The United States: FDA warns consumers to avoid certain topical pain relief products due to potential for dangerous health effects

The US Food and Drug Administration (FDA) is warning consumers not to use certain over-the-counter (OTC) analgesic (pain relief) products that are marketed for topical use to relieve pain before, during or after certain cosmetic procedures, such as microdermabrasion, laser hair removal, tattooing and piercing. The agency issued warning letters to 6 companies for marketing these products in violation of federal law. The affected products are:

Company	Product
TKTX Company	TKTX Numb Maximum Strength Pain Reliever Mithra+ 10% Lidocaine TKTX During Procedure Numbing Gel 40% J-CAIN cream [LIDOCAINE] 29.9%
SeeNext Venture, Ltd.	NumbSkin 5% Lidocaine Numbing Cream (15 grams) NumbSkin 5% Lidocaine Numbing Cream (30 grams) NumbSkin 10.56% Lidocaine Numbing Cream
Tattoo Numbing Cream Co.	Signature Tattoo Numbing Cream Miracle Numb Spray
Sky Bank Media, LLC, doing business as Painless Tattoo Co.	Painless Tattoo Numbing Cream Painless Tattoo Numbing Spray
Dermal Source, Inc.	New & Improved Blue Gel Superior Super Juice Premium Pro Plus Five-Star Vasocaine Maximum Zone 1
Indelicare, doing business as INKEEZE	Ink Eeze Original B Numb Numbing Gel Ink Eeze B Numb Numbing Spray Black Label Ink Eeze B Numb Numbing Foam Soap

Some of these products are labeled to contain ingredients, such as lidocaine, at concentrations that are higher than what is permitted for OTC, topical pain relief products. When these products that contain high concentrations of lidocaine intended to be used before or during certain cosmetic procedures are applied in ways that could lead to increased absorption of the drug product through the skin, it may lead to serious injury such as irregular heartbeat, seizures and breathing difficulties. These products may also interact with medications or dietary supplements a consumer is taking. Additionally, when lidocaine is applied over large areas of skin, particularly on irritated or broken skin, for prolonged periods of time and when the skin is covered, the product may cause serious injury.

The FDA recommends consumers:

- Not use OTC pain relief products with more than 4% lidocaine on their skin.

- Not apply OTC pain relief products heavily over large areas of skin or to irritated or broken skin.
- Not wrap skin treated with OTC pain relief products with plastic wrap or other dressings. Wrapping or covering treated skin with any type of material can increase the chance of serious side effects.

Please refer to the following website in FDA for details:
http://www.fda.gov/news-events/press-announcements/fda-warns-consumers-avoid-certain-topical-pain-relief-products-due-potential-dangerous-health

In Hong Kong, the above products are not registered pharmaceutical products.

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