

# FDA FACT SHEET

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## ANIMAL FOOD/BSE INSPECTION CONTRACT PROGRAM

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### 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 states' feed law (if the contractor's state's 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 states' feed law (if the contractor's state's 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: \$3M
- Current number of awards: 34

Animal Food/BSE Contract Program Awardees (FY2017)					
Alabama	Arizona	California	Colorado	Connecticut	Florida
Georgia	Iowa	Illinois	Indiana	Kansas	Kentucky
Louisiana	Maryland	Michigan	Minnesota	Missouri	Montana
North Carolina	North Dakota	Nebraska	New Jersey	New Mexico	Ohio
Oklahoma	Pennsylvania	South Carolina	Tennessee	Texas	Utah
Virginia	Washington	Wisconsin	West Virginia		

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