December 17, 2020

Mr. Daniel Waltz
Animal Legal Defense Fund
525 East Cotati Ave.
Cotati, CA 94931
dwaltz@aldf.org
cstella@aldf.org

Dear Mr. Waltz:

This letter is a partial response to the citizen petition you submitted on June 8, 2020 (Docket # FDA-2020-P-1506), on behalf of the Animal Legal Defense Fund, Food Animal Concerns Trust, and the Center for Biological Diversity.

The petition, which you submitted as a "Petition for Emergency Rulemaking," asserts that the novel coronavirus ("COVID-19") has created a bottleneck at meatpacking plants and a national slowdown of slaughtering and processing animals for meat. You claim that this situation has led to animals remaining with producers and in transport for "unexpected longer durations." As a result, you state, cattle and swine that are normally fed ractopamine during the last few weeks of their lives are receiving a greater amount of the drug and for longer durations. You also state that they are staying alive longer after they receive the drug or are being "euthanized" instead of being slaughtered for food, with high amounts of ractopamine in their systems (presumably raising food safety and environmental concerns). You state that these circumstances threaten animal safety and welfare, handler safety, consumer health, and the environment.

In urging FDA to take emergency action, you point out that, under the Food, Drug, and Cosmetic Act, FDA has the authority to suspend and withdraw approval of new animal drugs if such drugs present an "imminent hazard" or are shown to be unsafe. Your petition requests that the Commissioner "immediately suspend and/or withdraw the approval of ractopamine for use in pig and cow feed."

We believe you are asking us to use our "imminent hazard" authority in 21 USC 360b(e)(1) to immediately suspend approval of ractopamine for swine and cattle based on the conditions presented by the current global pandemic and, as a separate matter, withdraw approval of ractopamine for use in swine and cattle based on the grounds that the drug is unsafe (regardless of the conditions presented by the current global pandemic).[1,2]

Section 512(e)(1) provides that, "[I]f the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the health of man or of the animals for which such drug is intended, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection..."

[1] In asking us to withdraw approval of the drug for use in swine and cattle, you make assertions independent from those related to the conditions presented by the current global pandemic. Those assertions, and supporting evidence, are still being considered by the agency.

[2] 21 USC 360b(e)(1)(A)

FDA regulations at 21 CFR 2.5(a) provide that, "an imminent hazard to the public health is considered to exist when the evidence is sufficient to show that a product or practice, posing a significant threat of danger to health, creates a public health situation (1) that should be corrected immediately to prevent injury and (2) that should not be permitted to continue while a hearing or other formal proceeding is being held."

While we acknowledge the challenges presented by the current global pandemic to the agriculture industry, including producers, transporters, and processors, we do not believe that the evidence you submitted with your petition, or otherwise available to FDA, supports a finding that there is an imminent hazard as a result of the conditions presented by the current global pandemic.

You have not provided evidence of the circumstances alleged in your petition. Specifically, you have not provided evidence of changes in the use, duration, and amount of ractopamine administered to cattle and swine as a result of the Covid-19 pandemic. You state that the longer holding of animals or "euthanizing" of animals reported in April and May 2020 in the cited articles has resulted in increased duration and amount of ractopamine administered to cattle and swine. Moreover, you have not provided evidence of significant suffering and impairments, increased incidence and types of injuries, and increased drug residues in animal tissues or the environment as a result of these alleged circumstances. Without such evidence, we cannot conclude that the Covid-19 pandemic has resulted in an imminent hazard to the health of man or the animals for which ractopamine is intended.

We further note that you have not provided information showing extralabel use of the drug (e.g., that the duration of use or other use conditions are not being followed). As you know, it would be a violation of the Federal Food, Drug, and Cosmetic Act for ractopamine to be administered to animals in feed in an extralabel use manner.[3]

As for your contention that animals are being euthanized with high amounts of ractopamine residues instead of being slaughtered,[4] although you provided news reports and other limited information about animals being depopulated, you have not provided any documentation that any of the depopulated animals had illegal ractopamine residues, nor whether tissues from animals with violative levels of ractopamine entered the food supply.

In summary, your assertions about the impact of the current global pandemic on changes in the use, duration, and amount of ractopamine administered to cattle and swine and consequent impact on the public health are based on speculation and assumption, not data or other evidence. You have not provided, nor have we found, evidence of widespread illegal extralabel use of ractopamine or of animals with violative residues entering the food supply. Therefore, we deny your request to "use [our] authority to immediately suspend … the approval of ractopamine for use in pig and cow feed…"

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[3] Even if we had such evidence, we would not necessarily need to suspend and/or withdraw approval of the drug to address such violations. Instead, in those cases, we could address the violations through, for example, advisory letters, seizures, or injunctions.

[4]We reviewed the United States Department of Agriculture, Food Safety Inspection Service's (FSIS) residue violation data for the past several years and do not see an increase in ractopamine residue violations in animals presented for slaughter for this year compared to past years.

Your request to withdraw approval of ractopamine for use in swine and cattle remains under review at FDA.[5]

Sincerely,

Steven Solomon -S

Digitally signed by Steven Solomon -S
Date: 2020.12.17 09:28:34 -05'00'

Steven M. Solomon, DVM, MPH
Director, Center for Veterinary Medicine

[5] Petition FDA-2012-P-1252 also remains under review.