



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA-2016-F-0784]

Global Nutrition International; 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 we have filed a petition, submitted by Global Nutrition International, proposing that the food additive regulations be amended to provide for the safe use of calcium butyrate as a source of energy in dairy cattle feed.

DATES: The food additive petition was filed on February 12, 2016.

FOR FURTHER INFORMATION CONTACT: Chelsea Trull, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-6729, chelsea.trull@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5))), we are giving notice that we have filed a food additive petition (FAP 2294), submitted by Global Nutrition International, Zac de Paron, 5 Rue des Compagnons d'Emmaüs, BP 70166, 35301 Fougères Cedex, France. The petition proposes to amend the food additive regulations in 21 CFR part 573 Food Additives Permitted in Feed and Drinking Water of Animals to provide for the safe use of calcium butyrate as a source of energy in dairy cattle feed.

The petitioner has claimed that this action is categorically excluded under 21 CFR 25.32(r) because it is of a type that does not individually or cumulatively have a significant effect on the human environment. In addition, the petitioner has stated that to their knowledge, no extraordinary circumstances exist. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: March 15, 2016.

Tracey H. Forfa,

Acting Director,

Center for Veterinary Medicine.

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