



Veterinary Medicines Directorate

Ms. Tracey Forfa, J.D., M.Div.
Center for Veterinary Medicine
United States Food and Drug Administration
7500 Standish Place
Rockville, MD 20855
United States of America

Date : 23rd January 2024

Dear Ms. Forfa:

I write in reference to your letter dated 22 January 2024, which reads as follows:

“The Center for Veterinary Medicine (CVM) of the U.S. Food and Drug Administration (FDA) is pleased to cooperate with the Veterinary Medicines Directorate of the Department for Environment, Food and Rural Affairs of the United Kingdom (VMD), to further our collective activities in the promotion and protection of public health. CVM and VMD share a mutual high regard for the crucial role our respective regulatory systems perform to ensure that veterinary medicines are safe and effective. We recognize that CVM and VMD have a longstanding history of cooperation on veterinary medicine regulatory matters and recognize the benefits of continuing collaboration in areas of mutual interest.

CVM and VMD intend to strengthen existing collaboration in areas of mutual interest, explore new opportunities for cooperative engagement in veterinary medicine regulatory matters, and strengthen exchange of knowledge and expertise related to the veterinary medical products that our respective agencies regulate. Intended areas of cooperation include, but are not limited to:

- a) Exchanging information on veterinary medicine regulatory matters of mutual interest, including, but not limited to:
 - i. Upcoming regulatory issues that may impact the United States and United Kingdom;
 - ii. Routine veterinary medicine regulatory issues and new initiatives such as veterinary medicine quality, issues of public concern, risk reduction, minor uses, and animal health issues;
 - iii. Lists of new veterinary medicines under evaluation and existing veterinary medicines under re-evaluation; and
 - iv. Information technology, particularly in the area of electronic data submission and templates.
- b) Engaging staff and collaborating through teleconferences, relevant international fora and other international meetings as appropriate; and
- c) Jointly identifying and further developing areas of collaboration.

Information exchanged between CVM and VMD may be provided in a form appropriate for public dissemination under applicable domestic and international laws and regulations. CVM and VMD intend that exchanges of any non-public information be done in accordance with established confidentiality commitments and any applicable laws and regulations.

Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS

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This letter is not intended to create obligations under international or domestic law, and all cooperation is expected to be carried out pursuant in accordance with applicable laws and regulations.

If you find the areas of cooperation outlined in this letter acceptable, then this letter, together with your letter of acceptance in reply, constitutes an acceptance of the above letter, which commences on the date of your reply letter and will continue indefinitely until CVM or VMD notifies the other, in writing, of its intent to discontinue cooperation.”

The VMD confirms its acceptance of the proposed arrangement, and that your letter and this letter in reply constitutes an arrangement between the FDA and VMD, which commences on the date of this letter.

Sincerely,

-S-

Mr. Gavin Hall
Director of Authorisations, Deputy Chief Executive Officer
Veterinary Medicines Directorate
Department for Environment, Food and Rural Affairs
Woodham Lane, New Haw
Addlestone, Surrey KT15 3LS
United Kingdom

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