1805: Customs confirmation requirements concerning import restrictions in accordance with the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics Law (drugs, quasi-drugs, cosmetics or medical devices, etc.)

The Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics Law provides that the importation of drugs, quasi-drugs, cosmetics or medical devices for the purpose of business activities is only granted for those persons who have the business license for importation and sale of those goods issued by the Minister of Health, Labour and Welfare.

Here, drugs include veterinary drugs. And quasi-drugs include hair tonics, bath preparations, etc. and are supposed to have a mild effect on the human body.

For importing those restricted goods, it is necessary, at the time of import declaration, to provide Customs with the evidence that the goods have obtained the necessary permissions and authorizations in accordance with the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics Law. Specifically, it is necessary to submit a "business license for importation and sale" issued by the Minister of Health, Labour and Welfare, "notification on importation of drugs, etc.," etc.

When you desire to privately import those goods for your personal use or consumption, importation shall be granted without the permission or license required by the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics Law, provided that the volume of import is within a permitted scope. For more details, please contact a special pharmaceutical inspector of a Regional Bureau of Health and Welfare.

(Article 70 of the Customs Law, item 1, section 3, paragraph 70 of the General Notification of the Customs Law, and Article 12,13,13-3,14,19-2,23-2,23-2-3, 23-2-5,23-2-12,23-2-17,23-2-23,23-20,23-22,23-25,23-37,56-2 of the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics Law)

[Inquiries]

(Items imported within the jurisdictional district of Hakodate/Tokyo/Yokohama Customs)
Kanto-Shin'etsu Regional Bureau of Health and Welfare Tel: +81-48-740-0800

(Items imported within the jurisdictional district of Nagoya Customs and to the west)
Kinki Regional Bureau of Health and Welfare Tel: +81-6-6942-4096

[Reference] Website of Regional Bureau of Health and Welfare
https://www.mhlw.go.jp/english/policy/health-medical/pharmaceuticals/01.html