U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Enhancement Medical, Expression – Hyaluronic Acid Concentration

Recall Class: Class I

Date Recall Initiated: July 3, 2014

Product:

- Expression 1.5cc gel, all lots
- Manufactured between 8/15/2012 and 6/27/2014
- Distributed through 6/27/2014
- Total number of affected devices: 17,875

Please view **Enhancement Medical's Recall Notification (http://www.enhancementmedical.com/wp-content/uploads/2014/08/Recall_letter.pdf)** **(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)** for additional information.

Use:
Expression, manufactured by Enhancement Medical LLC, is listed with the FDA as a Class I intranasal splint, and is intended to minimize bleeding and swelling and to prevent adhesions (sticking together) between the septum and the nasal cavity. Intranasal splints are placed in the nasal cavity after surgery or trauma and are usually constructed from plastic, silicone, or absorbent material.

Expression consists of hyaluronic acid that is packaged in a syringe. When used as an intranasal splint the hyaluronic acid gel functions as a protective lubricating gel, a use that presents low risk to patients.

Recalling Firm/Manufacturer:
Enhancement Medical, LLC
10201 Innovation Drive, Suite 450
Wauwatosa, Wisconsin 53226

Reason for Recall:
Enhancement Medical is conducting this recall because the firm cannot ensure that Expression contains the correct concentration of hyaluronic acid. Incorrect concentration of hyaluronic acid may result in injury.

In August 2013, Enhancement Medical asked customers to return certain lots of the Expression after receiving multiple complaints documenting adverse events such as swelling, tenderness, firmness, lumps, bumps, bruising, pain, redness, discoloration, itching, and the development of hard nodules. The firm then provided customers with new product. All adverse events were associated with the subcutaneous injection of the Expression. Enhancement Medical's investigation determined that the adverse events referenced above were a result of hyper-concentrated lots of the Expression.

Since Enhancement Medical cannot confirm that the final concentration of the Expression meets established specifications, the firm has expanded its recall notification to all lots of the Expression since first date of manufacture (8/15/2012), including those lots identified in the product exchange that occurred in 2013.

In addition, the FDA has received reports of Expression being used as a dermal filler to fill in wrinkles on the face. Expression has not been approved by the FDA for this use. Other devices approved for this use as dermal fillers are class III devices, meaning they pose a higher risk to patient safety. FDA has also received information raising additional concerns for Expression. For example, certain lots of Expression exhibited bubbling post-sterilization. Also, in manufacturing this product the firm uses a source bacteria and crosslinking technology that is not consistent with other FDA-approved dermal fillers.

For additional information on FDA's safety concerns regarding this product please see the recently issued **Safety Communication (/MedicalDevices/Safety/AlertsandNotices/ucm407900.htm)**.

Health care providers are advised to **discontinue use of Expression**. The manufacturer has instructed customers to return any unused product. Please contact Enhancement Medical directly for instructions on returning product by calling 414-918-4280, 8:00 AM to 5:00 PM (CST) Monday through Friday.

Public Contact: For questions about this recall, contact Enhancement Medical at 414-918-4280.

FDA District:
Minneapolis District
250 Marquette Avenue, Suite 600
Minneapolis, MN 55401
Phone: (612) 334-4100
Fax: (612) 334-4134

More Information about this Recall:
Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death. Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/)** either online, by regular mail or by FAX.

All FDA-approved injectable dermal fillers are class III (high-risk) medical devices and manufacturers are required to submit a premarket application that includes clinical data supporting safety and effectiveness, for the FDA's review prior to marketing the dermal filler in the United States. The FDA has not received or reviewed data on the safety and effectiveness of Expression for use as a dermal filler.

Additional Resources:

- Enhancement Medical Recall Notification Letter (http://www.enhancementmedical.com/wp-content/uploads/2014/08/Recall_letter.pdf) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)