444164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA-2025-F-2423]

APIX Biosciences US LLC; Filing of Food Additive Petition (Animal Use)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a food additive petition, submitted by APIX Biosciences US LLC, proposing that we amend our food additive regulations to provide for the safe use of cholesterol as a source of sterol in food for honeybees at a level between 0.009 and 0.5% by weight of the food.

DATES: The food additive petition was filed on July 11, 2025.

ADDRESSES: For access to the docket to read background documents or comments received, 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: Wasima Wahid, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 240-402-5857, Wasima.Wahid@fda.hhs.gov.

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 2322), submitted by APIX Biosciences US LLC, 2580 NE Rivercrest Rd., Fayetteville, AR 72701. The petition proposes that we amend our 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 cholesterol as a source of sterol in food for honeybees at a level between 0.009 and 0.5% by weight of the food.

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 that may significantly affect the quality of the human environment. 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: July 25, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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