

# FDA FACT SHEET

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## ANIMAL FOOD / BSE 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 and gain licensure.
- FDA is required to inspect these firms once every two years.
- On June 5, 1997, FDA published a final rule prohibiting the use of mammalian protein in ruminant feeds.
- This action was taken 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.

### **Intended Outcomes**

- To obtain state assistance in the inspection coverage of animal food establishments.
- Conducting inspections of licensed and non-licensed medicated feed mills to determine compliance with 21 CFR 225, the Federal FD&C Act, State feed law, or both
- To verify compliance with the Veterinary Feed Directive (VFD) regulations in 21 CFR 558.6 by inspecting feed manufacturers, distributors, veterinarians, and animal producers involved in the

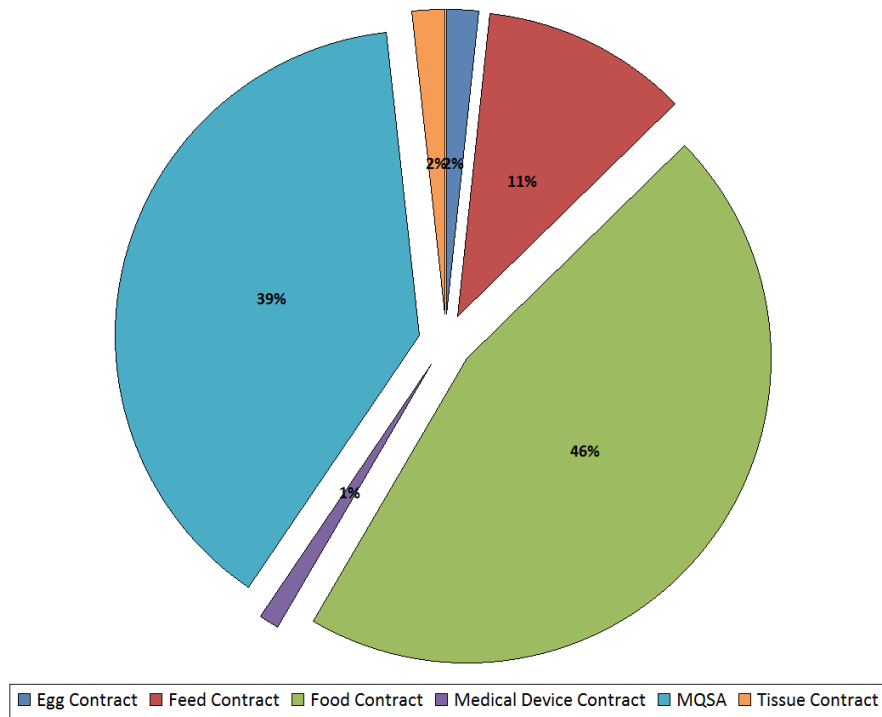
distribution of VFD drugs, the manufacture or distribution of VFD feeds, the issuance of VFD orders and the feeding of VFD feeds, respectively.

- Assuring compliance with the BSE Rule (21 CFR 589.2000 and 21 CFR 589.2001) by licensed and non-licensed medicated feed manufacturers, ingredient manufacturers, 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 CGMP provisions (subpart B and applicable parts of subparts A 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 encourage voluntary corrective action by the establishment when appropriate.

### **Program Metrics**

- Current program funding: \$2.778M
- Current number of awards: 33
- Number of contracted inspections: 3380

**Figure 1. Pie Chart showing the Animal Food Contract Program's budget in relation to the budgets of all other FDA Office of Partnerships administered state contracts (2016-2017)**



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The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, and products that give off electronic radiation, and for regulating tobacco products.