FDA Record # 225-07-7001

MEMORANDUM OF UNDERSTANDING BETWEEN THE U.S. FOOD AND DRUG ADMINISTRATION AND THE ASSOCIATION OF AMERICAN FEED CONTROL OFFICIALS

BACKGROUND

The Food and Drug Administration (FDA) is the primary federal agency responsible for enforcing the Federal Food, Drug, and Cosmetic Act (the Act). Included within the FDA's responsibilities under the Act is the responsibility for regulation of animal foods/feeds. This Act provides the authority for FDA to regulate essentially all ingredients and additives used in animal feed.[1] Depending on its intended purpose/use, an ingredient/additive could be classified as a food additive, a generally recognized as safe substance, a new animal drug, or a color additive.

The Association of American Feed Control Officials (AAFCO) is a voluntary membership organization of the states in the U.S. and Federal government agencies, as well as government agencies from other countries, responsible for the execution of laws and regulations pertaining to the production, labeling, distribution, use, and/or sale of animal feed and feed ingredients The purpose of AAFCO is to provide a mechanism for developing and implementing uniform and equitable laws, regulations, standards, definitions, and enforcement policies for the manufacturing, labeling, and sale of animal feeds and ingredients. AAFCO provides" model laws" and regulations that nearly all states have adopted as the basis for their feed control program. AAFCO membership consists of all fifty states, Puerto Rico, Costa Rica, Canada, FDA, U.S. Department of Agriculture and several universities. It is governed by Officers and a Board of Directors (known collectively as the Board) elected by the membership at the annual meeting of AAFCO. FDA is a member of AAFCO and serves in an advisory role on the AAFCO Board.

AAFCO provides a process (herein called the AAFCO New and Modified Feed Ingredient Definitions Process) to identify the suitability of ingredients used in animal feed. This process helps to ensure ingredients used in animal feed are suitable for that use and also establishes a common or usual name for the ingredients. This common or usual identity is required on feed labels by both federal law and state regulations. The AAFCO New and Modified Feed Ingredient Definitions Process is operated by AAFCO, with FDA providing scientific and technical assistance. The result of this collaboration has been the establishment of an effective program of benefit to feed regulatory officials, the industry and the public.

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[1]Some articles added to animal feed fall under the purview of other Federal agencies. Feed-through pesticides are regulated by the Environmental Protection Agency (EPA) and vaccines added to animal feed are the responsibility of the United States Department of Agriculture (USDA).

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PURPOSE

The purpose of this memorandum is to facilitate FDA' s collaboration with AAFCO in the AAFCO New and Modified Feed Ingredient Definition Process by clarifying the responsibilities of FDA and AAFCO during the feed ingredient definition and providing mechanisms for resolving disputes that arise and for modifying the process when required.

AGREEMENT

The FDA and AAFCO agree to the following:

A. AAFCO maintains definitions of various feed ingredients, which includes the ingredient name, description, and any appropriate limitations for its use, and publishes the currently accepted feed ingredient definitions annually in the AAFCO Official Publication (OP).

B. Petitions for potential new feed ingredients or petitions 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/Team Leader in the Division of Animal Feeds.

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

D. AAFCO will provide to FDA upon FDA's request (1) industry-generated petitions 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 request. AAFCO's Board-assigned AAFCO feed investigator will make the initial contact with FDA.

E FDA will allow the AAFCO Board or Board-assigned AAFCO feed investigator to request consultation from FDA on petitions for new feed ingredient definitions and modifications of existing definitions. AAFCO's initial contact will be the Director of the Division of Animal Feeds, Center for Veterinary Medicine, FDA. FDA will provide within 30 working days its decision whether it will be able to consult with AAFCO.

F. If FDA determines it will publish a food additive regulation 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 FDA completes the regulation.

G. Disagreements on existing feed ingredient definitions, the establishment of new ingredient definitions, or modifications of existing definitions between FDA and

AAFCO will be referred to an arbitration board comprised of the two individuals appointed by the AAFCO Board of Directors; the Director, FDA/CVM's Office of Surveillance and Compliance; and the Director, FDA/CVM Division of Animal Feeds.

H. AAFCO will accept all requests from FDA to remove an ingredient definition from the AAFCO OP upon FDA presenting convincing information/scientific evidence showing the ingredient is no longer suitable for its stated use. At that year's annual meeting, AAFCO will request a vote of the membership to remove the ingredient from the Feed Ingredient Definitions section in the AAFCO OP. Disagreements between AAFCO and FDA would be handled as stated in section G.

I. AAFCO is allowed, on its own initiative and with FDA concurrence, to request that an AAFCO Feed Ingredient Definition be removed upon AAFCO providing convincing information/scientific evidence showing the ingredient is no longer suitable for its stated use. At that year's annual meeting, AAFCO will request a vote of the membership to remove the ingredient from the Feed Ingredient Definitions section in the AAFCO OP. Disagreements between AAFCO and FDA would be handled as stated in section G.

J. This Memorandum of Understanding will be reviewed annually by the AAFCO Board and FDA and may be modified by mutual consent of both parties. Parties will provide each other with a 30 working day advance written notice regarding the modifications being sought. Any modification will be published in the Federal Register.

LIAISONS

For the FDA.

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PERIOD OF AGREEMENT

This agreement, when accepted by both parties, will have an effective period of performance from date of signature until 9/1/2012 (if no expiration date, so state), and may be modified by mutual consent by both parties or may be extended or terminated as agreed upon by FDA and AAFCO. Any notice of termination will be published in the Federal Register.

APPROVED AND ACCEPTED FOR THE AAFCO

By Ricky Schroeder

Printed Name Ricky Schroeder

Title President

Date 8/21/2007

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

By [signature]

Printed Name Stephen F. Sundlof

Title Director, FDA/CVM

Date 8/30/07