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To: PHARM-GENERAL@DCALISTS.CA.GOV
Subject: FDA MedWatch - Iodine-containing Contrast Agents for Medical Imaging
Date: Tuesday, November 17, 2015 2:46:37 PM

Iodine-containing Contrast Agents for Medical Imaging: Drug Safety Communication - Rare Cases of Underactive Thyroid in Infants

AUDIENCE: Radiology, Endocrinology, Patient, Pharmacy

ISSUE: FDA is advising that rare cases of underactive thyroid have been reported in infants following the use of contrast media containing iodine, also called "contrast dye" for X-rays and other medical imaging procedures. In all of the reported cases, the infants were either premature or had other serious underlying medical conditions. Available evidence leads FDA to believe that this rare occurrence is usually temporary and resolves without treatment or any lasting effects. See the [Drug Safety Communication](#) for a data summary and a list of approved Iodinated Contrast Media Products.

FDA approved changes to the labels of all iodinated contrast media (ICM) products to include information about these cases. No changes to current prescribing, administration, or monitoring practices are recommended. FDA will continue to evaluate this issue and will update the public when there is additional information. Manufacturers of ICM products have been required to conduct a study to investigate this safety issue further.

BACKGROUND: Iodinated contrast media are drugs containing iodine that are given to patients to enhance the ability to see blood vessels and organs on medical images such as X-rays or computed tomography (CT) scans. These images provide greater detail when necessary to help health care professionals diagnose potential problems.

RECOMMENDATION: Parents and caregivers should contact their baby's health care professional for additional information or if they have questions or concerns about their baby receiving an ICM product. Infants typically do not show any visible signs of underactive thyroid. Health care professionals should continue to follow the label recommendations for ICM products. They should continue to use their clinical judgment to determine if testing for underactive thyroid is necessary.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- [Download form](#) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Read the MedWatch safety alert, including a link to the FDA Drug Safety Communication, at:
<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm472995.htm>

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