



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA-2012-F-0480]

Gruma Corporation, Spina Bifida Association, March of Dimes Foundation, American Academy of Pediatrics, Royal DSM N.V., and National Council of La Raza; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Gruma Corporation, Spina Bifida Association, March of Dimes Foundation, American Academy of Pediatrics, Royal DSM N.V., and National Council of La Raza have jointly filed a petition proposing that the food additive regulations be amended to provide for the safe use of folic acid in corn masa flour.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 2A4796) has

been jointly filed by Gruma Corporation, Spina Bifida Association, March of Dimes Foundation, American Academy of Pediatrics, Royal DSM N.V., and National Council of La Raza, c/o Alston & Bird, LLP, 950 F Street, N.W., Washington, DC 20004-1404. The petition proposes to amend the food additive regulations in § 172.345 Folic acid (folacin) (21 CFR 172.345) to provide for the safe use of folic acid in corn masa flour.

The Agency has determined under 21 CFR 25.32(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: June 7, 2012.

Dennis M. Keefe,

Acting Director,

Office of Food Additive Safety,

Center for Food Safety and Applied Nutrition.