Health Canada | Santé Canada

Health Products and Food Branch | Direction générale des produits de santé et des aliments

Veterinary Drugs Directorate
Holland Cross Complex
14 - 11 Holland Avenue
Address Locator: 3000A
Ottawa, ON K1A 0K9

DSTS Sub. N^0: 217949

October 31, 2018

Mr. Mustapha Boucherit
Ingénieur Chimiste
Liberchem Inc.
572 avenue Orly
Dorval, QC H9P 1E9
Email: mboucherit@liberchem.com
cc: schenard@spharm-inc.com

INFORMATION SATISFACTORY LETTER (ISL) for IO-Pro
Drug Identification Number (DIN) 02482118

Dear Mr. Boucherit:

The information and material received in support of the DIN submission for IO-Pro has been reviewed and is considered satisfactory, including the label - version "03 19-10-18". The DIN for IO-Pro is 02482118 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. However, there is an additional transition period ending 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:
hc.drug.gmp.questions-bpf.medicaments.sc@canada.ca

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

In addition, 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 Regions Branch by telephone at 613-618-4529, by email at: hc.del.questions-leppp.sc@canada.ca or by visiting the Health Canada website.

Yours sincerely,

Dr. Aboubakar Mounchili
A/Director
Clinical Evaluation Division