



AUG 20 2001

Ruth Armstrong
302 South Street
Jonesville, Michigan 49250

Re: Docket No. 2001P-0034/CP 1

Dear Ms. Armstrong:

This letter is in response to your citizen petition, dated January 19, 2001, requesting that the Food and Drug Administration (FDA): (1) require that the presence of methylcellulose and carrageenan in food be declared on menus in restaurants, and on trains and airplanes, and (2) require that the ingredients "methylcellulose" and "carrageenan" be declared as such, rather than by terms such as "modified vegetable gum" or "carbohydrate gum."

In accordance with Title 21 of the Code of Federal Regulations (21 CFR) section 10.30(e)(3), and for the reasons stated below, this letter is to advise you that FDA is denying your petition.

First, you requested that FDA require that the presence of methylcellulose and carrageenan in food be declared on menus in restaurants, and on trains and airplanes. This request is based on your contention that foods with these ingredients have caused an adverse reaction consisting of a gelatinous diarrhea-like episode 2 to 3 hours after consumption. You further contend that avoiding these ingredients when eating out in restaurants, or during travel on trains and airplanes, is impossible because the presence of methylcellulose and carrageenan is not revealed on food menus.

FDA does not currently require the declaration of ingredients on food menus, nor does FDA believe, based on the information presently before the agency, that the absence of such declarations of methylcellulose and carrageenan on food menus renders such labeling false or misleading under the Federal Food, Drug, and Cosmetic Act (FFDCA).

The relevant labeling provisions in the FFDCA govern what information must be present in the labeling of a food. Section 403(a)(1) of the FFDCA provides that a food is deemed to be misbranded if its labeling is false or misleading in any particular. In determining whether the labeling or advertising of a food is misleading, section 201(n) of the FFDCA requires FDA to take into account "the extent to which the labeling or advertising [of a food] fails to reveal facts material in the light of . . . representations [made or suggested] or material with respect to consequences which may result from the use" of the food to which the labeling or advertising relates.

As evidenced by regulations in §§ 182.1480 and 172.620 (21 CFR 182.1480 and 172.620), FDA has previously evaluated the safety of the use of methylcellulose and carrageenan and considers these substances to be safe for use in foods within the boundaries of FDA regulations, i.e. for the intended use and conforming to the conditions described in the regulations and in accordance with good

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manufacturing practice. Methylcellulose is generally recognized as safe and is permitted for multipurpose use, including as a stabilizer and thickener in foods under § 182.1480. Carrageenan is a food additive permitted for direct addition as a stabilizer, thickener, and emulsifier in foods under § 172.620. Therefore, both methylcellulose and carrageenan are safe substances permitted for use in foods for human consumption.

You did not provide data to support your position that consumption of foods containing methylcellulose or carrageenan results in adverse reactions. From the anecdotal information provided in your petition, we were unable to conclusively determine that the adverse reactions you experienced after eating certain foods are due to the ingredients, methylcellulose or carrageenan. Given that methylcellulose and carrageenan are considered safe for use in human foods and do not present a safety concern to the general population, and in the absence of any substantiating data to support your position that these substances cause adverse reactions in certain people, FDA does not currently have a sufficient basis on which to require information about the presence of methylcellulose or carrageenan in food on menus, or on trains and airplanes.

FDA does, however, continually monitor the safety of the United States food supply. FDA encourages consumers who experience problems with an FDA-regulated product to report the problem so that we may evaluate the problem and promptly take any necessary actions. We suggest that you report any adverse reactions to foods that you consume to the FDA district office consumer complaint coordinator for the State of Michigan at (313) 393-8100. You may also visit the FDA website, <http://www.fda.gov/opacom/backgrounders/problem.html>, for information about how FDA handles adverse reactions and other problems associated with products that we regulate.

Second, you requested that FDA require that the ingredients “methylcellulose” and “carrageenan” be declared as such. Section 403(i)(2) of the FFDCFA provides that a food shall be deemed to be misbranded unless its label bears the common or usual name of each ingredient. The regulation that implements this section of the FFDCFA, 21 CFR 101.4, requires that labels of food fabricated from two or more ingredients bear a declaration of each ingredient, by its common or usual name, in descending order of predominance by weight in the ingredient statement. Under section 403(i)(2) of the FFDCFA and FDA’s ingredient labeling regulation (21 CFR 101.4), when methylcellulose and carrageenan are added to packaged foods, they are currently required to be declared in the ingredient statement of the food labels by their respective names “methylcellulose” and “carrageenan,” which are the names specified in the FDA regulations authorizing the use of these substances in food (§§ 182.1480 and 172.620, respectively). The terms “modified vegetable gum” and “carbohydrate gum” are not acceptable alternative names because they do not sufficiently describe the substances methylcellulose or carrageenan.

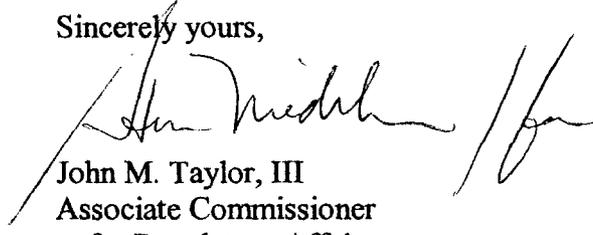
In conclusion, 1) based upon the available information and data regarding methylcellulose and carrageenan, FDA does not currently believe that a requirement that information about the presence of methylcellulose or carrageenan in food be declared on menus in restaurants, and on trains and airplanes,

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is warranted; and 2) FDA already requires that methylcellulose and carrageenan be identified by these names and not by terms such as modified vegetable gum or carbohydrate gum.

Therefore, for the reasons cited above, FDA is denying your petition.

Sincerely yours,

A handwritten signature in black ink, appearing to read "John M. Taylor, III", written over a horizontal line. The signature is cursive and includes a large flourish on the right side.

John M. Taylor, III
Associate Commissioner
for Regulatory Affairs