Safety Information and Adverse Event Reporting

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ADVICE ABOUT REPORTING

PURPOSE OF REPORTING

The Federal Food, Drug, & Cosmetic Act (FD&C) defines an adverse event as “any health-related event associated with the use of an adverse cosmetic product”. FDA has issued updated instructions for reporting serious adverse events that reflect events that may occur in the cosmetic industry.

TERMS

A “**serious adverse event**” is any adverse event that results in:

- Death or life-threatening experience,
- Hospitalization or infection,
- Persistent or significant disability or incapacity,
- Congenital abnormality or defect,
- Significant disfigurement (severe and persistent rashes, second- or third-degree burns, significant hair loss, or persistent or significant alteration in appearance not anticipated in the conditions of use).

An adverse event may also be considered serious if it requires “reasonable medical judgment, medical or surgical intervention” to prevent the outcomes described above.

INSTRUCTIONS

You can download the adverse event reporting form on the website. Reports of serious adverse events should be submitted immediately after receipt of the event information (laboratory tests or diagnosis).

Receipt of report: reports of serious adverse events should be submitted no more than 15 working days after receiving information about the event.
Examination: the report is received and examined within 15 days of receipt.
Recording: communication with the consumer is recorded. Consumer reports are kept for six years and accessible for inspection by FDA. Serious adverse events and any new reports within a year must be reported to FDA.

The form include:

- Patient information;
- Details of serious adverse events and outcomes;
- Suspected product(s) information;
- Copy of the label on the retail package or inside the cosmetic package(s).

Submission: reports can be sent by e-mail to **cosmeticreport@saponeriefissi.com**

RESPONSIBILITY

The RP (Responsible Person) is responsible for receiving adverse events, reporting serious adverse events, and maintaining records. All cosmetic products includes the Responsible Person's contact information on the product label so that consumers can submit information on adverse events.

A Responsible Person is defined by FDA as the “manufacturer, packer, or distributor of a cosmetics product whose name appears on the label of such cosmetic product in accordance with section 609(a) of the FD&C Act or section 4(a) of the Fair Packaging and Labeling Act.”