Johnson & Johnson GmbH, Postfach 210465, D-41430 Neuss

Dear [name],

Out of an abundance of caution, Johnson & Johnson [insert local affiliate] has made the voluntary decision to recall the NEUTROGENA® Light Therapy Acne Mask and activator at a distributor and retail level.

Affected Devices:

Neutrogena Light Therapy Acne Mask and Refill Activator

Description of device and its intended application

The Neutrogena Light Therapy Acne Mask (Starter Kit, Model 31000) is a reusable, non-invasive, nonsterile device intended to treat mild to moderate acne on the face. The device consists of an acne face mask and detachable corded activator. It is a home-use product operated by 4xAA batteries to deliver a combination of Red and Blue light via light-emitting diodes (LEDs), and weighs less than 400g.

The Neutrogena Light Therapy Acne Mask Activator (Model 71000) is offered separately to increase the number of doses available from the Neutrogena Light Therapy Acne Mask. The activator is a home-use product operated by 4xAA batteries.

Reason for Field Safety Corrective Action (FSCA)

As part of our quality and safety commitment, we routinely monitor our products and review the latest science. Following reports of mild, transient visual adverse events, combined with a growing scientific discussion around the safety of blue light, we further evaluated the potential effects of the NEUTROGENA® Light Therapy Acne Mask on the eye.

Our voluntary decision to recall this product has been taken out of an abundance of caution. Reports of visual effects associated with use of the NEUTROGENA® Light Therapy Acne Mask are rare, generally mild and transient. For a small subset of the population with certain underlying eye conditions, as well as for users taking medications which could enhance ocular photosensitivity, there is a theoretical risk of eye injury.

The NEUTROGENA® Light Therapy Acne Mask is safe for use by the general population when used as directed. However, if consumers experience any visual discomfort, they should stop use and consult their healthcare professional.

If consumers have questions or concerns, or if they would like to return the product and the activator, they are encouraged to contact us at [insert local CCC details].

If a consumer reports an adverse experience with the product to you directly, please contact us immediately on [insert local CCC details] so that we can investigate fully.

Johnson & Johnson GMBH

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Actions to be taken:

Our records show that you have received one or more of the products subject to this voluntary recall. Please take the following actions:

1. Immediately review your inventory to identify and quarantine the affected products listed above in a manner that ensures the affected products will not be used.
2. Return the affected products. A credit note will be issued for the returned items.
3. If the affected products have been forwarded to another professional retailer, contact that retailer to arrange return.
4. Maintain awareness of this notice until the products have been returned.
5. Keep a copy of this notice.

Return Address:

[address where to send products back to]

This product voluntary recall has been reported to the local competent authority.

We apologies for the inconvenience caused, but please be assured that our first priority is the health and safety of those who use our products. If you have any other question, please don't hesitate to contact [insert relevant local contact].

[Tailor sign off]