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FDA Freedom of Information Act Appeal

Susan Thixton <susan@truthaboutpetfood.com> Sun, Sep 22, 2019 at 11:24 AM
To: FOIARequest@psc.hhs.gov

Addendum to FOIA Request Number 2017-10123 appeal:

The information requested in this FOIA is a shared work product of FDA and AAFCO - per the agreement MOU 225-07-7001. Quoting MOU 225-07-7001:

"***B.*** *Requests for new feed ingredients or requests to modify an existing feed ingredient definition are reviewed by AAFCO investigators chosen by the AAFCO Board and FDA scientists assigned by the agency's division director or team leader in the Division of Animal Feeds (DAF).*

C. *AAFCO will seek advice and a letter of concurrence regarding the suitability of the feed ingredient for its proposed use from the FDA prior to adopting new feed ingredient definitions or amending existing ones.*

D. *AAFCO will provide to the FDA, upon FDA's request (1) industry-generated requests and (2) requests from AAFCO for new feed ingredients and for modifications of existing definitions within 30 working days of AAFCO's receipt of the complete request. AAFCO's Board-assigned AAFCO feed investigator will make the initial contact with the FDA.*

E. *The FDA will allow the AAFCO Board or Board-assigned AAFCO feed investigator to request consultation from the FDA on requests for new feed ingredient definitions and modifications of existing definitions. AAFCO's initial contact will be the director of the DAF, Center for Veterinary Medicine (CVM), FDA. The FDA will provide its decision on whether it will be able to consult with AAFCO and the DAF number assigned to the request within 30 working days.*

F. *If the FDA determines it will publish a food additive regulation of a requested ingredient definition under section 409 of the Act and FDA's implementing regulations in 21 CFR 571.1 for a feed ingredient, AAFCO will not include that ingredient in the AAFCO OP until the FDA completes the regulation.*

G. *Disagreements on existing feed ingredient definitions, the establishment of new ingredient definitions, or modifications of existing definitions between the FDA and AAFCO will be referred to a review board. The review board will be comprised of two representatives from AAFCO appointed by the Board and two representatives from the FDA that are appointed by the director, FDA CVM Office of Surveillance and Compliance and the director, FDA CVM Division of Animal Feeds.*

H. *AAFCO will consider all requests from the FDA to remove an ingredient definition from the AAFCO OP upon the FDA presenting scientific evidence substantiating their conclusion the ingredient is no longer suitable for its stated intended use. The Ingredient Definitions Committee will vote on the FDA request to remove the ingredient from the Feed Ingredient Definitions section in the AAFCO OP at their next scheduled meeting. Disagreements between AAFCO and the FDA would be handled as stated in G.*"

Being a shared work product, FDA is required to provide the requested information of the FOIA. FDA utilizes the shared work product to regulate pet food, thus it cannot be considered trade secret, confidential commercial information exempt from FOIA.

Susan Thixton

[Quoted text hidden]