DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

May 29, 2020

Aaron L. Schacht
Executive Vice President – Innovation,
Regulatory & Business Development
Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140

Sent via email to: schachtal@elanco.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA:

1) Commence withdrawal procedures for Huvepharma's ANADA for generic Monovet Type A medicated article for use in cattle and goats and all combination approvals as required by section 512(e)(1) of the FDCA when new information reveals that the drug is not safe, or that there is a lack of substantial evidence of efficacy; and

2) Consistent with 21 C.F.R. § 10.115(d)(3), as well as the Administrative Procedure Act ("APA") and section 701(h) of the FDCA, refrain from approving future ANADAs for generic monensin Type A medicated articles and combination approvals unless and until either: (1) the ANADA includes at least two clinical end-point bioequivalence studies consistent with FDA, CVM, GFI #35, Bioequivalence Guidance (Nov. 2006) ("GFI #35"); or (2) CVM issues a new guidance document explaining an alternative approach to demonstrating bioequivalence.

Your submission was received by this office on 05/28/2020. It was assigned docket number FDA-2020-P-1443. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby Digitally signed by Dynna Bigby Date: 2020.05.29 15:30:44 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)