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

Drug Safety Communications

FDA Drug Safety Communication: FDA determines 2013 labeling adequate to manage risk of retinal abnormalities, potential vision loss, and skin discoloration with anti-seizure drug Potiga (ezogabine); requires additional study

This information is an update to the FDA Drug Safety Communication: FDA Approves Label Changes for Anti-Seizure Drug Potiga (Ezogabine) Describing Risk of Retinal Abnormalities, Potential Vision Loss, and Skin Discoloration issued on 10/31/2013.

Safety Announcement

[06-15-2015] Based on reviews of additional safety reports from patients treated with the anti-seizure drug Potiga (ezogabine), the U.S. Food and Drug Administration (FDA) has determined that the potential risks of vision loss due to pigment changes in the retina and of skin discoloration can be adequately managed by following the current recommendations in the Potiga labeling. To further explore any potential long-term consequences of these pigment changes, we have required the Potiga manufacturer, GlaxoSmithKline, to conduct a long-term observational study.

Our review of additional safety reports does not indicate that the pigment changes in the retina observed in some patients affect vision. Skin discoloration associated with the use of Potiga appears to be a cosmetic effect and does not appear to be associated with more serious adverse effects. Therefore, we have determined that a modification of the Risk Evaluation and Mitigation Strategy (REMS) is not needed at this time to ensure that the benefits of Potiga outweigh the risks of retinal and skin pigment changes. We expect that the required long-term observational study will provide further information on whether pigment changes in the retina caused by Potiga can lead to vision loss or other long-term side effects. In addition, the study should provide more information on the relationship between pigment changes in the retina and skin discoloration.

Potiga is approved for use in combination with other anti-seizure drugs to treat partial-onset seizures in adult patients who have had an inadequate response to several alternative therapies and for whom the benefits of treatment outweigh the risks. Health care professionals should continue to follow the recommendations provided in the *Boxed Warning*, FDA's most serious type of warning, and the *Warnings and Precautions* and *Indications and Usage* sections of the labeling.

We urge patients and health care professionals to report side effects involving Potiga to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page.