



November 11, 2003

Dr. Stephen Sundlof, Director
Center for Veterinary Medicine HFV-1
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundlof:

On behalf of the Association of American Feed Control Officials (AAFCO), Laboratory Methods and Services Committee, I respectfully submit the following comments.

HISTORY

The new animal drug application (NADA) process has been operational for many years. Some analytical methods included in those NADA's for medications, both drugs and antibiotics, are decades old and utilize antiquated technologies. These methods were developed for a limited number of feeds and ingredients for the intended use at the time of submission. There is a need for improving these methods to reflect new analytical technology and provide increased applicability to the products in the current marketplace. As you may be aware, the number of ingredients used in animal feed today has expanded greatly from the time of NADA submittal. Thus, many NADA methods are no longer applicable to some of the feed products regulated by the states.

In addition, states are challenged with monitoring approved and unapproved drugs, drug combinations and uses. Examples include residue carryover in the mills and cross-contamination in the feed chain. These concerns are not addressed by the NADA.

There have been concerns expressed that opening NADA files for replacement or additional methods could potentially subject the file to other changes, such as review for resistance development in microorganisms. You were sent a previous inquiry, dated August 31, 1994, from Dr. Alan Hanks concerning this issue. Your response, dated October 5, 1994, revealed that the sponsor could submit a new method, with sufficient documentation, to be included in the NADA file without opening the NADA file for subjection to any other change.

PROPOSAL

The AAFCO Laboratory Methods and Services Committee have a number of methods that have been single-lab validated and are ready to submit for collaborative study. These methods demonstrate better performance characteristics, both in terms of precision and accuracy, than existing FDA regulatory methods.

AAFCO wishes to work cooperatively with FDA to ensure these methods, when successfully collaborated, may be considered as FDA regulatory methods. A mechanism to make these methods available for use by the States, FDA, and industry should be explored.

This process will greatly improve the regulation of animal feed in this country by increasing the surveillance ability of both the States and FDA for product control, product complaints, regulatory analyses and unintentional uses. Your insight and participation would be welcomed in establishing a successful mechanism for bringing this effort to a successful conclusion. I look forward to your response so AAFCO can proceed with method validation through collaborative study.

Thank you for your consideration in this matter.

Respectfully,

A handwritten signature in black ink, appearing to read "Ben L. Jones". The signature is written in a cursive, flowing style.

AAFCO President

cc: AAFCO Board of Directors
Nancy Thiex, AAFCO Laboratory Methods and Services Committee
George Graber, Director, Division of Animal Feeds, CVM
Gloria Dunnavan, Director, Division of Compliance, CVM
Dennis McCurdy, Team Leader, Division of Animal Feeds, CVM
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