No.29/Misc./03/2019-DC (194)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(Medical Device Division)

FDA Bhawan,Kotla Road,
New Delhi-110002.

Dated: 24 AUG 2020

To,

M/s. Healy World Trading India Pvt. Ltd.,
A/3, S/F Front Side Kundan Mansion,
Asaf Ali Road, Turkman Gate,
New Delhi-110002.

Sub: - Application for grant of NOC for the product viz., Healy - Regd.

Sir,

Please refer to your application no. Nil dated 09.06.2020 received by this office vide Diary no.4521 dated 22.06.2020 regarding the above mentioned subject.

The case has been examined in the light of documents submitted by you. In this connection, it is stated that the product viz., **Healy** used in pain management (chronic pain, fibromyalgia, skeletal system pain, migraine) and in case of mental illnesses such as depression, anxiety and associated disturbance) is not currently under licensing as per Drugs and Cosmetics Act and Medical Device Rules, 2017 thereunder. However, as per the S.O. 648(E) dated 11.02.2020 the proposed product falls under the definition of Medical Device.

In view of above, you are requested to comply with the voluntary registration requirements for the product in portal established by CSDCO as per G.S.R. 102 (E) dated 11.02.2020.

Yours faithfully,

(Dr. Ravi Kant Sharma)
Deputy Drugs Controller (I)