U.S. FOOD & DRUG ADMINISTRATION

May 18, 2021

Jeannie Perron, JD, DVM
Covington & Burling LLP
One City Center
850 Tenth Street, NW
Washington, DC 20001-4956

**Re: Docket No. FDA-2020-P-2312**

Dear Dr. Perron:

This is a tentative response to the Citizen Petition (FDA-2020-P-2312) you filed with the Food and Drug Administration (FDA) on November 17, 2020, on behalf of Phibro Animal Health Corporation.

The petition requests that "FDA refrain from finalizing, and withdraw, the Proposed Order, thereby allowing for a new, comprehensive Notice of Opportunity for Hearing (NOOH) proceeding addressing the method-revocation and NADA approval issues together, just as FDA has done in the past. In the alternative, Phibro requests that the Commissioner of Food and Drugs stay the effective date of any final order revoking the carbadox regulatory method pending the final resolution of any future proceeding to withdraw approval for the carbadox NADAs."

For administrative efficiency, FDA decided to assign two distinct docket numbers to your request. Docket Number FDA-2020-P-2312 has been assigned to the request for FDA to "refrain from finalizing, and withdraw, the Proposed Order" and Docket Number FDA-2020-P-2313 has been assigned to the request to "stay the effective date of any final order revoking the carbadox regulatory method pending the final resolution of any future proceeding to withdraw approval for the carbadox NADAs."

Pursuant to the administrative regulations at 21 CFR 10.30, FDA is required to respond to your citizen petition (FDA-2020-P-2312) within 180 days. FDA is currently considering the issues raised by your citizen petition; however, the Agency will require additional time to issue a final response. A copy of this letter will also be placed in the docket for your request to stay the effective date of any final order revoking the carbadox regulatory method (FDA-2020-P-2313).

Sincerely yours,

Steven Solomon -S
Digitally signed by Steven Solomon -S
Date: 2021.05.18 17:41:44 -04'00'

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