4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA-2013-N-0888]

Dean Foods Company and WhiteWave Foods Company; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition submitted by the Dean Foods Company and the WhiteWave Foods Company proposing that the food additive regulations be amended to provide for the expanded safe uses of vitamin D_2 and vitamin D_3 as nutrient supplements in food.

DATES: The food additive petition was filed on June 27, 2013.

FOR FURTHER INFORMATION CONTACT: Judith Kidwell, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1071.

SUPPLEMENTARY INFORMATION: Under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(b)(5)), we are giving notice that we have filed a food additive petition (FAP 3A4801), submitted by the Dean Foods Company and the WhiteWave Foods Company, c/o Hogan Lovells US LLP, Columbia Square, 555 Thirteenth Street, NW., Washington, DC 20004. The petition proposes to amend 21 CFR 172.379 to provide for the safe use of vitamin D_2 as a nutrient supplement in edible plant-based food products intended for use

as alternatives to milk and milk products and to amend 21 CFR 172.380 to provide for the safe use of vitamin D_3 as a nutrient supplement in milk at levels higher than those currently permitted.

We have 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: August 12, 2013.

Dennis M. Keefe,

Director,

Office of Food Additive Safety,

Center for Food Safety and Applied Nutrition.

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