MICRO TRACERS, INC.

1370 Van Dyke Avenue, San Francisco, California 94124 U.S.A.
Tel: (415) 822-1100 Fax: (415) 822-6615
EMAIL: MICROTRACE@AOL.COM
WEBSITE: www.microtracers.com

15 January 2003

Dockets Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Md. 20853

Ref: Docket No. 02N-0273- Substances Prohibited From Use in Animal Food and Feed; Animal Proteins Prohibited in Ruminant Feed.

To Whom It May Concern;

Thank you for requesting Comments as referenced,

I am pleased to respond to your Question #4. Preventing Cross Contamination and also to suggest FDA mandate inclusion of simple easy to detect tracers in meat and bone meal and other ruminant products as is now being considered in the European Union..

On the question of Preventing Cross Contamination, I comment as follows:

#1. The FDA must require data validating cleanout of feed manufacturing equipment and rendering equipment at least on an annual basis.

Without such data, it is impossible to know if written procedures including sequencing, flushing etc. are working adequately. The FDA should also require data validating proper mixing of feeds, as this is also important especially with medicated feeds. Testing of both mixing and cross-contamination at feedmills is a current requirement in all Eurpean Union countries (ref. Community Legislation in Force, Document 3951L0069, Council Directive of 22 December 1995) and is becoming a requirement in Korea, Japan and other economically advanced countries.

#2. The FDA must establish levels of cross-contamination that will be deemed acceptable so feed manufacturers will know if their cleanout procedures are working adequately.

Such levels could be established based upon good science, as are EPA regulated tolerances for pesticide residues in fruits and vegetables. The FDA may want to consult the European Union especially in developing validation requirements and tolerances. The FDA must not delay requiring validation data on this issue at it will take FDA some years to address the issue. The FDA considered setting cross-contamination tolerances for medicated feeds as long ago as 1976 but to date nothing has be done or is even pending.

02N-0273

C3

#3. Technology exists to inexpensively validate mixing and cleanout procedures.

Trade organizations supported by the feed industry in the various European countries TNO (Holland), IFF (Germany and Tecaliman (France) have all done extensive work in developing and approving acceptable testing procedures for validating both feed mixing and cleanout of batch mixing equipment. These issues should be studied in the USA also and the Kansas State University Department of Grain Sciences would be capable of doing so if provided the proper financial support.

#4. The FDA must overcome opposition from the American Feed Industry Association.

Comparatively little work has been done on these issues in the United States because the FDA has not required any validation testing as such a requirement has been consistently opposed by the American Feed Industry Association (AFIA), a very powerful lobbying group. The AFIA has opposed such testing not because of its cost but because of the cost of correcting manufacturing deficiencies that will be evidenced by such testing. The FDA must not succumb to industry pressure as it has repeatedly in the past.

I include with this letter documentation on the aforementioned points as well as on the European Union requirements for a tracer in ruminant by-products to be used in animal feed (discussed below).

On the issue of requiring a tracer in ruminant meat and bone meal and other ruminant products intended to be used in feed, the European Union is currently considering requiring this (ref. Council of The European Union, Interinstitutional File 2000/0259 (COD), Agrileg 174, Codec 670, Brussels, 8 November 2001). By including a simple, easy to detect tracer, the feed manufacturer and the various governmental authorities can test thousands of samples of feed at low cost to be as certain mistakes or willful violations of its regulations are not occurring. The cost of a tracer is 10 cents/ton of feed or less. This cost is trivial compared with the cost of not using ruminant by-products in feeds as is currently the policy of the European Union. Microtracers (tm) were formulated in more than 30 million tons of formula feed in 2002 primarily to allow feed manufacturers to know if vitamin, mineral or medicated premixes were present in their feeds. Similar tracers could be used for the same purpose to allow control of ruminant by-products in feeds.

Thank you for considering my views. Please let me know if you have questions or if I may respond further. Please note my company website: www.microtracers.com where extensive information on the use of tracers for quality assurance purposes in feeds is posted.

David A. Eisenberg
President
DAE:dae