



February 22, 2023

Harry Duty

(b) (6)

Re: Docket No. FDA-2022-P-0395

Dear Mr. Duty,

This letter responds to the email you sent various components of FDA on September 19, 2022, seeking clarification regarding the two responses you received to your citizen petition, Docket Number FDA-2022-P-0395. At the time CVM sent you our tentative response on September 19, 2022, we were not aware that FDA's Office of Regulatory Affairs (ORA) had already sent you a final response on September 12, 2022. Therefore, CVM is withdrawing its September 19, 2022, tentative response. We apologize for any confusion this may have caused.

Sincerely,

William T. Flynn -S Digitally signed by William T.
Flynn -S
Date: 2023.02.22 15:20:48 -05'00'

William T. Flynn, DVM, MS
Deputy Director for Science Policy
Center for Veterinary Medicine