Veterinary Drugs Directorate
Health Products and Food Branch
Ottawa, ON

DSTS Sub. N⁰: 270160

March 6, 2023

Liberchem Inc.
c/o Jacqui Jenskey
Director of Regulatory Affairs
Dell Tech Laboratories Ltd.
1331 Hyde Park Road Unit #3
London, ON N6H 5M5
Email: jjenskey@delltech.com

INFORMATION SATISFACTORY LETTER (ISL) for CDLA-MIX
Drug Identification Number (DIN) 02518880

Dear Jacqui Jenskey:

The information and material received in support of the Change to DIN submission for CDLA-MIX has been reviewed and is considered satisfactory, including the label - version "Liberchem February 14, 2023". The DIN for CDLA-MIX is 02518880 and the Drug Notification Form (DNF) is enclosed.

It is the responsibility of the DIN owner to ensure that the labelling material used for their products is in full compliance with all the regulatory requirements. Any post-approval labelling changes may need to be submitted to the VDD as a Change to DIN, for review and authorization. Please contact the Veterinary Drugs Directorate (VDD) for guidance.

Reminder - new rules for active pharmaceutical ingredients (APIs) have taken effect May 17, 2018 and the transition period has ended as of July 17, 2019 to submit a drug establishment license (DEL) application. For drug companies, the new rules for APIs for veterinary use require: manufacturing according to good manufacturing practices (GMPs); and persons who fabricate, package/label, test or import APIs for veterinary use to hold a DEL. Current Health Canada GMP and DEL guidance documents for human APIs can be applied to veterinary APIs. The associated guidance documents are being updated as needed.

For any questions about GMPs, email: drug.gmp.questions-bpf.medicaments@hc-sc.gc.ca

For any questions about DELs, email: del.questions-leppp@hc-sc.gc.ca

Please note that all Canadian drug establishments must hold an establishment license to fabricate, package, label, distribute, import, wholesale, or test a drug. For additional information, contact the Drug Establishment Licensing Unit at the Regulatory Operations and Enforcement Branch (ROEB) by telephone at 613-618-4529, by email at: del.questions-leppp@hc-sc.gc.ca or by visiting the Health Canada website.

Yours sincerely,

Jennifer Geduld
Director
Clinical Evaluation Division

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