

Urgente Field Safety Notice

Commercial name of affected product : REGENYAL IDEA BODY 1X20ML
FSCA-identifier: FSCA_01/2019 del 11/03/2019
Type of action: Attention Request

Date: 11/03/2019

Attention: **DETECTION OF A FAKE MEDICAL DEVICE, REGENYAL BODY 1X20ML, ON THE INTERNATIONAL MARKET**

Details on affected devices:

The intradermal medical device on the market, with the REGENYAL IDEA BODY 1x20ml mark is a fake.

Regenyal Laboratories srl is not the manufacturer of this medical device.

Description of the problem:



Sede amministrativa

REGENYAL LABORATORIES S.r.l.

Via Valtellina, 19/21/23 - 63074 S. Benedetto Tr. (AP)

Tel. +39 0735 757947 - fax +39 0735 652039

Sede produttiva

Via dell'Industria, 5/A - 06038 Spello (PG)

Tel. +39 0742 301716 - P. I. 01942840446

info@regenyal.eu - www.regenyal.eu

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Regenyal Laboratories srl is not the manufacturer of this medical device, therefore it is not responsible for the formulation and the production process.

Therefore it declares not to be responsible for any risk for the user and the final patient, deriving from the use of this product in object.

Regenyal is the only manufacturer and CE owner of the following Regenyal Idea brand medical devices:

- Regenyal Idea 1x1ml
- Regenyal Idea Lips 1x1ml
- Regenyal Idea Bioexpander 1x1.1ml
- Regenyal Super Idea 1x1ml
- Regenyal Super Idea 3x1ml

Advise on action to be taken by the user:

Regenyal Laboratories srl advises distributors and users:

- DO NOT use this fake product on patients or clients
- contact Regenyal Laboratories srl immediately if you come into contact with Regenyal Idea Body.

Transmission of this Field Safety Notice: (if appropriate)

This notice must be sent to all distributors and medical customers of Regenyal Laboratories srl and to the Healthcare Organization ON0373.

Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action.

Contact reference person:

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LABORATORIES

Regenyal Laboratories srl

Via Valtellina, 19/21/23

63074 San Benedetto del Tronto (AP) - Italy

tel: +39 0735 757947 fax: +39 0735 652039

email: farmacovigilanza@regenyal.eu

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Signature
Dr. Marco Zazzetta
Quality Manager



Sede amministrativa

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