



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA-2013-F-1539]

DSM Nutritional Products; Filing of Food Additive Petition (Animal Use)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA) is announcing that DSM Nutritional Products has filed a petition proposing that the food additive regulations be amended to provide for the safe use of ethoxyquin in vitamin D formulations, including 25-hydroxyvitamin D₃, used in animal food.

DATES: Submit either electronic or written comments on the petitioner's request for categorical exclusion from preparing an environmental assessment or environmental impact statement by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments to: <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Isabel W. Pocurull, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6853.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5)), notice is given that a food additive petition (FAP 2276) has been filed by DSM Nutritional Products, 45 Waterview Blvd., Parsippany, NJ 07054. The petition proposes to amend Title 21 of the Code of Federal Regulations (CFR) in part 573 Food Additives Permitted in Feed and Drinking Water of Animals (21 CFR part 573) to provide for the safe use of ethoxyquin as a chemical preservative in vitamin D formulations, including 25-hydroxyvitamin D₃, used in animal food.

The petitioner has requested a categorical exclusion from preparing an environmental assessment or environmental impact statement under 21 CFR 25.32(k). Interested persons may submit either electronic or a single copy of written comments regarding this request for categorical exclusion to the Division of Dockets Management (see DATES and ADDRESSES). Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: December 17, 2013.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.