

Food and Drug Administration Washington, DC

JUN 1 - 4 2001

Mr. David Ritchie

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General Manager Rocky Mountain Milling Post Office Box 1110 400 Platte Street Platteville, Colorado 80651

Dear Mr. Ritchie:

This is in reply to your letter to Mr. Henry Kim of the Office of Plant and Dairy Foods and Beverages, dated August 20, 1997, which was forwarded to the Office of Nutritional Products, Labeling and Dietary Supplements, formerly the Office of Food Labeling, for reply.

You asked what effect the Nutrition Labeling and Education Act of 1990 has on Federal preemption of State and local laws for products having a standard of identity. Further, you expressed concern regarding the legality of selling unenriched flour in certain States.

Section 403(a)(1) of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 343-l(a)(1)) preempts any State and local requirement for a food in interstate commerce that is not identical to the Federal standard of identity for that food. We understand this provision to mean that a State or local regulation may not preclude or prohibit the sale of food in interstate commerce that conforms to a Federal standard of identity. FDA has established several standards of identity for unenriched flour products. For example, the standard of identity for whole wheat flour is found at 21 CFR 137.200. Accordingly, the Agency believes that State and local requirements precluding or prohibiting the sale of whole wheat flour in interstate commerce that conforms to this standard of identity would be preempted under section 403A(a)(1) of the act.

However, the Agency does not determine which State and local laws are preempted under section 403A(a)(1) of the act. The courts make those determinations. Also, we do not monitor which State or local laws the courts have held are preempted under section 403A(a)(1) of the act. We are aware that some States have amended their regulations to be consistent with the provisions of the act, or regulations issued under the act, that are given preemptive effect by section 403A(a)(1) of the act.

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We recommend that you contact the appropriate regulatory officials in each State where you plan to market your flour products to ensure that your product complies with applicable State laws.

We hope this information is helpful. Please contact us if we may be of further assistance.

Sincerely yours,

Geraldine A. June

Acting Team Leader

Division of Standards

and Labeling Regulations

Office of Nutritional Products, Labeling

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and Dietary Supplements

Center for Food Safety

and Applied Nutrition