U.S. FOOD & DRUG ADMINISTRATION

April 16, 2025

Donavan Melton
(b) (6)
[redacted]

Re: Docket No. FDA-2022-P-0299

Dear Ms. Melton:

This is in response to your petition dated March 7, 2022, requesting FDA-CVM "to comply with § 553 of the Administrative Procedure Act, and publish the animal feed/pet food packaging definition for the animal feed/pet food term "human grade" on the federal register."

In support, you stated that, "'Human grade' is a term FDA allows to be used on animal feed and pet food packages under FDA regulatory jurisdiction. However, FDA-CVM refuses to comply with § 553 of the Administrative Procedure Act and publish this term and its definition on the federal register."

For the reasons explained below, we deny your petition.

We disagree with your premise that "FDA-CVM refuses to comply with §553 of the Administrative Procedure Act and publish this term and its definition on the federal register." That section of the Administrative Procedure Act (APA), 5 U.S.C. §553, sets out requirements for notice and comment rulemaking. FDA has not established a federal definition for the term "human grade" for use in animal food labeling or issued any other regulation specifically for the term "human grade" for use in animal food labeling. Therefore, the notice and comment rulemaking provisions in the Administrative Procedure Act do not apply. [1]

Although FDA had not established a federal definition for "human grade," manufacturers are not prohibited from using this term in their labeling, provided that such use is truthful and not misleading (see 21 U.S.C. 343(a)(1)). Your petition has not explained why a federal definition is necessary to ensure that use of the term "human grade" in animal food labeling is truthful and not misleading. Nor has your petition identified what definition of "human grade" you propose and how the proposed definition would ensure that animal food labeling complies with the Federal Food Drug and Cosmetic Act.

[1] We note that the Association of American Feed Control Officials (AAFCO) includes a definition of "human grade" in chapter six of its Official Publication. That definition states, "Human Grade. Every ingredient and the resulting product must be stored, handled, processed, and transported in a manner that is consistent and compliant with 21 CFR Part 117 and those applicable federal human food laws as required by ingredient, process, and/or facility type." https://www.aafco.org/resources/official-publication/op-chapter-6-public-access/. However, that definition is not a federal regulation and not subject to the APA's notice and comment rulemaking requirements.

For the reasons stated above and in accordance with 21 CFR 10.30(e)(3), we are denying your petition.

Sincerely,

William T. Flynn -S

Digitally signed by William T. Flynn -S
Date: 2025.04.16 12:25:54 -04'00'

William T. Flynn, DVM, MS
Deputy Center Director
Center for Veterinary Medicine