Gene Harrington

Who is commenting? *(choose the best fit)*
Representative of a product manufacturer(s)

If you are commenting as a representative, what is the name of the entity you are commenting on behalf of?
Animal Health Institute, the U.S. trade association for research-based manufacturers of animal health products – the medicines that keep pets, service animals, and livestock healthy.

If you represent a product manufacturer or industry group, what industry(ies) do you represent?
Animal health sector. The Animal Health Institute (AHI) is the U.S. trade association for research-based manufacturers of animal health products – the medicines that keep pets, service animals, and livestock healthy.

If you represent a product manufacturer, what types of components, products, or product categories do you manufacture that you will be requesting a CUU determination for?
AHI represents companies that develop and manufacture, among other products, pharmaceuticals, biologics (including biopharmaceuticals and vaccines), medical devices (including diagnostics), to veterinarians, pet owners, and food animal livestock owners.

PFAS, defined as a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom, can include the active pharmaceutical ingredients (APIs) in flea and tick medications, inhalation anesthetics, selected anti-inflammatory products, federally regulated packaging components of pharmaceuticals and biologics, and medical devices.

The veterinary uses of APIs qualifying as PFAS under the definition used are unavoidable and, in fact, vitally important for animal health and welfare and, importantly, for public health. For example, some active ingredients approved by the U.S. Food and Drug Administration (FDA) are fluorinated molecules that are administered to animals to prevent parasites and the diseases they carry, which can infect humans as well (e.g. Lyme disease, tick encephalitis). Other veterinary products contain fluorinated molecules as essential, functional parts of their administering components (e.g., vaccine syringes) that are federally evaluated and approved with the underlying health product.

While biologics (including vaccines) do not contain active PFAS ingredients, their packaging can include PFAS chemistries in stoppers for injectables, bottles, and syringe barrels and caps. Such PFAS chemistries, usually fluoropolymers, help prevent adulteration of pharmaceuticals, biologics and medical devices. A PFAS coating on a blister or vial stopper provides an effective barrier against organic and inorganic extractables and prevents interaction between the biological and the primary packaging component, which is indispensable to ensure the quality, safety and efficacy of the products. A well-known

example of how vaccines for animals can protect public health are the vaccines against rabies in dogs, cats and other animal species.

Unlike human drugs and medical devices (including diagnostics), which are all regulated by FDA, AHI members' animal health products are overseen and regulated by three distinct federal agencies including:

• Biologics (including vaccines and certain diagnostic kits) at the Animal and Plant Health Inspection Service (APHIS) within the U.S. Department of Agriculture (USDA) under the Virus Serum-Toxin Act (VSTA) (21 U.S.C. §§ 151-159). The VSTA authorizes USDA to review and license animal biologics manufacturers and their products; ensures animal biologics are pure, safe, potent, and effective; and requires every biologic to obtain a license and undergo a strict approval process. Any change in chemistries used in the product packaging needs renewed approval from the USDA to ensure its quality, safety and efficacy requirements are met.

• Small molecule pharmaceuticals and medical devices (including diagnostics) at the FDA under the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. §§ 301 et seq.). Evaluating that an animal drug product is safe is paramount to and required for FDA approval. All PFAS-APIs regulated as animal drugs go through this rigorous process. FDA review involves evaluation of safety to the animal and of the food products made from the treated animal if the drug is for use in food producing animals. FDA's required review process also evaluates the drug's potential impact on the environment and on the safety of the people who will give the drug to the animal or who may come in contact with the drug. Any change in chemistries used in the product packaging needs renewed approval from the FDA to ensure its quality, safety and efficacy requirements are met.

Additionally, the FFDCA provides FDA regulatory oversight of medical devices (including diagnostics) intended for animal use. Animal device manufacturers must ensure that devices are safe, effective, and properly labeled. Medical device labeling may not be false or misleading and must be adequately labeled for the intended use(s). An animal device that is also a radiation emitting electronic product must comply with all requirements for animal devices in addition to the FDA's extensive requirements for radiation-emitting electronic products at 21 CFR Parts 1000–1050.

Do you have any recommended changes or other considerations that you think the MPCA should take into account when defining the term "essential for health, safety, or the functioning of society"? *(Please review the proposed definitions in the rule concept document prior to answering)*

As proposed, the definition fails to acknowledge the societal significance of animal health and welfare. For example, rabies immunizations are required for cats, dogs, and ferrets by local governments throughout Minnesota, and a rabies outbreak in the state, and lack of an available rabies vaccines for companion animals, which may be unavailable in Minnesota after January 1, 2032, will adversely impact both human and animal health. The same is true for products preventing parasite infestations. The inhalation anesthetics qualifying as PFAS are used in both human and animal surgeries. Accordingly, AHI makes the following suggested changes:

Essential for health, safety, or the functioning of society. "Essential for health, safety, or the functioning of society" means a use of a PFAS in a product or component when the function provided by the PFAS is, at the time of a

determination by the commissioner, necessary for the product, component, or spare or replacement component to perform as intended, such that the unavailability of the PFAS for use in the product would cause the product's service to be unavailable, which would result in:
A. A significant increase in negative HUMAN OR ANIMAL health outcomes;
B. An inability to mitigate significant risks to human OR ANIMAL health OR WELFARE or the environment; or,
C. A significant disruption of commercial, public, or ecosystem services on which society relies, including:
(1) Provision of food, water, shelter, health, hygiene, or bare necessities for human OR ANIMAL survival;
(2) Provision of transportation and utilities such as gas, electricity, data, communications, and sewer;
(3) Provision of personal, occupational, or public safety particularly for extreme conditions of use; and,
(4) Other services not covered under subitems (1) through (3) that serve the basic needs of ANIMALS OR human beings.

Do you have any recommended changes or other considerations that you think the MPCA should take into account when defining the term "alternative"? *(Please review the proposed definitions in the rule concept document prior to answering)*
Given that an applicant's CUU waiver submission will automatically be disqualified for failing to assess all alternatives, the definition should qualify alternatives so it is not so open ended and theoretical. As such, AHI makes the following suggested revision to the proposed definition of "alternative."

Alternative. "Alternative" means a CURRENTLY AND REASONABLY AVAILABLE non-PFAS chemical, substance, material, manufacturing process change, non chemical change, or other product that, if used in place of a PFAS or PFAS-containing product, would result in a functionally equivalent product.

What safety or other standards require the use of PFAS in a product? *(Please include the specific citation)*
APIs qualifying as PFAS under the definition used are highly efficacious for the indications they are targeted for. Some have been on the market for a very long time with no functionally similar or superior alternatives; others represent the most recent and much welcomed innovations in their therapeutic area. Banning these products would put veterinary medicine in these areas back decades in time.

PFAS containing packaging materials (usually fluoropolymers), are widely used in veterinary products. These substances are used for the chemical stability, chemical compatibility with solvents, low leaching potential, oleophobic properties, and thermal resistance. The components used to administer animal drugs and biologics currently have to meet FDA and Good Manufacturing Practices (GMP) standards and US Pharmacopeia (USP) requirements including extractable and leachable data to ensure that these materials cause no adverse effect when used as packaging for veterinary products and vaccines. Research has demonstrated that to date, no functionally equivalent alternatives are available for these materials.

The agency is seeking feedback on the potential that the initial positive CUU determination duration for existing products will expire eight years from the date of issuance regardless of product category. This is intended to stagger renewal deadlines and ease the administrative burden of processing renewals.

- Do you have any concerns about unintended consequences with this proposal?
- Do you have any alternative recommendations to stagger renewal deadlines?

Given the administrative burden MPCA will face in having to consider CUU waiver applications by the proposed requested January 1, 2030 deadline, AHI suggests that MPCA instead provide a two-year window of January 1, 2029-January 1, 2031 in which manufacturers and others can apply for a CUU.

AHI also asks that initial CUU positive determinations run 10 years from the date of issuance and do not officially expire until MPCA has made a final determination regarding the renewal application, provided that the manufacturer (or other applicant) has applied for the renewal a year before the initial determination expires. This extended timeframe ensures that an applicant will not be penalized by delays in processing CUU renewal applications, will create more of a staggering of CUU applications, which will reduce MPCA's administrative burden, and better align with the 10-year recordkeeping requirement.

For manufacturers: Administrative cost of requesting a CUU determination (Part 1 of 2). *Please provide your best estimates or rough orders of magnitude (for example "approx. 200 hours"). Precise accounting data is not necessary to answer this question.*

If your company currently possesses information regarding intentionally added PFAS (to the CAS number level) for all components in your product lines, please estimate the number of technical staff hours that were required to establish this baseline.
Not applicable

For manufacturers: Administrative cost of requesting a CUU determination (Part 2 of 2). *Please provide your best estimates or rough orders of magnitude (for example "approx. 200 hours"). Precise accounting data is not necessary to answer this question.*

If your company <u>does not</u> possess information regarding intentionally added PFAS (to the CAS number level) for all components in your product lines, please estimate the number of technical staff hours needed to obtain this data from your Tier 2 or 3 suppliers for a single product line.
Not applicable

Do you have any additional questions or comments regarding the PFAS in products: Currently unavoidable use rule? *(Please note that we may be unable to respond to specific questions regarding rule content in this phase of the rulemaking process)*
As soon as possible, MPCA should issue a directive clarifying that all animal/veterinary health products containing intentionally added PFAS that are regulated by FDA are outside of scope of the January 1, 2032 phaseout. This will provide needed certainty to the animal health sector, veterinary clinics and practices, animal owners and veterinary medicine in general.