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Food and Veterinary Service

Peldu street 30, Riga, LV-1050, tel. 67095230, fax 67322727, e-mail pasts@pvd.gov.lv www.pvd.gov.lv

DECISION

Riga

21.10.2021.

No. 1264/21-UB

Limited liability company
"NL Continent Baltic"
msv@inbox.lv

**Regarding registration of
the food supplement "BIODRONE"**

On September 09th, 2021 the Food and Veterinary Service (hereinafter – the FVS) received the notification (hereinafter -the Notification) for registration of the food supplement "BIODRONE" (hereinafter – the Product) and the documents attached thereto (received correspondence No. 988/2021) as well as on September 27th, 2021 the FVS received additional documents (received correspondence No. 656/21/3.3-14.6)from the limited liability company "NL Continent Baltic", Reg. No. 40103781398 (hereinafter – the Applicant). The FVS also received additional documents on October 15th, 2021 (received correspondence No. 686/21/3.3-14.6 and 687/21/3.3-14.6).

The administrative file contains the following essential actual conditions for adoption of the decision:

- 1) The Applicant has submitted the documents in accordance with Article 9 of the Regulations of the Cabinet of Ministers No. 685 "Requirements for Food Supplements" of December 01st, 2015 (hereinafter – the Regulations No. 685);
- 2) The Applicant has made payment of the state fee for the Product in accordance with Sub-article 2.3 of the Regulations of the Cabinet of Ministers No.1145 "Regulations regarding State Fee for the Registration of Food Supplements" of December 21st, 2010 for initial registration of the food supplement produced outside the country of the European Economic Area,
- 3) Upon assessment of the documents submitted by the Applicant, the FVS stated that:
 - the submitted documents have been signed by the Applicant's authorized signatory;
 - all requested information is specified in the Notification;
 - the Product conforms to the requirements of Chapter II "Mandatory safety requirements" and Chapter IV "Requirements for additional labelling and advertising" of the Regulations No. 685;
 - in compliance with the Notification the Product is produced outside the European Economic Area.

The purpose of the Food Circulation Supervision Law (hereinafter – the FCSL), under the provisions of Section 2, is to ensure the food circulation which is qualitative and safe to human health, life, and the environment, eliminating the risks, promoting the trade, and protecting the interests of consumers. In accordance with Section 21, Paragraph one of the FCSL the state supervision and control of the food circulation is implemented by the Food and Veterinary Service.

Regulations No.685:

- Article 6 sets out that food supplements are foodstuffs whose purpose is to supplement the normal diet in the form of concentrated sources of nutrients (vitamins and mineral substances) or other substances with a nutritional or physiological effect, alone or in combination. Food supplements are marketed in specific doses in capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities;

-Sub-article 15.1 sets out that the FVS takes a relevant decision to register the food supplement in the FVS Food Supplement Register or to refuse registration if the product does not conform to the requirements of the regulatory enactments governing the field of food circulation.

Having regard to Paragraph two, Clause three of this decision the FVS concludes that the Product conforms to the requirements set out in Chapter II “Mandatory safety requirements” and Chapter IV “Requirements for additional labelling and advertising” of the Regulations No. 685.

On the basis of the above mentioned and in accordance with Section 63, Paragraph one, Clause 1, Section 65, Paragraph three of the Administrative Procedure Law (hereinafter – the APL), Sub-article 15.1 of the Regulations No. 685, the FVS **decides:**
to register the food supplement “BIODRONE” in the FVS Food Supplement Register under registration No. 13509.

Pursuant to Section 76, Section 77 and Section 79 of the APL, the decision may be contested to the Ministry of Agriculture within one month from the day of entry into force of this decision by lodging the application thereof to the FVS at Peldu street 30, Riga, LV-1050.

Pursuant to the Section 70, Paragraph one and two of the Administrative Procedure Law, the decision comes into effect at the moment, when the Applicant is notified thereof. Pursuant to the provisions of Section 8, Paragraph two and Section 9, Paragraph two, the document which is notified via electronic mail or as an ordinary postal item shall be deemed notified on the eighth day from the day when it was registered in the institution as the document to be sent or on the second working day after its electronic delivery.

General Director
M.Balodis

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THIS DOCUMENT IS SIGNED WITH A SECURE
ELECTRONIC SIGNATURE AND CONTAINS A TIME STAMP