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ACKNOWLEDGEMENT OF AN ACCEPTABLE NOTIFICATION

Product Name

Levact

Product Number

DE/H/1250/001/DC

Variation: DE/H/1250/001/IA/051

03/12/2024

The Federal Institute for Drugs and Medical Devices (BfArM) acknowledges that the Type IA variation detailed in your application is acceptable. The following change(s) has been notified:

A.5. a) The activities for which the manufacturer/importer is responsible include batch release

*Change in the address of the secondary packaging and batch release site "Magnalabs EOOD":
from "Bogdana Street, Stopanski Dvor, vlg. Bistrica 1443, Bulgaria"
to "Bogdana Street, Stopanski Dvor, vlg. Bistrica 1443, District Sofia (capital), Stolichna
Municipality, Bulgaria".*

The notification is considered acceptable on the basis of the Marketing Authorisation Holder undertaking that:

- i. The notification of change complies with all conditions specified in the Commission guideline on the classification of variations.
- ii. All supporting documentation as listed in the Commission guideline on the classification of variations have been provided.

- iii. The application has been submitted simultaneously to all Concerned Member States and the relevant fees have been paid as required by national competent authorities.

Failure to comply with any of the above may subsequently deem the notification unacceptable.

Only changes indicated in the application form are subject to assessment.

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