April 24, 2023
Paul Di Salvo
Office of Chemical Safety and Pollution Prevention
Registration Division (7505T)
Environmental Protection Agency
1200 Pennsylvania Ave. NW, Washington, DC 20460–0001
disalvo.paul@epa.gov

Re: Modernizing the Approach to the Environmental Protection Agency (EPA) and Food and Drug Administration (FDA) Oversight of Certain Products; Notice of Public Meeting and Request for Comments (EPA–HQ–OPP– 2023–0103)

Dear Mr. Di Salvo,

On behalf of the Household & Commercial Products Association[1] (HCPA) and its members, we want to convey our concerns on Modernizing the Approach to the Environmental Protection Agency (EPA) and Food and Drug Administration (FDA) Oversight of Certain Products. HCPA and its members take the concerns raised by EPA and FDA very seriously and work daily to ensure that critical products address public health and environmental considerations.

The products currently regulated by EPA are foundations of animal protection. They protect animals, indirectly people, by repelling and killing external parasites that can serve as vectors for disease, such as fleas, ticks, mites, and flying pests, such as mosquitoes and flies. These products improve the health and well-being of pets. Likewise, livestock, including horses and food animals, are protected from pests, improving animal welfare and productivity.

HCPA represents many companies that manufacture, distribute and supply the ingredients for pest control products that change in the current approach by EPA and FDA would impact. We will highlight recent industry efforts to assist the EPA in meeting the Agency's statutory and regulatory requirements.

- Worked with the Agency for improvements to enhanced pet product incident reporting.
- Successfully advocating for legislative reforms intended to provide additional

[1] HCPA is the premier trade association representing the interests of companies engaged in the manufacture, formulation, distribution and sale of more than $180 billion annually in the U.S. of familiar consumer products that help household and institutional customers create cleaner and healthier environments. HCPA member companies employ hundreds of thousands of people globally. HCPA represents products including disinfectants that kill germs in homes, hospitals and restaurants; air fresheners, room deodorizers, and candles that eliminate odors; pest management products for pets, home, lawn, and garden; cleaning products and polishes for use throughout the home and institutions; products used to protect and improve the performance and appearance of automobiles; aerosol products and a host of other products used every day.

resources to EPA and deliver technical expertise to improve efficacy testing guidance.

- Collaborating with EPA/FDA/PETA/AHI on New Approach Methods to reduce and refine the amount of efficacy testing.
- Frequent interactions to understand and share the challenges at EPA and assist where possible, e.g., bundling of regulatory requests, educational lunch and learns.

Finding the proper balance between adequately funding regulatory functions and modernizing the regulation of animal health products is complex. EPA and FDA have both sought additional resources to improve services. The proposal will require significant changes to statutory and regulatory requirements. Both EPA and FDA have a well-established regulatory framework with over fifty years of experience evaluating these products' safety, efficacy, and quality under the Memorandum of Understanding. Consequently, animal health products are reliably available and accessible to people seeking to protect their animals safe from pests and disease.

For this reason, HCPA encourages EPA and FDA to move cautiously and take the time necessary to appropriately address any statutory changes or each component of a future regulatory framework. A flawed process may result in the spread of misinformation to consumers, putting public health at risk. Unnecessarily costly rules that are burdensome, non-transparent, or otherwise born through a flawed process are likely to stifle innovation, hinder research, and affect the availability of vital products. Careful consideration should be given to the potential impact on access to existing product lines and supply availability. Moreover, some products may no longer be available to consumers in retail settings, increasing the cost of pet protection products for those who can least afford them.

Conversely, an open, transparent, risk-based process will enable innovation while ensuring ongoing access, as veterinarians and consumers rely on these products to protect their animals. We also have difficulty understanding how modernization would not lead to duplications of efforts between the Agencies without significantly more detail and direction.

Before such a significant change to US regulatory policy, several questions should be considered. Furthermore, it is premature to answer "if" the EPA should maintain a role in regulating animal health products until more clarity regarding the process is available. For instance, after reflecting on the whitepaper, the following clarifying questions were consistently raised by HCPA members:

- What is the problem that we are trying to solve? Stakeholders expect and deserve transparency in the Agency's decision-making, including evaluation of current challenges and alternative approaches, to justify such a dramatic change in regulatory policy. Even after participating in meetings with EPA, the public workshop, and reading the whitepaper in detail, we have difficulty determining how the proposed shifting of responsibilities from the EPA to the FDA would

address the concerns raised.

- The whitepaper's assertion that a modernized approach (transferring products to FDA) would help the Agencies adapt their approach to current science and technologies is misleading. For example, a vital issue with genetically engineered organisms is the potential environmental effects on the environment. EPA already has the expertise and is more qualified than the FDA to review the potential environmental impacts of genetically engineered organisms. In our members' experience, the EPA's environmental risk assessments and consideration of effects on non-target species are far superior to the environmental risk assessments conducted by FDA for orally applied drug products.
- The proposal intimates that the FDA can merely absorb these products without an increase in staffing. The question is, if more resources are required, where should they be located? We believe that topically applied pesticidal products are best managed by EPA, and EPA needs to commit to updating its internal capacity for such products. And in fact, the recent appropriations bill from Congress did give EPA funding to hire more staff. The OPP Administrator has publicly thanked the industry for their support in obtaining the increased appropriations.
- What range of products would be affected by this policy change and why? The scope of the products appears to include companion animals and food animals for any product applied topically to any animal, which includes spot-ons, sprays, powders, dips, shampoos, ear tags, pour-ons, dusts, and collars.
    - Would the scope include livestock products, including feed-throughs?
    - Will this also include 25(b) or "minimum risk" products applied to animals?
    - Will all products that are topically applied to animals shift to FDA, or just those intended to be absorbed? Current law stipulates that the EPA regulates topically applied products and would require changes to existing law.
    - Has the Department of Agriculture been consulted if the scope includes food animals?
- The whitepaper cites that "600 products" would be impacted. Many of the products have active ingredients with other FIFRA-regulated uses. How would these products be transitioned?
    - How would this prevent duplication of regulatory authority?
    - How would "Me Too" or "Cite all" products be transferred? PRIA Categories A530, A532, B673, R300, R301, and R333 are commonly used categories in which registrants can utilize previously submitted data to

support their registration.

- What if the owner of the active ingredient did not support transitioning products to FDA regulation, noting many actives are minor uses compared to agriculture uses?
- How would multiple products under one FIFRA registration be transferred to FDA?
- How would/could data protection/compensation be transferred from EPA to FDA jurisdiction? There are significant differences in how the EPA and FDA govern data compensation. Whole categories of submissions to the EPA based on data compensation issues are not allowed by FDA. This means that reasonable submissions under EPA would not become possible under FDA governance.
- The cost structure for pesticide registrations and maintenance fees significantly differs from that of FDA drugs. Has EPA considered the impact on small or medium-sized companies?

- What consideration have the Agencies given to supply chain issues, particularly regarding lessons learned during the pandemic? Stakeholders are concerned that if this is not handled inclusively and done correctly, products are at risk of coming off the market and will no longer be available.
- What about products that address public health pests?
  - How many of the "600 products" address public health pests?
  - Does FDA have the statutory authority to address public health pests?
  - Does FDA have the expertise to address public health pests?
  - What about products that address public health pests but are not used on companion animals? How would this prevent duplication of regulatory authority?
- How would FDA incorporate EPA's registration review process into the transferred products?

The following responses are to the specific question posed in the FR notice:

- *What do you perceive as the strengths and weaknesses of each Agency in regulating these types of products?*
  - HCPA represents EPA-regulated products and will limit comments to the strengths and weaknesses of the EPA. HCPA is concerned that shifting authority and responsibility from one Agency to another may generate more challenges than solutions for the government and regulated stakeholders. As noted, the Memorandum of Understanding (MOU) between the EPA and

FDA has existed for fifty years. Replacing the MOU will need to replace fifty years of regulatory development. Each Agency has its own regulatory culture with separate processes, procedures, labeling requirements, and complex guidance. There is concern that such a transition will be disruptive to regulators and the regulated. Both Agencies suffer from management challenges that must be addressed through leadership decision-making, prioritizing Agency resources, and securing federal appropriations. The potential fallout from transitioning a management challenge, exacerbated by insufficient funding to a different Agency, cannot be understated and may not resolve underlying deficiencies.

- EPA has significant expertise with public health pests (for example, "Lists of Pests of Significant Public Health Importance," PRN 2023-01).[2] How would FDA effectively utilize these efforts with duplicating activity?
- EPA has significant expertise with efficacy testing guidance, for example, the Series 810 Group C - Invertebrate Control Agent Product Performance Test Guidelines.[3] How would FDA effectively utilize these efforts with duplicating activity?

- *Are there additional or different challenges that EPA and FDA did not identify in the whitepaper?*
  - Will FDA oversight then trigger requirements such as facility inspections, etc.?
  - If facility inspections are required, is there existing guidance available for manufacturers?
  - Will FDA provide training or technical assistance to manufacturers unfamiliar with FDA inspections?
  - Has EPA/FDA considered the additional private sector costs required for transitioning to FDA compliance requirements?
  - Has EPA considered the significant changes in distribution - in many cases, consumer-retail products may no longer exist if current EPA products are no longer available without a prescription.
  - Has the impact on state pesticide registration been considered? States review pesticide products; generally, states do not review FDA-regulated drugs. What Federal outreach and collaboration would be provided at the state level for this transition? Would legacy EPA products no longer be subject to state-by-state approval?
  - What financial and human resources are required by FDA to manage the

[2] https://www.epa.gov/system/files/documents/2023-03/EPA-HQ-OPP-2020-0260-001.pdf
[3] https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-810-product-performance-test-guidelines

initial product transition from EPA to FDA oversight and then in the future? There needs to be transparency in this decision's financial and resource analysis, and it should be made available to all stakeholders. An explanation should be provided on how resource allocation would be done to prevent risk to the current FDA workload. Furthermore, Agencies should give consideration to the resources required for any inspection.

- The terms "treat" and "control" refer to pests in the whitepaper. Do those terms include repelling or just killing?

- *How can EPA and FDA communicate with their stakeholders about the regulation of these products in a clearer and more transparent manner?*
  - How to transition 600 products?
    - Would this occur gradually, e.g., would there be a cutover period?
    - Would it be staged, i.e., single actives vs. multiple actives?
  - What does "grandfathering" mean? How will it be determined which existing products may be grandfathered? What is the process for determining which products have significant safety concerns and which do not? How are these decisions being made, and by whom?
  - If products were to move to FDA, how would they be transitioned between Agencies without disrupting the market? Products currently regulated by EPA are essential to public health. These products need to remain accessible to producers and animal owners. A sufficient transition period will be required to mitigate supply disruption risks. Essential items to consider include:
    - Ingredient sourcing differs between FDA and EPA products, and suppliers may be unable to provide raw materials necessary for the differing grade of ingredients at the FDA.
    - Not only do GMP processes not exist for almost all pesticidal products, but pharmaceutical-grade ingredients only exist for some of the inert ingredients used in pesticide products. So, not only would pesticide manufacturing have to undergo significant changes, but the whole supply chain would also have to undergo significant revisions. These revisions can take up to 10 years.
    - How would FDA manage products currently registered with EPA? Requirements for manufacturing, post-approval surveillance, OTC marketing status, Adverse Event reporting, labeling, and promotional materials are implemented differently at FDA than at EPA.
    - How would future label amendments be handled once a product is transitioned to FDA? Would FDA require additional work to be

done to get a product's file aligned with FDA's current requirements and formatting? EPA data packages are separate for the active ingredient and the end-use product.

- Will active ingredients registered with EPA also have to undergo a separate FDA evaluation/registration?

- What is a "serious safety concern," and what is the process for evaluation?
- The whitepaper notes that products regulated by FDA must be manufactured under "validated manufacturing processes by Good Manufacturing Process regulations (21 CFR Part 200)." The simple issue is that GMP processes for almost all pesticidal products do not exist under the current regulatory environment. Thus, while the whitepaper presents this issue as a simple administrative issue, the reality is that it contains enormous obstacles. Any administrative transfer would require years and years of unnecessary regulatory work to ensure these products meet GMP requirements.

- *For regulated entities, how have you historically determined which Agency to approach first to bring your product to market?*
  - Companies have 50 years of experience working under the regulatory conditions of the MOU and are well-versed in the considerations of FIFRA and FD&C Act definitions and requirements. They also employ early information meetings with the Agencies to explain their understanding of the mode of action (MoA) of the product (e.g., dermal activity vs. systemic), target pest(s), method of application (e.g., oral for systemic distribution, dermal for external/surface spread) to ensure they properly identified the statutory and regulatory requirements and any necessary testing to support registration.

- *For consumers, do you know who is regulating the products you use on your animal(s)? If you have a concern or complaint about a specific product, do you know which Agency to contact?*
  - It is always critical that consumers read the label.
  - It will be important that any changes in the availability of any impacted products be communicated to consumers. There may be confusion by consumers and retailers if longstanding products are no longer available in retail outlets or require a veterinary prescription.
  - Has the impact of a lack of consumer access been assessed? There may be socioeconomic or environmental justice considerations if the products are no longer readily available in retail outlets.
  - Has the impact on "equitable access" to critical products to prevent pest infestations been assessed? There may be socioeconomic or

environmental justice considerations if the products are no longer readily available to consumers, especially in economically disadvantaged areas.

- *How should EPA and FDA modify product oversight to better align with each Agency's mission and expertise?*
    - Revisiting and modifying the MOU to address these needs would be more effective.
        - EPA cited the utilization of cross-functional work and FDA expertise in market surveillance.
        - Clarify jurisdiction lines through administrative tools.
        - Clear definition of which Agency oversees each category.
    - EPA is equipped with broad authority to assess human health and environmental health, but FDA does not have the authority to assess environmental health; what will FDA do about products previously deemed as pesticides?
- *What difficulties would you envision if EPA and FDA were to modify product oversight to better align with each Agency's mission and expertise, and how could they be mitigated?*
    - If done too quickly and/or without careful consideration of public and stakeholder feedback, critical public health products with be unavailable.

HCPA members take the regulation of pest control products very seriously. These products improve the health and well-being of pets and livestock, protecting animals and people by repelling and killing external parasites that can be vectors for devastating diseases. As currently regulated, these products are equitably accessible to all veterinarians, producers, and animal owners. Without careful consideration and appropriate implementation, regulatory policy and framework changes could negatively affect the availability of these essential products, both presently marketed and via future innovation.

We recognize that this is the first of many discussions on this critical topic, but there are too many unanswered questions to support this in its current form. Careful consideration must be given to the many aspects of a potential policy change before legislative changes are requested from Congress or changes to the regulatory process are implemented.

Sincerely,

Steven Bennett, Ph.D.
Executive Vice President, Scientific & Regulatory Affairs