DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

January 16, 2009

Dear Colleague:

The Food and Drug Administration (FDA) is seeking your help to communicate an important health safety issue for patients undergoing mammography. We hope you will share the following information with your members.

We are writing to you because we are concerned that women may improperly use topical anesthetics, such as lidocaine gel, prior to mammography and want to remind the public and healthcare professionals about the potential for topical anesthetics to produce life-threatening adverse effects when used improperly. This concern is due in part to the reports of deaths following similar use of topical anesthetics by women preparing for laser hair removal procedures.

Improper use may include (but is not limited to):

- Applying too much of the topical anesthetic
- Applying to a large area of skin
- Applying to irritated or broken skin
- Covering the skin with a wrap or using a heating pad after applying the topical anesthetic

Improper use of topical anesthetics can lead to excessive absorption of the drug into the bloodstream and may cause life-threatening side effects such as irregular heartbeat, seizures, breathing difficulties, coma and even death.

FDA is aware of a recently published small study in *Radiology* that looked at lidocaine gel (topical/local anesthetic drug product) applied to the skin to decrease discomfort felt by patients undergoing mammography[1]. During the study, the topical product was spread over a wide area and covered with plastic wrap. While no serious side-effects were seen in this study, we remain concerned about the potential for topical anesthetics to cause serious and life-threatening adverse effects when used under certain conditions, such as when applied to a large area of skin or when the area of application is covered. As women become more aware of information from this study via internet sites or word of mouth, increased use of the drug may result in an increase in severe adverse events.

FDA's message for patients regarding the use of a topical anesthetic prior to mammography is as follows:

- Do not use unless you consult your healthcare professional
- If recommended, use a product containing the lowest amount possible of anesthetic drug

- Apply only the amount recommended by your healthcare professional
- Do not apply to broken or irritated skin
- Do not wrap or cover the skin with any type of material or dressing as it may increase the risk of potential life-threatening side effects

FDA's message for healthcare professionals who are considering recommending a topical anesthetic prior to mammography is that the following should be discussed with your patients:

- The potential side effects of topical anesthetics
- How to detect any side effects of topical anesthetics
- How to lower the chance of life-threatening side effects from topical anesthetics
- What to do if side effects from a topical anesthetic occur

For more information see our public health advisory at www.fda.gov/cder/drug/advisory/topical_anesthetics2009.htm.

Consumers and healthcare professionals can report adverse events to the FDA's MedWatch program at 800-FDA-1088, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or online at www.fda.gov/medwatch/report.htm.

Thank you for your support of FDA and its public health mission.

Sincerely,

Theresa Toigo, RPh, MBA
Director, Office of Special Health Issues

[1]*Lambertz CK et al. Premedication to Reduce Discomfort during Screening Mammography. Radiology 2008; 248 (3): 765-72.*