



National Bison Association

8690 Wolff Court, Suite 200 Westminster, CO 80031-3646
www.BisonCentral.com Phone: 303-292-2833 Fax: 303-845-9081

Weekly Update from the National Bison Association

A news and update service *exclusively* for members of the National Bison Association.
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September 27, 2019

Long To-Do List After D.C. Roundup

The National Bison Association staff spent much of this week compiling a lengthy to-do list following the series of meetings at USDA and on Capitol Hill in Washington, D.C. last week.

“Our Policy Roundup delegation held some extremely productive meetings last week. Throughout USDA, officials were willing to work with us to advance the priorities of the bison business, and they sent us home with a long list of follow-up items,” said Dave Carter, executive director of the National Bison Association. “Now, we have to follow through on that follow-up.”

Among the items discussed in D.C. were:

- Expanding the bison commodity purchase program, and increasing utilization of bison meat in federal food and nutrition programs;
- Adding a live animal price report, and a calving report to the current USDA wholesale bison price report;
- Development of a new Mycoplasma bovis vaccine;
- Federal resources available to support the NBA’s science and research priorities;
- Collaboration among USDA’s Animal and Plant Health Inspection Service to improve traceability in the bison business;
- Streamlining the process for bison marketers to implement minor label changes in the retail marketplace; and
- Opening new export markets in Mexico, Japan, Korea and Taiwan.

Carter noted that the NBA will be following us with the offices of Senators and Representatives who expressed a willingness to support the Truth in Buffalo Labeling Act, which was introduced September 16th by U.S. Sens. John Hoeven (R-ND) and Michael Bennet (D-CO).

BuySome Bison Consumer App Launched

The National Bison Association this week officially launched *Buysome Bison*, a location-based app that will allow potential customers to easily locate NBA members who can provide them with deliciously healthy, locally raised bison meat and a variety of bison artisan goods. The app will also allow users to locate nearby bison ranches offering tours, wedding venues, weekend getaways and other agritourism experiences for the whole family.

Jim Matheson, NBA assistant director, explained, "Using the resources available through USDA's Farmers' market Promotion Program, we were able to create this new, user friendly app that will replace the outdated Bison Finder app. This new app ties directly into the NBA Buyers Guide, so members should make sure their information is up to date here.

<https://bisoncentral.com/buyers-guide/>

The Farmers Market Promotion Program grant being administered by the NBA provides financial resources for the association to actively promote the app in on-line sites, and in publications focusing on food and recreation.

"This is a great opportunity to let the public know what you have to offer," Matheson said. "Be sure to utilize it effectively."

Ranchers Prepare to Court Mommy Bloggers

As social media influences head to Atlanta, GA next week for Shiftcon, the nation's largest gathering of "eco-wellness" bloggers, the National Bison Association will be front-and-center to provide information on the important role bison are playing in providing healthy food, and restoring healthy ecosystems.

An estimated 400 female bloggers, often called Mommy Bloggers, are expected to gather at Shiftcon next week for presentations and workshops focusing on families, food and environmental issues.

Thanks to resources in the National Bison Association's Growth Fund, the NBA is among the primary sponsors of Shiftcon, and will have a major presence at the event.

The highlight of the NBA's presentation will be the keynote presentation during the October 5th luncheon. During that luncheon, NBA members Mimi Hillenbrand of South Dakota and Carrie Bennet of Colorado will discuss the vital role that women of playing in developing the bison business, and in connecting with consumers seeking healthy, responsibly produced food for their families.

"The attendees at Shiftcon are at the forefront in shaping public opinion about food, and how that food is produced," said Dave Carter, NBA executive director. "This is a prime opportunity for us to let these social media influencers that Bison is truly nature's original plant-based protein. Mimi and Carrie, along with our communication director, Karen Conly, will help carry that message at the conference."

More information on Shiftcon is available here. <https://shiftconmedia.com/>

Information on NBA's sponsorship is available here. <https://shiftconmedia.com/2019/09/27/2019-shiftcon-sponsor-national-bison-association/>

Wholesale Prices Tumble in August

The wholesale prices paid for dressed bison carcasses tumbled in August, according to the latest USDA report issued last week by the agency's Grain and Livestock Market Reporting Service.

Dressed young bull carcasses averaged \$418.75/cwt. in August, which was \$25.40/cwt. lower than the previous month and \$63.84/cwt. lower than the previous year. Dressed heifers averaged \$422.05 in August, which was down \$20.45/cwt. from the previous month and \$54.59/cwt. from the previous year. Older bulls and cows were also lower.

Average carcass weights were lower than in July in most categories, but still heavier than the previous August. Young bulls comprised 62 percent of the young animals processed year-to-date (YTD). That compares with the 10-year average of 61 percent.

According to USDA's National Agricultural Statistics Service, 38,304 head of bison have been processed under federal inspection YTD. That is four percent higher than the 36,840 processed YTD last year, and the highest number of bison processed under federal inspection since 2010.

NBA Holds Second Training on Producer App

The NBA held a webinar training on its new Bison Producer's App, available to NBA members now at no charge.

The training was facilitated by assistant director, Jim Matheson, and app developer Melissa Brandao, CEO of HerdDogg, Inc. Many members joined the training and learned about its many features, as well as tutorials on how to enter animal and herd records, and more.

The next training will be offered on October 23rd at 2 pm MDT. To register, please email jim@bisoncentral.com.

The app's extensive features result in a very powerful resource that literally fits in the palm of your hand. App features are to include animal photo ID, birthdate, herd and tag ID, weight, gender, vaccination/dewormer schedule, North American Bison Registry animal history, notes for things like body condition, health, transfer history, animal test results, genetic/parentage information, calving rates, USDA RMA Crop Insurance fact sheets, NBA push notifications including Trading Board ads, Weekly Update, NBA membership data and more.

The app is among the deliverables resulting from a grant from the U.S. Department of Agriculture's Risk Management Agency (USDA RMA) and the project it's underwriting - *Record Keeping for Risk Mitigation*.

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Bison Preparing For 53rd Annual Buffalo Roundup

(From South Dakota Public Radio)

This weekend, about sixty cowboys will herd thousands of bison to Custer State Park's corrals. The Buffalo Roundup draws spectators from all over the country. But the bison earn the big bucks.

The smell of sage and buffalo dung wafts through the air. Bison snort as park staff drive trucks over small yellow hills, following dirt tire tracks in the dry brush. A group of the animals drinking from a creek ignore the vehicle for a few minutes before moving down the waterbed. These bison are used to people pulling over to gawk.

"Somebody can sit on the loop road and they'll stand there in the road. I swear half the time it's just to see how long somebody will wait for them."

Mark Hendrix is the Natural Resource Program Manager at Custer State Park. He says there are about 14 hundred bison.

"The bulls have a lot bigger bases to their horns and they're a lot longer. You know an older cow can have really long horns but they're going to be skinny."

They can weigh more than two thousand pounds, but they're fast runners.

"Up to 35 miles an hour. I mean they jump six feet fence just from flat footed. So, they're very agile even though they look nice and docile out here on the prairie."

This weekend, about sixty cowboys will herd them into corrals for sorting. Some will be kept at the park and bred. Others get sold to buyers--sometimes for ranching.

"Custer State Park has sold a lot of bison and provided a lot of genetics to bison producers all over the United States and into Canada."

Full story and audio here. <https://listen.sdpb.org/post/bison-preparing-53rd-annual-buffalo-roundup>

North American Meat Institute Releases Revised Edition of Animal Handling Guidelines and Audit Guide

(From Perishable News)

WASHINGTON, DC - The North American Meat Institute (Meat Institute) today released its latest science-based animal care guidelines and audit for the meat industry. The guidelines and audit were authored by Colorado State University Professor of Animal Behavior Temple Grandin, Ph.D., working with the Meat Institute's Animal Welfare Committee.

"The meat and poultry industry is always looking for ways to improve humane animal handling for both the welfare of the animal and the safety of our workforce," said Meat Institute President and CEO Julie Anna Potts. "The new Animal Handling Guidelines and Audit are the product of member company participation with the guidance of the Meat Institute's veterinarian Dr. Tiffany Lee and the world's foremost expert on animal welfare and the meat industry, Dr. Temple Grandin."

"It is important to update these guidelines in order to facilitate continuous improvement of animal welfare standards in the meat industry," said Grandin.

The revised "Recommended Animal Handling Guidelines & Audit Guide: A Systemic Approach to Animal Welfare" can be found here:

http://www.animalhandling.org/producers/guidelines_audits

Major changes in this year's edition include:

Adding a new section about how to handle occasions when there is a non-ambulatory or disabled animal on a truck and in the yard;

Providing a new definition of "non-ambulatory animal" consistent with U.S. and Canadian regulations;

Justifying using 100 head as the recommended sample size; and

Allowing plants to determine, using outcomes-based measures, when water should be provided to animals in drive alleys, which follows Food Safety and Inspection Service policy.

Full text: <http://tinyurl.com/y2rsxv67>

Water Buffalo Or Bison? Legislation Seeks Clarity In Food Labeling

(From the Rapid City Journal)

The “buffalo” listed as an ingredient in some foods marketed for people and pets is actually from water buffaloes, not bison, according to supporters of new legislation that would require greater accuracy in labeling.

Last week, U.S. senators from North Dakota and Colorado introduced the Truth in Buffalo Labeling Act. A spokesman for U.S. Sen. John Thune, R-S.D., said Monday that he has agreed to sign on as a co-sponsor of the bill.

The legislation would add two sentences to the end of an existing section of federal law that pertains to misbranded food. One of the sentences would define food items as misbranded if they contain water buffalo that is labeled only as “buffalo.” The other sentence would clarify that “buffalo” is an acceptable reference to bison.

Full story. https://rapidcityjournal.com/news/local/water-buffalo-or-bison-legislation-seeks-clarity-in-food-labeling/article_af8025d3-7e90-565b-9aa9-7d522e155e7b.html

Proposed Legislation Aims To Eradicate Misleading Labels On Water Buffalo Meat

(From the grand Forks Herald)

Bison ranchers are aiming to stomp out erroneous labeling of buffalo meat by those selling the meat of water buffaloes.

Senators John Hoeven and Michael Bennet announced that they have introduced the Truth in Buffalo Labeling Act, legislation aiming to provide a fix to deceptive labeling that is impacting the U.S. bison industry. The legislation would provide the Food and Drug Administration with the authority to prohibit water buffalo products from being marketed as “buffalo.”

“This legislation prevents the deceptive marketing of water buffalo as buffalo,” Hoeven said. “Our bill provides clarification to consumers by giving FDA the authority necessary to ensure proper labeling of water buffalo and establishing that buffalo is a common name for bison.”

Last year, the senators led a letter to the FDA highlighting concerns with the growing number of imported water buffalo meat and pet food ingredients on the market being labeled as “buffalo.” In response, FDA indicated that it does not currently have a specific regulation regarding the marketing of either water buffalo or bison, but the agency agreed that water buffalo should be labeled as “water buffalo” and bison should be labeled as “bison” or “buffalo.”

“Misleading labeling does a disservice to bison ranchers, who have worked hard to create a growing market for bison” Bennet said. “By requiring that water buffalo products be labeled accurately, our legislation will go a long way in addressing this misleading practice, provide transparency for American consumers and safeguard the U.S. bison industry.”

Full story. <https://www.grandforksherald.com/business/agriculture/4666015-Proposed-legislation-aims-to-eradicate-misleading-labels-on-water-buffalo-meat>

USDA Issues New Holiday Rule for Voluntary Meat Inspection

The USDA’s Agricultural Marketing Service this week issued a notice amending its regulations governing the voluntary grading and certification relating to meats, prepared meats, meat products, shell eggs, poultry products, and rabbit products.

Amendments include changing terminology to scheduled and non-scheduled, billing of holidays, billing excessive hours over and above agreement hours, and removing the administrative volume charge.

According to the notice in the Federal Register, the amendments will standardize and align billing practices for services provided by the Livestock and Poultry Program.

The amendments will revise federal rules by adding the definition of observed legal holidays. The addition of observed legal holidays will establish the “in lieu of holiday” for a holiday that falls on a Saturday or Sunday. Amendments will also charge the holiday rate for hours worked on observed legal holidays.

Previously, services were billed the holiday rate only on the actual holiday when worked, and if the actual holiday was not worked, no charge was applied. Additionally, holidays that fall on Saturday or Sunday but were observed on a Friday or Monday were billed at the commitment rate, not the holiday rate.

The full Federal Register notice is available here. <https://www.govinfo.gov/content/pkg/FR-2019-09-23/pdf/2019-20123.pdf>

Huge Nature Reserve Shrinks Bison Plan After Pushback

(From Associated Press)

BILLINGS, Mont. (AP) — A conservation group trying to create the largest nature reserve in the Lower 48 states said Tuesday it was scaling back its request to expand bison grazing in Montana, following strong opposition from ranchers and Republican lawmakers. The group's long-term goal remains unchanged: A 5,000-square-mile (12,950-sq. kilometer) expanse of public and private lands with at least 10,000 bison in the north-central area of the state.

But that would happen more slowly than anticipated after the idea encountered resistance from surrounding landowners. They worry year-round grazing could destroy the range and that the reserve is displacing ranching families as it grows.

The American Prairie Reserve's revised application to the U.S. Bureau of Land Management would allow bison to graze on about 94 square miles (243 sq. kilometers) of public lands instead of the 450 square miles (1,166 sq. kilometers) originally requested.

The Bozeman-based group does not want neighboring landowners to feel "bulldozed," reserve vice president Pete Geddes told The Associated Press in advance of the public announcement. Founded in 2001, the reserve is located on rolling grasslands along the Missouri River near the Charles M. Russell National Wildlife Refuge.

Massive herds of migrating bison once passed through the area before the animals were hunted to near extinction in the late 19th century. Today the landscape is broken up by the fence lines of sprawling cattle ranches, many run by the same families for generations.

"We want our neighbors to feel very comfortable with our management," Geddes said. "We have every intent as a conservation organization to make sure this range is in really good condition." In addition to paring back areas where bison grazing would be allowed, the revision would allow only seasonal grazing on most of the land instead of the year-round grazing originally requested. It reduces the amount of interior fencing removed — to allow bison and other wildlife to roam more freely — from 300 miles to 40 miles.

Full story. <https://www.apnews.com/f25626000bda4bd19134d75ab247659e>

First Group Of Bison Make The Move From The Grand Canyon To Oklahoma

(From azcentral.com)

More than two dozen bison that once roamed the North Rim of the Grand Canyon now call the Quapaw Nation of Oklahoma home, the goal of a pilot project to reduce the animals' runaway population in the national park.

In all, 31 bison were loaded into livestock trailers earlier in September for the 1,150-mile trip to the Quapaw tribe's lands in northeastern Oklahoma. It's the second attempt to hold the roundup after weather halted the first try in 2018.

The Grand Canyon bison herd is the legacy of a failed experiment to crossbreed bison with cattle. Charles "Buffalo" Jones, a former bison hunter, brought a small herd to House Rock

Valley, now known as House Rock Wildlife Area, in the early 1900s. The experiment failed, but the bison, now carrying small bits of cattle DNA, remained behind.

Until the mid-1990s, the herd lived in the House Rock Valley, south of the Vermilion Cliffs, and the nearby Kaibab National Forest, managed by the Arizona Game and Fish Department. However, they eventually found fertile grazing areas and safety within the national park's boundaries, and nearly all the herd now lives along the North Rim.

"The bison found a disturbance-free refuge (within park boundaries)," said Scott Poppenburger, Flagstaff regional director for the Arizona Game and Fish Department. "They understand that at Grand Canyon they're free from hunters."

The agency, which has the mandate to manage the state-owned herd, holds bison hunts for the few bison that currently set hoof out of the park. Poppenburger says that the hunts have about a 35% success rate, about 45 bison a year.

Read more. <https://www.azcentral.com/story/news/local/arizona-environment/2019/09/24/first-group-bison-make-move-grand-canyon-oklahoma/2423347001/>

Bison Rescued From Cruel Conditions In Washington Seeking New Home

(From K5News)

QUILCENE, Wash. — You'll find many four-legged creatures at [Central Valley Animal Rescue](#) in Quilcene, Wash., including your standard dogs, cats, some horses, a few iguanas, and maybe even the occasional emu.

But you'll also find a species not so common for the organization that's now in need of a permanent place to call home.

"They're unlike any animal I've ever worked with," said Sara Penhallegon, who runs the center. The animals are seven bison that were seized in an animal cruelty case. The bison were malnourished and few were expected to survive.

"It was devastating to see," said Penhallegon. "They're such majestic creatures and they looked like just like leather stretched over a skeleton."

Over the past year and a half, Penhallegon and her team nursed all of the animals back to health.

Read more. <https://www.king5.com/article/news/local/bison-rescued-from-cruel-conditions-in-washington-seeking-new-home/281-cfeb53b9-c9d1-4ac5-a551-b1b30b25a8a2>

Epic Co-founders to 'Reclaim the Legacy of Meat' Under New Brand

(From NOSH)

Seven years ago, Taylor Collins and Katie Forrest helped steward a snacking revolution, introducing consumers to better-for-you, more sustainably raised meat snacks through their brand Epic Provisions. In 2016, the company was sold to General Mills for a reported \$100 million. Now the husband and wife duo, joined by former Epic CFO/COO Robert Sansom, are ready to bring transparency and sustainability to what they say is one of the last frontiers of the grocery store, the meat counter, with the launch of their new brand Force of Nature.

Formerly vegan, Collins and Forrest are now stretching their belief in animal protein as a key link in the regenerative agriculture cycle. The company is launching in retail with pasture raised ground meat “bricks” including bison, a bison blend, wild boar, and beef and pre-shaped burgers (in a bison/bacon blend and a venison/wagyu beef blend). Online and in foodservice, the company offers even more cuts, such as tenderloin and short ribs.

Although it officially debuted to the trade at Natural Products Expo East, the brand was already in several regional grocery chains, most notably Central Market in Texas. The patties are sold frozen, but other cuts and grinds can be sold frozen or fresh, with the latter offering a 21-day shelf life.

At \$9.99 to \$12.99 for the ground product, which comes in a 14 oz. pack, Force of Nature is at the high end of ground meat price per pound. The founders hope that with scale, they can drop the price, but Collins added that consumers are clearly willing to pay more for a transparent, sustainably raised product — even in commodity categories such as dairy and eggs — and the team believes these shoppers will “vote at the registers” with their dollars.

“The way you grow and scale a supply chain around regenerative is via the consumer,” Sansom added. “When the consumer demands a better product, a regenerative protein product, they are going to get it.”

Shoppers also, he added, are currently unaware that while they may save now buying conventional meat, they will “pay” later on as climate change issues continue to emerge, driving up the cost to the planet and to food supplies. Through marketing efforts, the company hopes to expose these costs.

The company grew out of Forrest’s and Collin’s side project, Roam Ranch — a 450-acre ranch on the outskirts of Fredericksburg, Texas where bison, turkeys, ducks, chickens, pigs, geese and other wildlife such as honeybees and white tail deer. The ranch is farmed using regenerative agriculture, a conservationist approach to food and farming systems that focuses on regenerative topsoil, increasing biodiversity of species and improving the water supply in order to reduce the ongoing effects of climate change while rehabilitating land that may have been damaged over time.

Read more. <https://www.nosh.com/news/2019/epic-co-founders-to-reclaim-the-legacy-of-meat-under-new-brand>

USDA Announces Cooperative Agreement Funding for Radio Frequency Identification (RFID)

(From Hoard's Dairyman)

The United States Department of Agriculture's Animal and Plant Health Service (APHIS) is announcing the funding to support animal disease traceability (ADT) and electronic identification for cattle. The money will fund 3 of the 11 projects submitted with each coordinated by state organizations. The 3 to be funded are the Florida Cattleman's Association, Texas Animal Health Association and The University of Wisconsin at Madison which will jointly help USDA increase the accuracy, efficiency, and cost effectiveness of collecting key pieces of traceability information, while supporting the cattle industry's management and marketing needs. These projects will document how to link ultrahigh frequency (UHF) Backtags with other identification devices to collect animal movement and disease data while still maintaining the speed of commerce. We need to learn more about how adding RFID functionality will support traceability in these high-volume, fast-paced environments. The projects will gather important real-world data to help USDA; States, Tribes and industry advance animal disease traceability and implement electronic ID.

ADT helps health officials know where diseased and at-risk animals are, where they've been, and when. This helps ensure a rapid response during disease events, which can reduce the number of animals and the response time, ultimately reducing the economic impact on owners and affected communities.

Full text: <http://tinyurl.com/y6ajil2o>

TAHC Commission Adopts Amendment to Trichomoniasis Rule and Proposes Bovine Viral Diarrhea Rule

(From Texas Animal Health Commission)

Austin, TX - The Texas Animal Health Commission (TAHC) held a regularly scheduled commission meeting on August 13, 2019, at its headquarters in Austin.

The following rules were adopted and will go into effect on October 6, 2019.

Chapter 38, Trichomoniasis

Three amendments were proposed to the Trichomoniasis (Trich) chapter; however, only one was adopted.

The adopted rule limits the use of a virgin certificate as an exemption to Trich test requirements. The rule states that sexually intact male cattle under 18 months of age, or verified by birth date listed on the breed registry papers, must be certified by the breeder on a virgin certificate in order for the animal to be sold without a test. Therefore, the use of virgin certificates is restricted to breeding animals belonging to a breed registry which maintains an official list of animals for which there is an association of unique identification for the cattle.

Chapter 49, Equine (Official Identification)

The adopted rule adds electronic identification (ID) and digital photographs as additional options for officially identifying equine. The use of hand-drawn identification marking is still accepted.

Chapter 51, Entry Requirements (Equine)

The proposed amendment incorporates forms of electronic identification (see Chapter 49, Equine rule adoption) as official identification for all equine entering Texas, whether they are

moving on an extended equine interstate passport (EECVI) or standard CVI. To learn more about the EECVI option visit <https://www.globalvetlink.com/products/eecvi/>.

The following amendments were proposed, and TAHC will accept public comments on the proposals from September 27 - October 28, 2019.

Chapter 44, Bovine Viral Diarrhea Program

The chapter was originally proposed at the May 21, 2019 commission meeting for the purpose of establishing a Bovine Viral Diarrhea (BVD) program. However, the rule proposal was withdrawn, and a new rule proposal was approved and submitted for public comment.

The newly proposed rule would provide mitigation from the risk of Texas cattle being exposed to persistently infected (PI) bovine viral diarrhea virus (BVDV) cattle. The rule defines which cattle are classified as BVDV PI, and would require the seller to disclose the status in writing to the buyer prior to or at the time of sale.

For more information on the Chapter 44 rule proposal visit

https://www.tahc.texas.gov/regs/proposed/2019_08_13_Ch44BovineViralDiarrhea.pdf

Full text:

https://www.tahc.texas.gov/news/2019/2019-09-24_TAHCCommissionMeeting.pdf

'Antibiotic Resistance In Farm Animals Is Rising Fast'

(From MedicalNewsToday.com)

Researchers have found that antibiotic resistance is on the rise among farm animals in low-to-middle income countries. This could have a severe impact on the animals' well-being and the health of consumers. For this reason, they urge the development of better farming policies around the world.

For the past few years, scientists have been sounding the alarm about [antibiotic](#) resistance repeatedly.

Antibiotic resistance refers to dangerous bacteria's increasing adaptability and imperviousness to the action of antibiotics, which are potent drugs designed to fight bacterial infections. Humans may soon face an antibiotic resistance crisis, as the bacteria we are vulnerable to may stop responding to treatments that used to be effective against them.

Now, a new threat has become apparent: the rise of antibiotic resistance among farm animals, including pigs, cattle, and poultry.

[Previous research](#) has found that an increasing number of farmers are treating farm animals bred for human consumption with antimicrobial drugs. Researchers have expressed concerns about the impact this might have on human health in the long run.

Now, a new study — featured in the journal [Science](#) — confirms that this practice has led to an increased number of antibiotic or antimicrobial resistance cases among farm animals all over the world.

Source: <https://www.medicalnewstoday.com/articles/326436.php>

FDA Issues Draft Guidance on Expanded Conditional Approval for Certain Animal Drugs

[\(From FDA\)](#)

The U.S. Food and Drug Administration this week released draft Guidance for Industry, entitled [“Eligibility Criteria for Expanded Conditional Approval of New Animal Drugs,”](#) to assist animal drug sponsors and potential sponsors who may be interested in pursuing conditional approval to market animal drugs to address serious or life-threatening diseases or conditions, or an unmet animal or human health need, and for which demonstrating effectiveness would require complex or particularly difficult study or studies.

Until recently, only new animal drugs intended for minor use in major species or for use in a minor species (MUMS) were eligible for conditional approval. In 2018, as part of the reauthorization of FDA’s Animal Drug User Fee Act (ADUFA) program, Congress amended section 571 of the Federal Food, Drug and Cosmetic Act (FD&C Act) to expand FDA’s authority to grant conditional approval to include certain animal drugs for use in major species (horses, dogs, cats, cattle, pigs, turkeys, and chickens) for diseases or conditions that would not be eligible for conditional approval under the MUMS provisions of the FD&C Act.

Expanded conditional approval has the potential to incentivize drug development and provide veterinarians with legally marketed new animal drugs to treat serious or life-threatening diseases or conditions and to fill treatment gaps where currently no therapies are available. The draft guidance issued today includes proposed definitions for the key terms, “serious or life-threatening disease or condition,” “unmet animal or human health need,” and “complex or particularly difficult study or studies,” that appear in section 571 of the FD&C Act. With the release of the draft guidance, the agency is fulfilling a statutory requirement to provide information to the animal drug industry to further clarify the criteria for determining a drug’s eligibility for the new expanded conditional approval pathway.

The FDA currently reviews applications for conditional approval of MUMS drugs, i.e., new animal drugs intended for minor uses (animal diseases and conditions that occur infrequently or in limited geographic areas and in small numbers of animals) in major species, or for use in minor species (those other than horses, dogs, cats, cattle, pigs, turkeys, and chickens). Expanded conditional approval extends the availability of the conditional approval pathway beyond MUMS drugs to also include new animal drugs not intended for MUMS uses that address a serious or life-threatening disease or condition, or an unmet animal or human health need, and for which demonstrating effectiveness would require a complex or particularly difficult study or studies. FDA intends to use the term “expanded” conditional approval only when referring to applications for conditional approval under the new expanded pathway for non-MUMS drugs. Applications for conditional approval involving MUMS drugs would not be covered by that term.

Conditional approval, including under the new expanded pathway, allows an animal drug sponsor to legally market its product after demonstrating that the drug is safe and manufactured in accordance with full approval standards, and that there is a reasonable expectation of effectiveness for use. The initial conditional approval is valid for one year with the potential for four annual renewals. During this time, the animal drug sponsor must demonstrate that it is actively working toward collecting the remaining effectiveness data needed to achieve full approval. The animal drug sponsor must attain full approval within five years after receiving conditional approval or the conditional approval will be terminated.

The FDA is accepting public comments beginning on September 30, 2019. To electronically submit comments to the docket, visit www.regulations.gov and type FDA-2019-D-3361 in the search box. For assistance in submitting electronic comments, please see [regulations.gov help](#).