



## How FDA's Latest Compounding Guidance Affects Veterinarians

BY: SAMANTHA BARTLETT, DVM

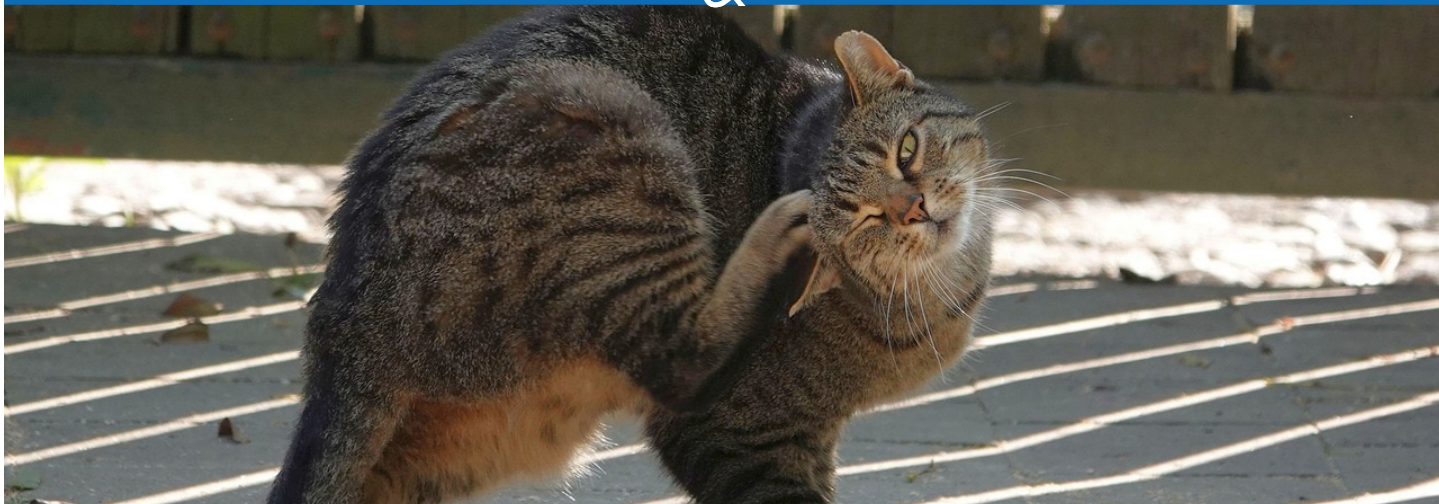
The U.S. Food and Drug Administration (FDA) published new guidance on the use of bulk active pharmaceutical ingredients to compound veterinary preparations and began enforcing in April. The guidance, known as GFI #256, no longer allows veterinarians to stock compounded preparations from bulk ingredients for future use. Instead, these medications can only be prescribed to individual patients on an as-needed basis. Veterinarians may only use compounded medications when the unique needs of the patient cannot be fulfilled by FDA approved drugs. GFI #256 does not apply to compounded preparations based on FDA-approved finished drugs.

GFI #256 also requires veterinarians to give a clinical rationale for prescribing a bulk compounded medication and pharmacies must document why a finished FDA-approved drug cannot be used as an active ingredient and bulk active ingredient must be used to compound the medication.

The FDA states it does not intend to inspect veterinary practices that don't compound from bulk substances but does plan to inspect state-licensed pharmacies. The GFI (Guidance for Industry) is not a law, but provides the basis for the FDA to investigate/inspect compounding pharmacies. Compounding pharmacies prepare the majority of medications using bulk drug substances. The FDA is still identifying which preparations from bulk drug substances may be ordered for office stock and which may only be prescribed for individual patients.

The FDA is currently creating three lists. The "listed" medications and those "under review" may currently be ordered for office stock. Medications on a "not listed" list may not be used as office stock but may be prescribed for individual patients if a medical rationale is documented. Of 200+ bulk drug substances asked to be "listed", the FDA has only allowed about 30 to be compounded for office use. Roughly the same may not be compounded, including apomorphine hydrochloride tablets, mirtazapine oral suspension and enrofloxacin oral paste for horses.

The FDA is asking for input from veterinarians why access to these medications for office use is necessary for patient care. Veterinarians can comment and provide case examples on the FDA's online GFI#256 commenting docket, which can be accessed at <https://www.regulations.gov/document/FDA-2018-N-4626-0001>.



## A Generic Oral Cyclosporine Product Has Been Approved by the FDA for Cats with Allergic Dermatitis.

BY: SAMANTHA BARTLETT, DVM

In March of this year, the U.S. Food and Drug Administration approved the first generic oral cyclosporine solution for cats. The product, Modulis, is indicated for control of itching, dermatitis, overgrooming and plaques associated with feline allergy. Cyclosporine is immunosuppressive and focuses on cell-mediated immune response. It primarily acts by suppressing T-cell activation, but also has some inhibitory effect on cytokine production and release.

Cyclosporine is contraindicated in cats that have neoplasia or a past history of neoplasia and in cats that are FELV or FIV positive. It should be used cautiously in cats with diabetes mellitus or renal insufficiency. Cats should be tested for FELV and FIV and toxoplasmosis before starting treatment with cyclosporine. Additionally a baseline CBC and blood chemistry along with urinalysis should be performed. Rechecks of CBC, chemistry and urinalysis are recommended every 3-6 months.

Extra-label indications for oral cyclosporine include chronic stomatitis, pemphigus erythematous and foliaceus, and inflammatory bowel disease.

Modulis is the same concentration and dosing as Atopica for Cats, the only approved name brand

product. Atopica for cats was approved in 2011. Modulis is available in 4.7, 15 and 30mL bottles. Cats must be at least 6 months old and weight 3 or more pounds to use Modulis. The product is available by prescription only.

Cyclosporine is classified as hazardous and personal protective equipment is recommended by the National Institute for Occupational Safety. Safety considerations for pet owners handling Modulis include avoiding ingestion of the product and washing hands immediately after administration. Some people have hypersensitivity to cyclosporine and should avoid contact with Modulis.

### References:

FDA approves first generic cyclosporine oral solution for cats for treatment of allergic dermatitis. News release. FDA. March 29, 2023. Accessed June 23, 2023. [https://www.fda.gov/animal-veterinary/cvm-updates/fda-approves-first-generic-cyclosporine-oral-solution-cats-treatment-allergic-dermatitis?utm\\_medium=email&utm\\_source=govdelivery](https://www.fda.gov/animal-veterinary/cvm-updates/fda-approves-first-generic-cyclosporine-oral-solution-cats-treatment-allergic-dermatitis?utm_medium=email&utm_source=govdelivery)

Plumb DC. Cyclosporine. Plumb's Veterinary Drugs. <https://app.plumbs.com/drug-monograph/b2qDVutWDRPROD>. Updated March 2022. Accessed June 23, 2023.

# USDA Tracking Bird Flu Spillover Events in Mammals

BY: SAMANTHA BARTLETT, DVM

Highly Pathogenic Avian Influenza (HPAI) is responsible for the death of approximately 60 million chickens and turkeys across the United States. Infections have been identified in wild, commercial and backyard birds in every state except Hawaii. The U.S. Department of Agriculture (USDA) has been tracking not only avian infections, but also cases that have spilled over into mammals across the nation. The USDA published a report of mammalian cases that had been tracked from 2022 until March 2023.

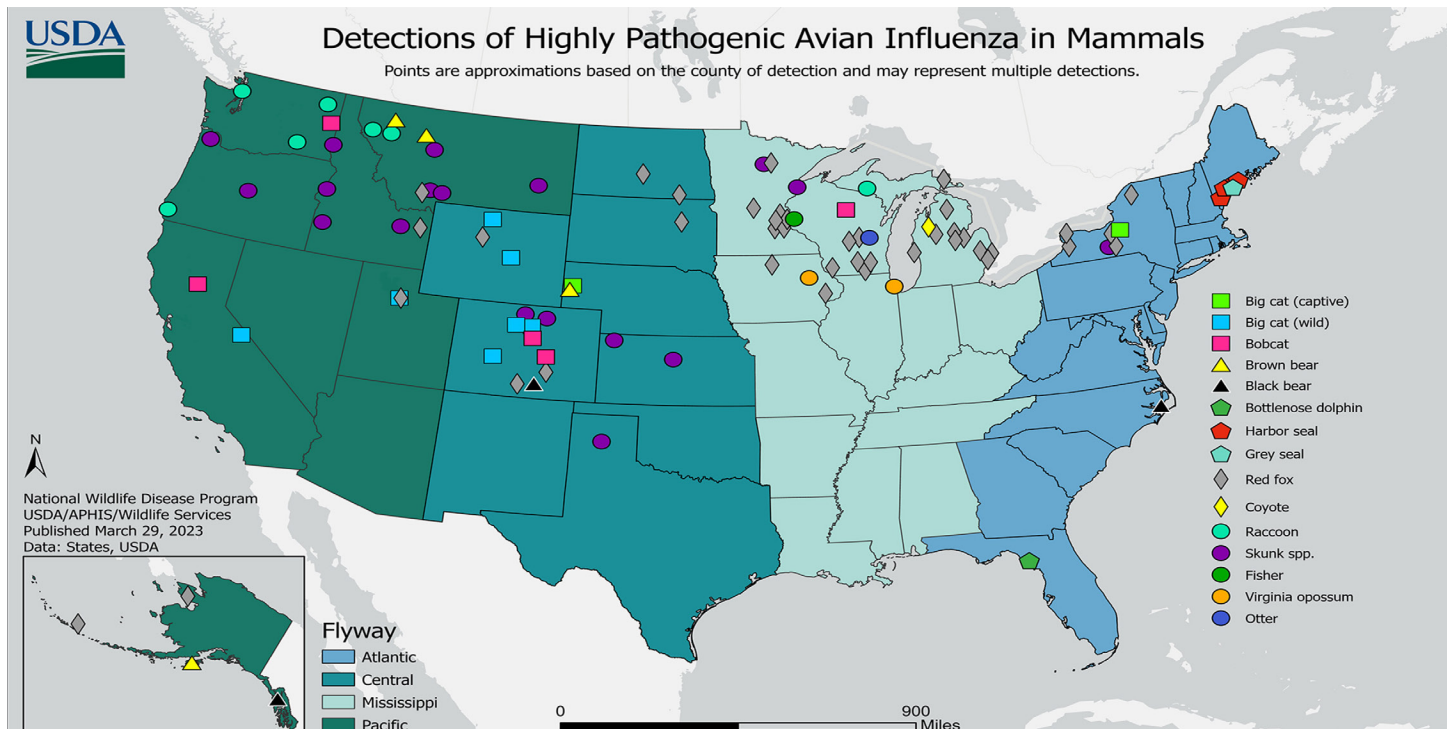
There are four types of influenza – A, B, C, and D. All four types can infect animals, although Type D is only known to affect humans. Type A viruses include HPAI as well as swine flu subtypes. The avian subtype currently affecting birds is H5N1. Although no known human-to-human transmission of H5N1 has occurred, a few cases have been reported in humans after exposure to infected poultry. However, according to the USDA report published in March 2023, H5N1 has been detected in numerous mammalian species, including most noticeably in bobcat, black and brown bears, bottlenose dolphin, harbor and grey

seals, mountain lion, red fox, raccoon, and striped skunk.

Researchers believe that most animals contracted the virus by eating infected host birds. It is unknown once infected if these mammals can spread the virus to offspring or other mammals in contact. According to Dr. Rebecca Poulson, assistant researcher with the Southeastern Cooperative Wildlife Disease Study at the University of Georgia College of Veterinary Medicine, individuals within a species differ in their susceptibility to HPAI. Seals seem to have a lot of morbidity and mortality within affected populations on the North Atlantic coast and sea lions in Peru seem to have been susceptible to spread of HPAI among close populations.

Studies and surveillance are ongoing as researchers try to determine the significance and danger of HPAI to other species as well as to develop management practices to control and contain outbreaks among mammalian species.

A map showing species and locations of mammals reported with HPAI can be found at <https://www.avma.org/sites/default/files/2023-04/AVMANews230424-HPN1-mammals-2880w.jpg>.





## Hearing Loss in Dogs Associated with Dementia

BY: SAMANTHA BARTLETT, DVM

A study published in the Journal of Veterinary Internal Medicine (JVIM) in August 2022 has shown a link between hearing loss in senior dogs and increased symptoms of canine cognitive dysfunction (CCD). It is known that hearing loss is a risk factor for dementia in aging humans. Study lead, Gilad Fefer at North Carolina State University, set out to determine if the same was true for older canines.

It has been suggested that the link between hearing and mental function is due to the fact that the interpretation of sound and a large amount of cognitive processing for short-term memory both occur in the temporal lobe. Loss of hearing results in associated cells of the brain being understimulated and eventually deteriorating affecting the function of the rest of this area of the brain. Age relating hearing loss in canines typically begins around 8 to 10 years of age. The greatest loss begin with high frequencies then middle frequencies of sound.

The study involve 39 dogs whose median age was 13 years old and otherwise healthy. Each dog was tested for hearing using the brainstem auditory evoked response (BAER) method, which measures the electrical response to sound in the cochlear nerve. Dogs without hearing loss could hear tones at 50 dB, the group with moderate hearing loss could hear tones at 70 dB and the severely impaired group could only hear tones at 90 dB or more.

Dog owners were asked to complete a questionnaire evaluating their dog's quality of life including vitality and companionship. They were also asked to complete a second questionnaire evaluating symptoms of cognitive decline. Researchers found that vitality and companionship behaviors declined significantly with the deterioration of hearing ability.

OF the dogs with normal hearing, 61 percent were free of symptoms of CCD – 31 percent had mild symptoms and 5 percent showed moderate symptoms of decline. Of dogs with moderate hearing loss, 50 percent showed moderate signs of dementia. Notably, of dogs with severe hearing loss, none were free of CCD symptoms with half of the group exhibiting severe symptoms of CCD.

This study suggests that the same correlation between hearing and cognitive function exists between people and dogs. This opens the possibility that finding a way to correct age-related hearing loss in dogs, possibly through cochlear implants, can prolong mental health in these individuals.

The JVIM article can be accessed at <https://onlinelibrary.wiley.com/doi/10.1111/jvim.16510>.

## New Research Shows Peas in Grain Free Dog Food Not Linked to Heart Disease

BY: SAMANTHA BARTLETT, DVM

A new study by researchers at the University of Guelph has found that pulses (lentils, beans and peas) in grain free dog foods are not linked to heart problems in healthy dogs, specifically diet-related dilated cardiomyopathy (DCM). The study was published in April in The Journal of Nutrition. Dogs in the study were observed over 20 weeks as they ate a grain-free diet containing up to 45 percent pulse ingredients. The dogs developed no signs of heart disease and maintained lean body weight.

Pulses are used in plant-based dog food to provide dietary protein. There have been concerns that pulses do not contain adequate amino acids needed for heart health. Specifically amino acids key for making taurine. The lack of amino acids can also lead to loss of lean muscle mass due to lack of proper protein absorption.

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Twenty-eight Siberian huskies were entered into the randomized controlled trial. The breed was chosen because huskies are not traditionally at risk for genetic causes of DCM. A diet containing either 0, 15, 30 or 45 percent whole pulse ingredients was assigned to each dog. The pulse ingredients included green and yellow peas, pinto beans, chickpeas and lentils. The diets also included chicken as an animal protein and all had the same protein and fat levels.

Veterinary cardiologist, Dr. Shari Raheb, performed echocardiographs to detect heart changes and blood was collected routinely to evaluate for cardiac biomarkers and amino acid changes. The dogs were weighed weekly and scanned to assess body composition at the beginning and end of the study. None of the dogs developed any changes associated with DCM nor did they show any changes to body composition throughout the study.

The lead author of the study is Dr. Kate Shoveller who is a professor in the Department of Animal Biosciences at the Ontario Agricultural College and Chaire in Canine and Feline Nutrition, Physiology and Metabolism for Champion Petfoods. According to Dr. Shoveller, this study represents the longest controlled feeding trial to assess cardiac health in dogs eating pulse diets. Dr. Shoveller also explained that previously conducted studies were not conclusive on whether dogs not genetically predisposed to DCM were adversely affected by pulse ingredients.

The study was funded by Champion Petfoods and the diets were all processed in Champion facilities. The published article can be accessed at <https://www.sciencedirect.com/science/article/pii/S0022316623355007>.

## JULY CE EVENT

**Speaker:** Dr. Ruggiero

**Topic:** ONC Care – Powerful Nutrition Designed for Pets Fighting Cancer

**Date:** July 20th, 2023

**Time:** Dinner/Registration: 6:30 | Presentation: 7:00

**CE:** 1 Hour

**Location:** YaYa's Overland Park

**Fee:** No fee to attend this event, but RSVP is required by **July 17th**. Current membership dues cover all CE..

**Sponsor:** Hills

## Classifieds

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### June 12, 2023

Westwood Animal Hospital is seeking an experienced, compassionate veterinary technician to join our team. The applicant must share our love, respect and compassion for dogs and cats, be able to accomplish assigned duties while keeping pet restraint to a minimum, and have strong but easy going client and staff interaction skills. This position requires surgery and dental experience. We place high value on empathy, a caring touch, technical expertise with attention to detail, and teamwork. We are a busy three-doctor AAHA practice. We have digital XR, digital dental XR, an IM3 dental unit, IDEXX in-house labs (cbc, chemistry and automated urinalysis equipment) and a GE LOGIQ 2 ultrasound unit. We acknowledge the importance of a good work-life balance and strive to schedule accordingly. Benefits include a 401K program, paid continuing education, supplemental insurance, paid holidays, personal days and a personal pet discount.

Our employment application and information about our hospital can be found at:

<http://westwoodanimalhospital.com/front-page/forms-2/job-application-form/>