U.S. FOOD & DRUG ADMINISTRATION

FDA FACT SHEET

ANIMAL FOOD SAFETY INSPECTION CONTRACT PROGRAM

Program Description

- Firms using Category II Type medicated articles to make medicated feeds are required to register with FDA as a drug establishment and gain licensure. FDA is required to inspect these firms once every two years.
- FDA published a final rule prohibiting the use of mammalian protein in ruminant feeds to prevent the spread of *Bovine Spongiform Encephalopathy* (BSE) in the U.S.
- The rule, which is codified in 21 CFR 589.2000, provides for labeling, record keeping and clean out requirements for renderers, feed manufacturers, haulers of feed, and producers. The new rule, codified in 21 CFR 589.2001, prohibits the use of certain cattle-origin materials as ingredients in the foods of all animals.

Intended Outcomes

- To conduct inspections and verify compliance of licensed and non-licensed medicated feed establishments with 21 CFR Part 225, FD&C Act, and/or State feed law (if the contractor's State feed law has incorporated the provisions of the current AAFCO Model Bill and Regulations, or FDA Ruminant Feed Ban Regulations, or both.
- To verify compliance with 21 CFR 589.2000 and 21 CFR 589.2001 by licensed and non-licensed medicated feed manufacturers, ingredient manufacturers such as rendering facilities, and other types of operations engaged in the manufacturing, distribution, retail, and use of animal feed.
- To conduct inspections and verify compliance with 21 CFR 507 as it relates to Part 507 CGMP provisions (subpart B and related requirements of subparts A and F) and/or PCAF PC requirements (subparts C and E and related requirements of subparts A, D, and F) for animal food facilities that are registered with FDA to manufacture, process, pack or hold food for animals in the United States or State feed law (if the contractor's State feed law has incorporated the provisions into their law), or both.
- To collect samples that shall be used for contaminant surveillance, to determine compliance with applicable regulations, and/or for other possible situations, when mutually agreed.
- To prepare and submit reports of assigned inspections and sample collections, as well as, reports on any compliance follow-up and corrections achieved by the Contractor under its own program for FDA review.

Program Metrics

- Current program funding: $2.95M
- Current number of awards: 30

Animal Food/BSE Contract Program Awardees (FY2023)					
Alabama	California	Colorado	Connecticut	Florida	Georgia
Illinois	Indiana	Iowa	Kansas	Kentucky	Louisiana
Maryland	Michigan	Minnesota	Missouri	Nebraska	New Jersey
New Mexico	North Carolina	North Dakota	Ohio	Pennsylvania	South Carolina
Tennessee	Texas	Utah	Virginia	Washington	West Virginia

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