4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA-2015-F-2712]

Adisseo France S.A.S.; Filing of Food Additive Petition (Animal Use)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; petition for rulemaking.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that Adisseo France S.A.S. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of silicon dioxide as a carrier for selenomethionine hydroxy analogue at a level not to exceed 95 percent of the selenomethionine hydroxy analogue in its packaged form.

DATES: The food additive petition was filed on June 18, 2015.

ADDRESSES: For access to the docket, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts; and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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))), notice is given that a food additive petition (FAP 2291) has been filed by Adisseo France S.A.S., Immeuble Antony Parc II, 10 Place du Général

de Gaulle, 92160 Antony, France. The petition proposes to amend Title 21 of the Code of Federal Regulations (CFR) in part 573 (21 CFR part 573) *Food Additives Permitted in Feed and Drinking Water of Animals* to provide for the safe use of silicon dioxide as a carrier for selenomethionine hydroxy analogue at a level not to exceed 95 percent of the selenomethionine hydroxy analogue in its packaged form. In an earlier notice of petition (80 FR 48471, August 13, 2015), the use of silicon dioxide was omitted.

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.

Date: October 25, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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