General Procedures Policy

Analytical Method Development for Feed Contaminants

1. PURPOSE:

To provide a standard operating procedure (SOP) for the research, development and validation of new analytical methods or modification of an existing method to measure feed contaminants. These procedures will help ensure that animal and public health is protected.

2. SCOPE:

The FDA relies upon validated analytical methodology to enforce its regulatory programs. Methods exist for most of the Agency's regulated products, such as drugs and food additives. These methods can be found in new animal drug applications, food additive petitions and other official listings. However, one may need to look elsewhere for methods not associated with pre-approval activities of the Agency, such as when safety guidance is made available for the control of feed contaminants.

3. PROCEDURES

1. The Director of the Division of Animal Feeds will identify the contaminant, the level of quantitation sought and any other attribute/issue of importance.

2. An Analytical Chemistry Panel (ACP) consisting of chemists and subject-matter specialists from the Division of Animal Feeds, HFV-220 and elsewhere in the Center and Agency will be convened by the Director, Office of Surveillance and Compliance or his/her designee.

3. The ACP will be responsible for:

a. conducting a thorough review[1] to determine whether a suitable method[2] already exists;

b. identifying analytical issues requiring special attention, such as matrix concerns and type of procedure sought;

c. locating laboratories capable of conducting the research, beginning under most circumstances with CVM's Office of Research and progressing from there to other facilities in the Agency, such as ORA's Division of Field Science and NCTR, and possibly to other federal, state or private laboratories[3];

[1] See Appendix A for partial list of review sources.

[2] Method development is a multi-step process that includes optimization of the instrumental detection system, and the determination of precision and accuracy in authentic samples

[3] If no laboratory facility within the Agency can be engaged, the ACP will refer to the FDA Leveraging Handbook, which is a compendium of tools that can be used in the formation of collaborative arrangements, cooperative agreements, and partnerships, and inter-agency agreements that allows the FDA to fulfill its protection of public health. Chapter Four of the handbook describes a range of contractual and financial mechanisms that can be used by the FDA whether or not the partnership is within or between government and non-government groups such as industry and academia.

d. following the progress of the research and providing assistance/guidance to help bring the research to a successful conclusion;
e. developing the conditions for validation of the new or modified method; and,

f. delivering status reports and a final report to the Directors of the Office of Surveillance and Compliance and the Division of Animal Feeds.

4. REFERENCES

1. Title 21 CFR 2.19 Methods of Analysis FDA
2. The Leveraging Handbook, Guidance for FDA Staff, a resource for effective collaborations, June 2003
3. FDA Laboratory Information Bulletin, Office of Regulatory Affairs
4. Official Methods of Analysis, Association of Official Analytical Chemists International
5. Cooperative Research and Development Agreement Model PHS CRADA Revised 05/27/99

APPENDIX A - REVIEW SOURCES

The following is a partial list of cites that should provide information on methodology for contaminants of feed:

- FDA Laboratory Information Bulletin for rapid information dissemination about methods.
- FDA Bacteriology Analytical Manual
- FDA Food Additive Analytical Manual
- FDA Pesticide Analytical Manual
- FDA Laboratories and Research Facilities
- Joint Institute of Food Safety and Nutrition (JIFSAN)[4]
- National Center for Food Safety and Technology (NCFST)[5]
- National Food and Agriculture Laboratory Committee (NFALC) and its associated organizations[6]
- Food Emergency Response Network (FERN) and its electronic laboratory exchange network (eLexnet)[7]
- Other Federal agencies, e.g. EPA and USDA
- Official Methods Compendia, Association of Official Analytical Chemists and its Research Institute through its analytical communities and through the Association of American Feed Control Officials
- Peer-reviewed scientific literature

4 Joint Institute of Food Safety and Nutrition (JIFSAN) was established between the United States Food and Drug Administration (FDA) and the University of Maryland (UM) in April 1996. The Institute is a jointly administered, multidisciplinary research and education program and includes research components from the FDA Centers for Food Safety and Applied Nutrition (CFSAN) and Veterinary Medicine (CVM), and UM.

5 The National Center for Food Safety and Technology (NCFST) in Chicago, Illinois, is a research consortium among the FDA Center for Food Safety and Applied Nutrition (CFSAN), Illinois Institute of Technology (IIT) and the food industry. Established 17 years ago, the NCFST incorporates the FDA Division of Food Packaging and Processing and was set up by FDA to form a link with industry for its expertise in food technology.

6 The National Food and Agriculture Laboratory Committee (NFALC) unites veterinary, public health, and environmental laboratories with industry and traditional agriculture. Its Web site identifies laboratories with particular expertise regionally and nationally.

7 FERN is an interagency cooperation between USDA/FSIS and the FDA dedicated to the safety and security of food. It consists of a central office and 5 regional coordination centers. FERN develops and standardizes methods internally for microbiology, chemistry, and radiation, with training and proficiency. eLEXNET is one of FERN's projects. FERN is also a part of the Integrated Consortium of Laboratory Networks (ICLN) under the Department of Homeland Security (DHS).