COMMISSION IMPLEMENTING REGULATION (EU) 2016/842

of 27 May 2016

amending Regulation (EC) No 167/2008 as regards the name of the holder of the authorisation and the trade name of a coccidiostat

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (¹) and in particular Article 13(3) thereof,

Whereas:

- (1) KRKA d.d. has submitted an application in accordance with Article 13(3) of Regulation (EC) No 1831/2003 proposing to change the name of the holder of the authorisation as regards Commission Regulation (EC) No 167/2008 (²) concerning the authorisation of a coccidiostat (Kokcisan 120G).
- (2) The applicant claims that, with effect from 5 February 2016, it has transferred the marketing rights of the feed additive Kokcisan 120G to Huvepharma EOOD. Furthermore, Huvepharma EOOD, as the new owner of the marketing rights of the feed additive requests to change the trade name of the feed additive. The applicant has submitted relevant data supporting its request.
- (3) The proposed changes of the terms of the authorisation are purely administrative in nature and do not entail a fresh assessment of the additive concerned. The European Food Safety Authority was informed of the application.
- (4) To allow that feed additive to be marketed under the name of Huvepharma EOOD and under the new trade name, it is necessary to change the terms of the authorisation.
- (5) Regulation (EC) No 167/2008 should therefore be amended accordingly.
- (6) Since safety reasons do not require the immediate application of the amendments made by this Regulation to Regulation (EC) No 167/2008, it is appropriate to provide for a transitional period during which existing stocks of the additive, premixtures and compound feed containing the additive may be used up.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Commission Regulation (EC) No 167/2008 is amended as follows:

- (1) in the second column, the words 'KRKA, d.d Novo mesto, Slovenia' are replaced by 'Huvepharma EOOD, Bulgaria';
- (2) in the third column, the words 'Kokcisan 120G' are replaced by 'Huvesal 120 G'.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

^{(&}lt;sup>2)</sup> Commission Regulation (EC) No 167/2008 of 22 February 2008 concerning a new authorisation for ten years of a coccidiostat as an additive in feedingstuffs (OJ L 50, 23.2.2008, p. 14).

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Article 2

Existing stocks of the additive, premixtures and compound feed containing the additive, which are in conformity with the provisions applying before the date of entry into force of this Regulation may continue to be placed on the market and used until they are exhausted.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 27 May 2016.

For the Commission The President Jean-Claude JUNCKER