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Extra Communiqué

National Animal Supplement Council Newsletter - Supplemental

Report from the National Research Council on the Safety of Dietary Supplements for Horses, Dogs and Cats – Comments from the NASC President

By Bill Bookout

To assist in making decisions about the safety of dietary supplements for horses, dogs and cats, the Food and Drug Administration's Center for Veterinary Medicine (FDA-CVM) requested the National Research Council of the National Academies to produce a report on the safety of supplements. A committee of experts was established and charged with two main goals: review factors that should be considered when evaluating the safety of any animal dietary supplement, and secondly, assess the safety of three specific ingredients (lutein, evening primrose oil and garlic) for horses, dogs and cats. The committee addressed safety only; efficacy or utility of animal dietary supplements was not part its task. The full report will be available next month; however, a 4-page report brief and an executive summary prepared by the National Research Council based on the committee's full report are now available.

Key Observations from the Committee on Examining the Safety of Dietary Supplements for Horses, Dogs, and Cats

- Many people presume that supplements are safer than drugs and there are very limited safety data on supplements for horses, dogs and cats.
- The committee was unable to determine the upper safe level of use for the three ingredients lutein, evening primrose oil and garlic due to the insufficient safety data currently available. Because most ingredients in animal dietary supplements are not proprietary substances, it is unlikely that the amount of adequate target data will ever be sufficient for safety assessment.
- An adverse event reporting system is badly needed.
- Regulations addressing animal dietary supplements are in disarray.

As president of NASC, I would like to take this opportunity to comment on the committee's findings and recommendations. I am very familiar with this committee's examination of the safety of lutein, evening primrose oil and garlic. While not a committee member, I was asked to make presentations to the committee and submit information regarding the objectives commissioned by CVM. In addition, I also reviewed the committee's findings and provided comments along with 11 others with expertise in this area.

While I believe that certain conclusions of the committee are technically correct with respect to safety under the current system of evaluation and approval for feed ingredients, animal owners who use these products, as well as businesses who sell them, should realize this is a complex issue. Oversimplification in the report brief provided by National Research Council may cause undue and unfair concern. Readers of the report brief or subsequent published articles based only on this 4-page overview may have the impression that the animal supplement industry has not made an effort to monitor product quality, safety and risk, or establish a system of responsible conduct. The majority of the industry are members of NASC and those familiar with our organization know this is an inaccurate portrayal.

NASC was established in 2002 because current laws were developed prior to the widespread use of animal "supplements". Most stakeholders agree that applying drug laws or feed laws to animal supplements under existing regulations simply does not work. Human dietary supplements faced this same issue until Congress created a specific legal category for them with the passage of the Dietary Supplement Health Education Act in 1994.

NASC's mission is to work constructively and cooperatively with state and federal regulatory agencies to ensure that animal owners continue to have access to these important products, while creating rigorous systems to ensure quality and risk management for products and ingredients. In 2003, NASC established the NASC Adverse Event Reporting System (NAERS) that is available to FDA-CVM.

NAERS works effectively when issues arise as demonstrated by the discovery of melamine contamination in pet food last year. Through NAERS, we proactively searched the entire database for any NASC members' products containing grain-based proteins such as wheat gluten, one of the ingredients found to be contaminated with melamine. Within one day, we alerted companies with potentially affected products and FDA-CVM as to our findings. Fortunately, sources of grain-based protein contaminated with melamine were not used by NASC members.

NASC continuously tracks more than 6,000 products for adverse events that might indicate a safety issue. Monthly reporting of adverse events is mandatory for NASC members. More than 100 companies representing over 90% of the animal supplement industry now belong to NASC. **Our database of product usage contains 21 billion bytes of data for over 850 ingredients.**

From collective NAERS data, we have **0.31 Adverse Events Reported / million administrations of all products sold** by NASC members, an extremely low incidence. These data are even more significant when considering **NASC's broad definition of an Adverse Event:** *"a complaint for a product linked to any negative physical effect or health problem that may be connected to or associated with use of the product."* This means that even transient events like vomiting, diarrhea and lethargy would be reported, recorded and evaluated. Reporting an adverse event does not mean that it was necessarily associated with use of the members' product; the broad definition was developed with input from FDA-CVM.

NAERS also tracks Serious Adverse Events, defined as "*an adverse event with a transient incapacitating effect (i.e., rendering the animal unable to function normally for even a short period of time, such as a seizure) or a non-transient (i.e., long-term or permanent) health effect. Transient vomiting or diarrhea does not constitute a serious adverse event. A purported serious adverse event requires follow-up with a veterinarian. A diagnosis by a lay person does not constitute a serious adverse event."* From collective NAERS data, we have **0.001 Serious Adverse Events / million administrations of all products sold** by NASC members. Again, this does not necessarily indicate that the adverse event was due to the use of the product, only that it occurred when the product was used.

We introduced the NASC Quality Seal as an additional indicator to consumers that products bearing the seal are being monitored through NAERS which has been verified by an independent quality audit. This level of rigor and oversight far exceeds what is required for human supplements, helping to ensure that the animal supplement industry is conducting itself responsibly and pursuing objectives that are in the best interests of all stakeholders. Just a few highlights of the many accomplishments achieved by NASC:

- Established NAERS to continuously track, trend, and assess adverse events associated with either products or ingredients beginning in August 2003. NASC received high praise for NAERS during the pet food recalls in 2007.
- Developed and implemented current Good Manufacturing Practices (cGMPs) for our industry in July 2004 with several major revisions.
- Established an independent Scientific Advisory Committee providing oversight for ingredients. This committee submitted risk stratification recommendations to FDA-CVM for over 850 ingredients found in our members' products.
- Developed product labeling and claims guidelines.
- Established an independent quality audit verification program for member companies.

While the scientific skills and qualifications of the committee participants are excellent, unfortunately the committee included no one from the industry that actually participates in purveying these types of products to the marketplace for dogs, cats or horses. The Association of American Feed Control Officials (AAFCO), beginning as early as 1998, established five different committees in an attempt to address similar issues; all were disbanded without reaching viable options for a solution. While I agree that the conclusions of the National Academies study may be accurate on a very broad application, I feel it unfairly represents the conduct of the majority of the industry and what has been done to ensure animal owners have confidence in the products they receive from NASC Member Companies.