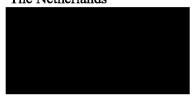


Orion Corporation Orionintie 1 FI-02200 Espoo Finland

> 29.08.2022 EMEA/V/C/003764/II/0022

European Medicines Agency (EMA) Veterinary Applications Domenico Scarlattilaan 6

Domenico Scarlattilaan 6 1083 HS Amsterdam The Netherlands



<u>Subject</u>: Submission of Variation Application Dossier for Sileo (dexmedetomidine hydrochloride), 0.1 mg/ml oromucosal gel EMEA/V/C/003764/II/0022

Dear Sir/Madam,

We would like to inform you that, at this point in time, Orion Corporation has taken the decision to withdraw the application for a variation submitted concerning addition of new therapeutic indication.

The reason for withdrawal is based on a commercial decision.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s)/target species, if applicable.

I agree for this letter to be published on the EMEA website.

Yours sincerely,



Cover Letter Variation Withdrawal EMEA/V/C/003764/II/0022 Page 1/1