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COMMITTEE ON EDUCATION AND THE
WORKFORCE

August 24, 2012

The Hon. Daniel R. Levinson
Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, SW
Washington, D.C. 20201

Dear Inspector General Levinson:

I write to request an immediate investigation into the U.S. Food and Drug Administration's handling of the thousands of complaints about illness and death resulting from jerky treats for dogs. It has now been five years since reports of problems from dog owners to the FDA began to accumulate.

In September 2007, the FDA issued a warning of possible health dangers of feeding chicken jerky products imported from China to dogs. In 2008, another warning was issued. In November 2011 a third warning was issued following what it describes as "an increase in the number of complaints it received of dog illnesses associated with consumption of chicken jerky products imported from China...reported to FDA by dog owners and veterinarians." The FDA "warnings" in this case constituted mere press releases, requiring no action by the manufacturer, leaving unsuspecting pet owners to feed their dogs poisoned treats.

The FDA's adverse event reporting system, which necessarily underestimates the true number of potential incidents, has now yielded over 2000 reports of dogs that have been sickened or killed from the jerky treats.

In April of 2012, FDA officials traveled to China to inspect jerky manufacturing facilities. The results were not reassuring. Upon arrival, the inspectors learned that they would not be able to take samples back to the U.S. for analysis in a U.S. lab. The FDA was, however, able to discover that the raw materials (meat) were not being tested for contamination as required.

The inspectors were also able to learn that the Chinese manufacturers claimed to have received few, if any, complaints about their products, even though the FDA claims to have transmitted the complaints to the manufacturers. The inspection reports paint a picture of factories that clearly cannot be trusted to produce food fit for consumption. The FDA's inaction has effectively declared that the food from these factories is perfectly fit for consumption.

The FDA has defended its abject failure to act by claiming it does not have the authority to do so until the adulterant(s) is (are) positively identified. It is true that if the FDA has not identified an

adulterant, it will not be able to initiate a mandatory recall. The FDA has broad authority to request a voluntary recall at any time.

In addition, section 807(b) of the Federal Food Drug and Cosmetic Act gives the FDA authority to halt imports of the food if the food is "from a foreign factory, warehouse, or other establishment of which the owner, operator, or agent in charge, or the government of the foreign country, refuses to permit entry of United States inspectors or other individuals duly designated by the Secretary, upon request, to inspect such factory, warehouse, or other establishment," if an inspection is refused "during the 24-hour period after such request is submitted, or after such other time period, as agreed upon by the Secretary and the foreign factory, warehouse, or other establishment." An inspection in which samples are requested but not received is incomplete.

The FDA has also defended its failure to act by claiming it cannot act on complaints alone. If, after five years of investigating, the FDA still has no more clues about the chemical or biological culprit than the original consumer complaints, the competency and/or integrity of the investigation is called into question. I do not make this statement lightly.

My requests for information from the FDA as Ranking Member of the Subcommittee on Regulatory Affairs, Stimulus Oversight and Government Spending of the House Committee on Oversight and Government Reform have not met with the transparency necessary to perform oversight. When I first requested a meeting with the FDA about the complaints, I asked for "considerable scientific detail (about) the scope of potential biological and chemical contaminants for which testing has been conducted, the raw data from such testing with an accompanying summary, methodological protocols, and any other supporting qualitative and quantitative data." I was given a one page data summary of highly aggregated, non-specific and incomplete data. After exchanges with FDA staff and requests for more data, including specific requests for the results from the part of the investigation involving the trip to China and the complaints, the information was released on their website, but neither my office nor the Subcommittee staff was notified. The consumer complaints registered until late June of 2012, as well as the inspection reports from the trip to China, were buried in a lengthy Questions and Answers web page. Congressional efforts to perform oversight must not be thwarted.

After five years, there have been well over 2000 potential incidents of illness or death of beloved pets. The lack of cooperation by manufacturers is glaring. The FDA has clear authority to act. Their actions have created the appearance of impeding Congressional oversight. Dog owners deserve to know why the FDA is refusing to put a stop to the accumulation of dog illnesses and deaths. It is stunning that the FDA continues to allow these products to be sold. I urge you to investigate the FDA's handling of tainted jerky treats.

Sincerely,

A handwritten signature in black ink that reads "Dennis J. Kucinich". The signature is written in a cursive, flowing style.

Dennis J. Kucinich
Member of Congress