to whether an article is a food additive, GRAS, prior-sanctioned or not a food additive. § 170.6 nevertheless in paragraph (d) states that because of the time span involved with the letters and loss of the letters in our file, these food additive status opinions are to be revoked. Since FDA established the GRAS affirmation procedure in § 170.35 in 1972, we have stopped rendering an advisory opinion on the GRAS status of a substance that FDA has not previously evaluated other than in response to a GRAS affirmation petition.

However, we are always willing to offer our interpretation of the current GRAS and food additive regulations with respect to whether a specific use of a substance in food is covered by an existing FDA regulation. Therefore, our interpretation regarding the regulatory status of the above four ingredients is stated below.

Although there are no regulations on rice flour, rice flour has been used as a component of many traditional foods. Microcrystalline cellulose has been used in food as an anticaking or binding agent, and is considered by many experts to be GRAS for such use. It was specifically mentioned in the old § 133.146 as one of the anticaking agents used as an optional ingredient, but the new § 133.146 has been revised to permit use of any anticaking agent without naming individual substances. Annatto extract is permitted under § 73.30 to color foods. Because there are no regulations concerning bacterial cultures, we are unable to comment on them.

If you have further questions, please feel free to contact us.

Sincerely yours,

Lawrence J. Lin

Lawrence J. Lin, Ph.D.
Biotechnology Policy Branch, HFS-206
Division of Product Policy
Center for Food Safety
and Applied Nutrition

BURDITT & RADZIUS, CHARTERED

PHILADELPHIA OFFICE
1608 WALNUT STREET
SUITE 703
PHILADELPHIA, PA 19103
TELEPHONE: (215) 772-3010
FAX: (215) 772-3017

SAN FRANCISCO OFFICE
201 SPEAR STREET
SUITE 1600
SAN FRANCISCO, CA 94105
TELEPHONE: (415) 957-0101
FAX: (415) 957-5905

WASHINGTON OFFICE
901 FIFTEENTH STREET, N.W.
SUITE 901
WASHINGTON, D.C. 20005
TELEPHONE: (202) 466-4500
FAX: (202) 466-5777

JOSEPH R. RADZIUS
(1965 - 1989)

LAW OFFICES
333 WEST WACKER DRIVE
SUITE 2600
CHICAGO, ILLINOIS 60606-1218
TELEPHONE: (312) 781-6633
FAX: (312) 781-6630

WRITER'S DIRECT LINE
(312) 781-6638

December 23, 1994

Mali Reddy, Ph.D.
International Media And Cultures
2550 Larimer Street
Denver, Colorado 80205

Dear Mali:

Thank you for sending to me a copy of FDA's November 29, 1993 letter responding to an inquiry regarding the anticaking agent which you have developed for grated cheese. Although the agency would not comment per se on the GRAS status of the finished product, three of the individual ingredients were reviewed and no objection was raised; FDA did not comment on the bacterial cultures because there were no specific regulations. With respect to the other ingredients, the agency recognized that each was either used widely in foods, recognized as GRAS or had specific regulations promulgated supporting its use in food products.

The specific question you requested that we address is whether there are any limitations to the anticaking agents which may be used in grated cheeses subject to 21 CFR § 133.146. Under the paragraph dealing with optional ingredients which permits anticaking agents, 133.146(c), the only limitation placed on such substances is that they be safe and suitable. This is consistent with a number of amendments which the agency made to standards of identity eliminating the recipe type standards and making them broader so that industry had more flexibility and alternatives in developing standardized foods.

The safe and suitable limitation is broadly defined in 21 CFR § 130.3(d) as follows:

> (d) "Safe and suitable" means that the ingredient:

> (1) Performs an appropriate function in the food in which it is used.
> (2) Is used at a level no higher than necessary to achieve its intended purpose in that food.
> (3) Is not a food additive or color additive as defined in section 201 (s) or (t) of the Federal Food, Drug, and Cosmetic Act as used in that food, or is a food additive or color additive as so defined and is used in conformity with regulations established pursuant to section 409 or 721 of the act.

Any anticaking agent which meets this definition would be appropriate for use in shredded cheese.

Another regulation which may apply is 21 CFR § 130.8(a), a copy of which is enclosed. This rule concerns ingredients which are components of ingredients that are approved for use in standardized foods. This may have no bearing on your anticaking agent but it could be useful in evaluating finished product labeling.

If you have any questions, please contact me.

Sincerely,

John F. Lemker

JFL:dll
G:\USERS\JAN\LEMKER\M-R\DLL1491

ments of part 101 of this chapter, except that where a definition and standard of identity has specific labeling provisions for optional ingredients, optional ingredients may be declared in accordance with those provisions.

[42 FR 14357, Mar. 15, 1977, as amended at 58 FR 2876, Jan. 6, 1993]

§ 130.5 Procedure for establishing a food standard.

(a) The procedure for establishing a food standard under section 401 of the act shall be governed by part 10 of this chapter.

(b) Any petition for a food standard shall show that the proposal, if adopted, would promote honesty and fair dealing in the interest of consumers.

(c) Any petition for a food standard shall assert that the petitioner commits himself to substantiate the information in the petition by evidence in a public hearing, if such a hearing becomes necessary.

(d) If a petitioner fails to appear, or to substantiate the information in his petition, at a public hearing on the matter, the Commissioner may either (1) withdraw the regulation and terminate the proceeding or (2) if he concludes that it is in accordance with the requirements of section 401 of the act, continue the proceeding and introduce evidence to substantiate such information.

[42 FR 14357, Mar. 15, 1977, as amended at 42 FR 15673, Mar. 22, 1977]

§ 130.6 Review of Codex Alimentarius food standards.

(a) All food standards adopted by the Codex Alimentarius Commission will be reviewed by the Food and Drug Administration and will be accepted without change, accepted with change, or not accepted.

(b) Review of Codex standards will be accomplished in one of the following three ways:

(1) Any interested person may petition the Commissioner to adopt a Codex standard, with or without change, by proposing a new standard or an appropriate amendment of an existing standard, pursuant to section 401 of the act. Any such petition shall specify any deviations from the Codex standard, and the reasons for any such deviations. The Commissioner shall publish such a petition in the FEDERAL REGISTER as a proposal, with an opportunity for comment, if reasonable grounds are provided in the petition. Any published proposal shall state any deviations from the Codex standard and the stated reasons therefor.

(2) The Commissioner may on his own initiative propose by publication in the FEDERAL REGISTER the adoption of a Codex standard, with or without change, through a new standard or an appropriate amendment to an existing standard, pursuant to section 401 of the act. Any such proposal shall specify any deviations from the Codex standard, and the reasons for any such deviations.

(3) Any Codex standard not handled under paragraph (b) (1) or (2) of this section may be published in the FEDERAL REGISTER for review and informal comment. Interested persons shall be requested to comment on the desirability and need for the standard, on the specific provisions of the standard, on additional or different provisions that should be included in the standard, and on any other pertinent points. After reviewing all such comments, the Commissioner either shall publish a proposal to establish a food standard pursuant to section 401 of the act covering the food involved, or shall publish a notice terminating consideration of such a standard.

(c) All interested persons are encouraged to confer with different interest groups (consumers, industry, the academic community, professional organizations, and others) in formulating petitions or comments pursuant to paragraph (b) of this section. All such petitions or comments are requested to include a statement of any meetings and discussions that have been held with other interest groups. Appropriate weight will be given by the Commissioner to petitions or comments that reflect a consensus of different interest groups.

§ 130.8 Conformity to definitions and standards of identity.

In the following conditions, among others, a food does not conform to the definition and standard of identity therefor:

(a) If it contains an ingredient for which no provision is made in such definition and standard, unless such ingredient is an incidental additive introduced at a nonfunctional and insignificant level as a result of its deliberate and purposeful addition to another ingredient permitted by the terms of the applicable standard and the presence of such incidental additive in unstandardized foods has been exempted from label declaration as provided in § 101.100 of this chapter.

(b) If it fails to contain any one or more ingredients required by such definition and standard;

(c) If the quantity of any ingredient or component fails to conform to the limitation, if any, prescribed therefor by such definition and standard.

§ 130.9 Sulfites in standardized food.

(a) Any standardized food that contains a sulfiting agent or combination of sulfiting agents that is functional and provided for in the applicable standard or that is present in the finished food at a detectable level is misbranded unless the presence of the sulfiting agent or agents is declared on the label of the food. A detectable amount of sulfiting agent is 10 parts per million or more of the sulfite in the finished food. The level of sulfite in the finished food will be determined using sections 20.123 through 20.125, "Sulfurous Acid (Total) in Food Modified Monier-Williams Method Final Action" in "Official Methods of Analysis of the Association of Official Analytical Chemists," 14th ed. (1984), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, and the refinements of the "Total Sulfurous Acid" procedure in the "Monier-Williams Procedure (with Modifications) for Sulfites in Foods," which is appendix A to part 101 of this chapter. A copy of sections 20.123 through 20.125 of the "Official Methods of Analysis of the Association of Official Analytical Chemists" is available from AOAC International, 1111 North 19th St., Suite 210, Arlington, VA 22209, or available for inspection at the Office of the Federal Register, 800 North Capitol St. NW., Suite 700, Washington, DC.

(b) Any standardized food that, as a result of actions that are consistent