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DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE
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INTRODUCTION

Good afternoon, Chairman Brown, Co-Chairman Smith, and Members of the Commission. I am Tracey Forfa, Deputy Director of the Center for Veterinary Medicine (CVM) at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to be here today to discuss FDA's investigation into reported illnesses in pets that consumed jerky pet treats.

FDA has been receiving reports of pet illnesses associated with the consumption of jerky pet treats since 2007. As of May 1, 2014, FDA has received approximately 4,800 such reports, including 1,800 complaints received since FDA's website update in October 2013. The reports received involve illnesses in more than 5,600 dogs, 24 cats, three humans, and, sadly, more than 1,000 canine deaths. Most of the reported cases involve chicken, duck, or sweet potato jerky products imported from China. Unfortunately, to date, FDA has not been able to identify a specific cause for the reported illnesses or deaths despite an intensive scientific investigation. Getting to the bottom of this problem is a priority for FDA, and the Agency is continuing its comprehensive investigation into the potential cause of the pet illnesses.

The ongoing global investigation is complex and includes a wide variety of experts at FDA, including toxicologists, epidemiologists, veterinary researchers, forensic chemists, microbiologists, field investigators, state research partners, and senior Agency officials. FDA has collaborated with our colleagues in academia and industry and has reached out to U.S. pet food firms to enlist their help and to share data involving this public health investigation. FDA is updating veterinarians and pet owners about the investigation regularly via the Agency's website

and a webpage dedicated specifically to issues related to jerky treats. This information has been further disseminated to veterinarians by various groups, including the American Veterinary Medical Association (AVMA). Most recently, on May 16, 2014, CVM released an update entitled “FDA Provides Latest Information on Jerky Pet Treat Investigation.” CVM also has a webpage entitled “FDA Progress Report on Ongoing Investigation into Jerky Pet Treats.” In addition, the Agency will continue to remind pet owners that jerky pet treats are not necessary for pets to have a fully balanced diet, so eliminating them will not harm pets since commercially produced pet food contains all of the nutrients that pets need.

ADVERSE EVENT REPORTS

The 4,800 reports of pet illnesses received by FDA cover many sizes and ages of dogs, and multiple breeds. About 60 percent of the reports are for gastrointestinal illness and about 30 percent relate to kidney or urinary issues. Some dogs with kidney or urinary issues were diagnosed with Fanconi or Fanconi-like Syndrome, a rare kidney disease normally seen primarily in certain breeds as a genetic disease, although Fanconi can also be acquired following exposure to kidney toxins. Affected dogs were reported to involve a wide variety of breeds, which makes genetic Fanconi Syndrome unlikely. The background incidence of Fanconi Syndrome in dogs is currently unknown, but it appears to be increasingly reported in association with jerky treat ingestion. The remaining 10 percent of cases involve a variety of other symptoms, including convulsions, tremors, hives, and skin irritation.

In October 2013, FDA published an update on the Agency’s website which resulted in a surge of 1,800 adverse event reports received by FDA. The Agency has determined that about 25 percent

of the 1,800 reported cases were “historic”; that is, the illnesses occurred several months or even years previously. The remaining cases were more recent, but may or may not have received veterinary attention. Of the new cases since October, the Agency has identified about 125 well-documented cases for further investigation, and has continued to correspond with the owners and veterinarians of these pets to track their progress and to obtain test samples of blood, urine, feces, and tissue.

In addition to the October 2013 website update, FDA reached out through the AVMA to solicit information about new or ongoing cases currently under veterinary care. This is a novel approach, and it resulted in the submission of tissue samples (blood, urine, feces, necropsy, etc.) from affected dogs that were associated with jerky pet treat exposure.

FDA has also had the opportunity to perform post-mortem examinations on dogs suspected of having jerky-pet-treat-associated illnesses. As of May 1, 2014, the Agency completed 26 post-mortems on the samples submitted since October 2013. In half of the cases, the dogs’ cause of death was due to a variety of other causes, such as widespread cancer, trauma or infections; in the remaining 13 cases, 11 had kidney disease and two involved gastrointestinal disease. An exact causal relationship between these deaths and jerky pet treats has not been determined, but involvement of jerky pet treats has not been ruled out. We are exceptionally grateful to the owners who consented to allow FDA to perform post-mortem examinations of their beloved pets. We understand this is a difficult decision to make and sincerely appreciate the opportunity to learn more about the potential cause of their pets’ deaths.

Beginning in May 2014, FDA has partnered with the Centers for Disease Control and Prevention

(CDC) to collaborate on a study of cases reported to FDA of sick dogs compared with “controls” (dogs that have not been ill). The goal of the study is to compare the foods eaten by the sick dogs (cases) to those eaten by the dogs that did not get sick (controls), in order to determine whether sick dogs are eating more jerky pet treats than healthy dogs.

Investigators have identified about 100 cases of kidney illnesses in dogs reported to FDA to have occurred on or after July 1, 2013. The cases included dogs diagnosed with Fanconi or Fanconi-like illness, or dogs that were five years of age or younger and had kidney failure, regardless of jerky pet treat exposure. Cases were selected solely on this case definition and not on what food they consumed. Data collected during this investigation will allow Federal investigators to better understand what is making pets sick. The study is still ongoing, and FDA will share results when the study is completed.

PET FOOD SAMPLE TESTING

Since 2011, in concert with FDA’s Veterinary Laboratory Investigation and Response Network (Vet-LIRN), which partners with state and university veterinary diagnostic laboratories, the Agency has collected approximately 250 jerky treat samples related to more than 165 consumer-related complaints, plus more than 200 retail samples (unopened bags obtained from a store or shipment), and has performed more than 1,000 tests on these samples. In addition, the team at Vet-LIRN ran more than 240 tests on historical samples (those received in 2007-2011).

FDA’s Vet-LIRN program has included intensive testing for numerous contaminants such as: *Salmonella*; metals or elements such as arsenic; pesticides; antibiotics; antivirals; mold and toxins

from mold testing; rodenticides; nephrotoxins such as ethylene glycol and melamine; and other chemicals and poisonous compounds. FDA's test results of jerky treat product samples for toxic metals, including tests for heavy metals, have been negative.

Testing has also included measuring the composition of jerky pet treats to verify that they contain the ingredients listed on the label and do not contain ingredients that are not listed on the label. FDA is reaching out to private food testing laboratories for help with this work to better allow FDA to focus efforts on other aspects of the investigation. It is important to understand the composition of a product and its ingredients to determine where there might be a potential for problems to occur. For example, during a prior investigation involving contaminated pet food, FDA looked carefully at all the ingredients and it was later discovered that melamine was being used to raise the level of the protein in the products. Currently, FDA is investigating whether potentially contaminated glycerin could be a possible source of the reported illnesses in pets. FDA has tested a limited number of samples of glycerin obtained from inspections and is actively investigating new methodologies for analyzing glycerin for a variety of contaminants or impurities.

Testing of jerky pet treats from China has revealed the presence of the drug amantadine in some samples containing chicken. These samples were from jerky pet treats that were sold a year or more ago. Amantadine is an antiviral medication that is FDA-approved for use in humans. It has also been used in an extra-label manner (using an approved drug in a way that is not listed on the label) in dogs for pain control, but FDA prohibited its use in poultry in 2006.

FDA does not believe that amantadine contributed to the illnesses because the known side effects or adverse events associated with amantadine do not seem to correlate with the symptoms seen in the jerky-pet-treat-related cases. Amantadine, however, should not be present at all in jerky pet treats, and the Agency has notified the Chinese Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) that the presence of amantadine in these products is an adulterant.

Chinese authorities have assured FDA that they will perform additional screening and will follow up with jerky pet treat manufacturers. FDA has notified the U.S. companies that market jerky pet treats that were found positive for amantadine of this finding and is testing both imported and domestic jerky pet treats for amantadine and other antivirals. FDA is in the process of conducting a survey assignment of both domestic and imported jerky pet treats for amantadine, as well as other antivirals. Of the 41 samples analyzed thus far, only one has tested positive for antivirals.

FDA's testing also found various antibiotic residues in chicken jerky pet treats, which were also found by the N.Y. State Department of Agriculture and Markets. Though FDA does not believe the presence of these residues contributed to the reported illnesses in jerky pet treats, they should not be present in the products. These findings led to the temporary removal from the market of two major brands of jerky pet treats.

INTERACTION WITH CHINA

It was just over a year ago that FDA testified before this Commission about FDA's efforts to ensure global product safety and quality, particularly in our work related to China. China is the source of a large and growing volume of imported foods, drugs, and ingredients. Every product imported from abroad must meet the same standards as those produced here in the United States.

Firms always have the primary responsibility to produce safe products, but it is important that governments provide meaningful and robust regulation to ensure public safety. FDA is continuing its work with Chinese officials to help them improve their regulatory system and educate them on the new standards that are being implemented in our regulatory system.

FDA has held regular meetings with the Chinese authority, AQSIQ, about the jerky pet treat issue. These meetings have helped to ensure that AQSIQ is aware of U.S. requirements for pet food safety and to share information in support of FDA's investigation.

In April 2012, FDA conducted inspections of several facilities in China that manufacture jerky pet treats for export to the United States. FDA selected these firms for inspection because the jerky products they manufacture have been associated with some of the highest numbers of pet illness reports in the United States. These inspections provided valuable information on these firms' jerky pet treat manufacturing operations, including the ingredients and raw materials used in manufacturing, as well as manufacturing equipment, the heat treatment of products, packaging, quality control, sanitation, and product testing. Although these inspections helped to identify additional areas that FDA may investigate, the Agency found no evidence indicating that these firms' jerky pet treats are associated with pet illnesses in the United States. FDA, however, did identify concerns about the record keeping practices of several of the inspected Chinese firms. In particular, one firm falsified receiving documents for glycerin, which is a common ingredient in jerky pet treats. As a result of the inspection, the Chinese AQSIQ informed FDA that it had seized products at that firm and suspended exports of the firm's products to the United States.

As a follow-up to these inspections, FDA sent a delegation to China in April 2012 to express our

concerns to AQSIQ about the complaints we continue to receive concerning jerky pet treat products imported from that country. As a result, FDA and AQSIQ agreed to expand the investigation of jerky pet treats. In addition to sharing our epidemiological findings with AQSIQ, FDA initiated a scientific collaboration, and has taken other steps to attempt to identify the root cause of the illness complaints. As noted, FDA and AQSIQ are meeting regularly to share findings and discuss further investigational approaches. FDA has also hosted Chinese scientists at the Agency's veterinary research facility to further scientific cooperation.

PET FOOD SAFETY IN GENERAL

Pet food safety in general continues to be a priority issue for FDA. In response to section 1002 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), FDA established the Pet Food Early Warning Surveillance System. The goal of the surveillance system is to quickly identify contaminated pet food and illness outbreaks associated with pet food. The system uses data collected by two surveillance resources to collect information about pet-food-related problems: FDA's Consumer Complaint Reporting System (through the FDA District Consumer Complaint Coordinators) and the FDA-National Institutes of Health Safety Reporting Portal (SRP) (where consumers can submit complaints regarding adverse events in animals associated with the consumption of pet food). Information provided through these reporting mechanisms helps provide early detection of problems with pet food, enabling FDA to respond quickly to prevent or mitigate risks to people and animals.

The SRP launched in May 2010, allowing the public to submit complaints electronically. Using the portal's pet food questionnaire, consumers can report possible adverse health effects associated

with their pets' food. Veterinarians may also report pet food safety problems on behalf of their clients and provide valuable medical information. Within days of opening the SRP for pet food complaints, veterinarians identified a thiamine deficiency in a cat that only ate one brand of canned food and reported it through the SRP. FDA notified the manufacturer, which promptly initiated a recall.

Another important safety surveillance tool is a new requirement, provided for in section 1005 of FDAAA, that manufacturers, processors, packers, and holders of human or animal food report to FDA if there is reasonable probability that an article of human or animal food will cause serious adverse health consequences or death to animals or humans. In conjunction with that requirement, section 1005 also required FDA to establish the Reportable Food Registry (RFR), an electronic portal to which such reports can be submitted. The intent of the registry is to help FDA better protect public health by tracking patterns of possible food and feed adulteration and to better target inspection resources. By providing early warning signals about potential health risks, it has increased the speed with which FDA, its state and local partners, and industry can remove hazards from the marketplace. For example, in 2011, a pet treat distribution company submitted a report to the RFR that their pig ear dog treats were contaminated with *Salmonella*. After FDA's investigation, two lots of the affected pet treats that had been distributed to 18 states were recalled.

In addition, FDA uses a system called the Pet Event Tracking Network (PETNet) to share information about emerging pet-food-related illnesses and product defects. PETNet is a secure network launched in August 2011 that allows the exchange of information between FDA and other Federal and state regulatory agencies. Using the shared information, state and Federal agencies can work together to quickly determine what regulatory actions are needed to prevent or quickly

limit adverse effects associated with pet food products.

Finally, section 1002 of the FDAAA required FDA to establish processing standards for pet food. The process controls standards for pet food have been incorporated into the proposed rule, “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals,” which, when finalized, will implement, for animal food, section 103 of the FDA Food Safety Modernization Act. The proposed rule, which issued on October 25, 2013, establishes requirements for the safe manufacturing, processing, packing, and holding of animal food to protect animals and humans from foodborne illness.

CONCLUSION

Thank you for the opportunity to describe FDA’s ongoing efforts to determine a definitive cause of the reported pet illnesses associated with jerky pet treats. The Agency is devoting significant resources to actively investigate the problem and its origin. FDA continues to work in collaboration with a wide variety of experts, including our colleagues in academia and industry, our international counterparts, and Federal, state and university laboratories, on this investigation. If FDA’s investigation leads to the identification of any particular jerky pet treat ingredient or contaminant that is associated with illnesses in pets, the Agency intends to act quickly to notify the public of its findings and take steps, as appropriate, to ensure the affected product is promptly removed from the market.

FDA encourages consumers to check our website for updates on the ongoing investigation. As noted above, we will continue to remind pet owners that jerky pet treats are not necessary for a pet's healthy diet.

I am happy to answer any questions you may have.