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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

RE: FDA Modernization Act Comments
Docket No. 98N-0339

Enclosed are comments submitted for the American Association of Feed Control Officials (AAFCO) per the above reference.



Alan R. Hanks

98N-339V

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FDA MODERNIZATION ACT - COMMENTS

SECTION 406b INPUT TO CVM FROM AAFCO

[DOCKET NO 98N-0339]

Feed safety is an integral part of the AAFCO regulatory philosophy. A major function of feed regulation is to safeguard the health of man and animals. Standards must be set for substances determined to be unsafe in feeds, and analytical methods are necessary to determine when standards have been breached. Products which contain unsafe levels of substances or labeled such as to be potentially used unsafely, may be harmful to animals being fed while posing a threat to the human food supply.

AAFCO relies heavily upon the strong science base, standard setting and support activity of FDA in limiting mycotoxins and other contaminants in feeds. Support for standards needs to continue either by participation and input in Codex or independently at CVM. Codex standards would only be acceptable if they are science based.

AAFCO feels CVM needs to devote the necessary resources for development or selection, and validation, where needed, of analytical methods for detection, especially, of certain potentially high risk feed contaminants. This is a potential third party activity using a contractor. Further, Codex methods, if fully validated, might be acceptable.

AAFCO's strategic plan for 1996-2000 makes feed safety the top priority. The emphasis is

food/feed safety in ongoing regulatory programs. The emphasis here includes development of strategies covering process control. Feed safety must include safe manufacturing of feeds and accurate labeling while guarding against contamination with pesticides, mycotoxins, industrial chemicals and various microbial species. Manufacturing process controls are especially critical in safe production of medicated feeds and are found in the Current Good Manufacturing Practice inspections of licensed and unlicensed medicated feed mills. Equal inspection vigilance at both types of medicated feed mills, licensed and unlicensed, is required to assure safe, uncontaminated feed.

AAFCO and feed manufacturers have developed and agreed on a Draft Model National Medicated Feed Program including a proposal for revised GMPs treating licensed and unlicensed mills essentially the same. The proposed GMP revisions are the subject of a July, 1998 Citizens Petition to CVM. AAFCO would very much like to see this petition given high priority and emphasis for review and decision making. Proposed revisions greatly clarify the GMPs and could lead to efficiencies in regulation of medicated feeds.

Areas of feed safety include the development, approval and adoption of definitions for safe ingredients to be used in manufacturing safe, wholesome and effective feeds.

Strong technical support and science review are of great importance in the establishment of feed ingredient definitions and AAFCO needs the underlying strength of CVM in these areas in its ingredient definition process to help assure safe feeds. CVM needs to more clearly define what is needed regarding documentation and data in defining and supporting

claims for a feed ingredient.

In priority setting, state and federal programs need to work more closely together, or at least know and understand the basis of each other's priorities in regulation of animal feeds. Often, states find a reasonably high priority for them may be a low priority at the national level, perhaps for lack of resources. Equally, states may not have a clear picture of national priorities or lack a clear appreciation or understanding of the basis for such priorities.

The states, probably through AAFCO, and CVM need to review together and where possible coordinate feed regulatory emphasis and priorities. While for many reasons such as variations in the goals of some state programs, it is not likely that we can always match all priorities at the state and national levels, we all do need to know and understand each other's priorities. We may all be able to share more resources and support each others programs if we share our priorities early in planning processes.

There is a trend today for inclusion of unapproved ingredients and sometimes extraordinary claims on labels of some animal feeds. States may act individually to police these problems, but greater and wider successes can be achieved with strong support from FDA. Admittedly, in most, if not all cases, high risk to animals and humans may not be at stake, but truth and legality in labeling is in question. The states have long been the guardians against fraud and misleading claims in the regulation of animal feeds. We believe we could be more effective in this area with stronger FDA backing and support,

even when we are dealing with an issue of low regulatory priority for CVM.

In the area of third party involvement in the regulation of feeds, the AAFCO Draft Model National Medicated Feed Program contains a Voluntary Self Inspection Program (VSIP) which allows a certain level of self certification for the feed manufacturer. Audit and other inspections of the self inspected manufacturer would be performed by certified inspectors from the states or FDA.

A third party "Certification Organization" (CO) is envisioned for certifying inspectors. Qualified faculty for training would be selected by the CO from FDA, State Inspection Authorities, industry experts and others deemed qualified and appropriate. The CO or another organization working with the CO would be responsible for providing training and distribution of informational and educational materials to all certified inspectors. This use of a third party type program element could relieve some of the current load on both state and federal feed regulators while maintaining adequate regulation of animal feeds.

In summary, several areas mentioned here (standard setting for contaminants, provision of analytical methods, support in defining safe feed ingredients, review of petitions, back up of the states in the area of fraud, etc.) can only be acted upon if CVM has adequate funding and other resources. In some instances research is required which likewise needs to be funded. Thus, in general, for feed safety and, in particular, in support of the states who perform the bulk of inspections, sampling and analysis of feeds, AAFCO strongly supports adequate funding and

resources be available to CVM to be used accordingly.

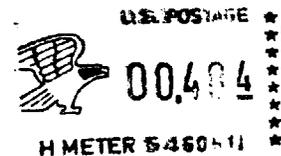
AAFCO and CVM have worked together very productively for many years. This working relationship has grown and improved over the years as CVM's contributions to the on going work of AAFCO and participation in AAFCO meetings and committees has developed. Final AAFCO work products such as model legislation or regulations frequently represents a consensus of the states, CVM and industry today. No doubt further partnering is the logical movement for the future as we all seek to manage our large and interactive responsibilities together for the benefit of all.

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