Update on Vet-LIRN’s activities in FDA’s investigation into Jerky Pet Treat Related illnesses

Office of Research
Center for Veterinary Medicine
U.S. Food and Drug Administration
to
JIFSAN Advisory Council
11/14/2013
ACKNOWLEDGEMENTS

- Vet-LIRN Program Office
- Vet-LIRN Network Laboratories
- CVM Office of Research
- CVM Office of Surveillance and Compliance
- Consumers/Veterinarians
2007  FDA Cautionary warning to consumers about JPT
2008  FDA Preliminary Animal Health Notification for pet owners
2011  Canadian Veterinary Medical Association- Notice
2011  FDA continues to caution consumers about JPT
2012  FDA Update - inspections 5 JPT manufacturing firms in China
2013  FDA Update - includes Vet-LIRN testing
Reporting over time

- FDA Update 2007
- FDA Update 2008
- FDA Update 2011
- FDA Update 2012
- Market W/D

Report date vs Event date

Slide from Dr. Palmer-CVM
Jerky Pet Treat Reports to FDA by Month
(9/2012 to 10/2013)

1300 in 2 weeks

Slide from Dr. Palmer-CVM
Organs affected

- GI: ~55%
- Renal: ~31%
- FANCONI: 4-5%

Slide from Dr. Palmer-CVM
How are the JPT made?

1. Thawing
2. Loading carts
3. Auxiliary ingredients
4. Mixing/Tumbling
5. Screening/Racking
6. Drying
7. Screen for metal chips
8. Packaging
9. Irradiation

Check for metal flakes.
What Vet-LIRN Does

• Prior to 2010 we did not exist

• FDA relied on medical history as is
  – No opportunity to request additional information

• Vet-LIRN has funds to request further diagnostic workup
  – Owner’s vet
  – Network Laboratory
What Vet-LIRN Does

• Usually Office of Regulatory Affairs does product testing for regulatory action
  – Routine testing has not identified Root Cause

• 2011 Vet-LIRN began to do assist by conducting INVESTIGATIONAL TESTING of consumers’ jerky products
  – Use product collected from consumer’s bag
  – Conduct tests trying to identify or eliminate toxicants thinking about the BIG picture – not individual cases
    • No individual owner’s product can be tested for all the potential toxicants
    • Need aggregate data
Product Testing Plan

• Developed list of toxicants related to various signs.

• Developed budget for testing
  – Purchase orders
  – Contracts (can take 3-6 months)
  – Network collaborative projects (FERN laboratories- months)

• Collect samples from compelling cases
  – Cases without pre-existing medical issues
  – Cases ingesting only 1 type of treat
  – Good veterinary medical history
Product Testing Plan

• Identified laboratories in the network that can do the testing
  – Different laboratories have different capabilities
  – Unknown tox screens have different chemicals
  – Element screens include different compounds (heavy metals, Sulfur).

• Which case sample goes to which laboratory?
  – GI cases
  – Renal cases
  – Renal - Fanconi cases
Challenges

• How many pieces in the bag vs. how many grams the laboratory needs to test the sample?
  – Only 1-2 pieces left

• How many tests to run on each sample?
  – Can we do multiple tests on single pieces?
  – How many tests should/can be done per case?

• Matrix problems - hard/brittle, method validation
Challenges

• New Information – 3 different inspections
  – Add new potential toxicants to the list

• Cost – testing just one piece can cost $1000-2000.

• Government budget 2013 – no contracts till mid year

• Government Shutdown 2013
**What does the testing plan look like?**

| J | K | L | M | N | O | P | Q | R | S | T | U | V | W | X | Y | Z | AA | AB | AC | AD | AE | AF | AG | AH | AI | AJ |
| **DNA** | Coronal | **MV** | **ADN** | Coronal | **ADN** | Schu | **ADN** | **DNA** | **ADN** | **ADN** | **DNA** | **ADN** | **DNA** | **ADN** | **DNA** | **ADN** | **DNA** | **ADN** | **DNA** | **ADN** | **DNA** | **ADN** | **DNA** | **ADN** | **DNA** | **ADN** | **DNA** | **ADN** | **DNA** | **ADN** | **DNA** | **ADN** | **DNA** | **ADN** |
| **RNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** | **DNA** |
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What does the testing plan look like?

| J | K | L | M | N | O | P | Q | R | S | T | U | V | W | X | Y | Z | AA | AB | AC | AD | AE | AF | AG | AH | AI | AJ |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 1 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 2 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 3 |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |

Note: The table and diagram provide specific details about the testing plan, including dates, sample sizes, and procedures. The exact information is not clearly visible in the image provided.
VET-LIRN JERKY PRODUCT TESTING

- Metals
- DNA-species (mislabeling)
- Organic screens
- Unknown screens
- Compositional (mislabeling)
- Vitamin D
- Nitrites
- Dyes
- Micro (few positive)
- Enterotoxins (S. aureus, C. perfringens)
- Glycerin (phorbol esters, other toxicants)
- Molds, Mycotoxins
- Antibiotics residues (few positive, low levels, ppb)
- Physical characteristics (tough)
- Histology and Histopathology
- DEG, EG, PG (few positive, low levels)
- Melamine
- Furans, Irradiation markers (ACB’s)
- Biogenic amines
- Diagnostic samples (tissues, urine, blood necropsies...)

Slide from Dr. Ceric-CVM
Vet-LIRN Jerky testing: Physical Properties

• Gastrointestinal complaints ~ half of the complaints.
  – Question – is there something inherent in the nature of the product that can cause the reported illnesses?

• Diagnostic sample - Necropsy
  – Dog ate treat 3 days prior to death and did not eat anything else before euthanasia.

Stomach Contents at necropsy 3 days after eating.
Soaking/Rehydration

Dry jerky
1 day
2 - 7 days

Stomacher

Dry

30 min

90 min
Vet-LIRN Jerky testing: Physical Properties

Results:
- Tough consistency, even after rehydration
- Many samples resistant to mechanical disruption

Conclusion:

Some of the milder digestive disturbances could be related to the physical properties of jerky.
Additional Information from Inspections

- Falsification of data about glycerin source and quality
- Concern about potential contaminants in glycerin
- Evaluate sources of glycerin, potential biodiesel source
- Potential toxicants from biodiesel production
  - Sulfur
  - *Jatropha curcas* plant toxins

Following various paths

- Identification of potential hazards such as *Jatropha* use to produce biodiesel with subsequent by production of glycerin resulted in:
  - New methods developed to test for toxic elements in *Jatropha*
  - Notification to industry of potential risks
  - Evaluation of production system for glycerin
  - Evaluation of production levels of *Jatropha* to estimate risk

Species Validation

Atlantic salmon

[Image of Atlantic salmon]

Illustration-Ted Walke

[Image of Atlantic salmon]


http://fishandboat.com/pa/fish/atlantic_salmon.jpg

http://1.bp.blogspot.com/-Uean_IqUdcA/T6L2jgrafoI/AAAAAAAABNw/r1Nh6AgzZcU/s1600/chicken+public+speaker.jpg


http://static.ddmcdn.com/gif/how-to-draw-animals-12.jpg
The Importance of Negative Data

• Sometime a first step to understand a problem is to first identify what it is NOT.

• How many negative test results do you need before you eliminate that particular toxicant? E.g., heavy metals

• What about positive data? If you find something does it necessarily mean that it is the cause of the illness? (ie. in very, very tiny amounts)
Vet-LIRN tests Diagnostic Samples

• New to FDA – a way to understand more about the case
  – Helps focus product testing strategies
  – Can identify alternate reasons for illness
  – May identify emerging issues in the food supply

• Relies heavily on our network partners
  – Brings expert’s opinions on cases within reach of FDA
  – Enhances communications between diagnostic experts.
Diagnostic samples

**Body**
- Necropsy

**Tissues**
- Toxicology
- Histopathology
- Raman analysis of crystals

**Urine**
- Fanconi panel
- Urinalysis

**Blood**
- Clinical hematology

**Feces**
- Cultures
- Parasitology
Questions?