From:	Board of Pharmacy
To:	PHARM-GENERAL@DCALISTS.CA.GOV
Cc:	Pharmacy_Subscriberlist@DCA
Subject:	FDA MedWatch (corrected link) - Canagliflozin (Invokana, Invokamet): Drug Safety Communication - Clinical Trial Results Find Increased Risk of Leg and Foot Amputations
Date:	Thursday, May 19, 2016 9:14:26 AM

CANAGLIFLOZIN (INVOKANA, INVOKAMET): DRUG SAFETY COMMUNICATION - CLINICAL TRIAL RESULTS FIND INCREASED RISK OF LEG AND FOOT AMPUTATIONS

AUDIENCE: Internal Medicine, Family Practice, Pharmacy, Patient

ISSUE: FDA is alerting the public about interim safety results from an ongoing clinical trial that found an increase in leg and foot amputations, mostly affecting the toes, in patients treated with the diabetes medicine canagliflozin (Invokana, Invokamet). FDA has not determined whether canagliflozin increases the risk of leg and foot amputations. FDA is currently investigating this new safety issue and will update the public when we have more information.
See the FDA Drug Safety Communication for additional details regarding the ongoing Canagliflozin Cardiovascular Assessment Study (CANVAS) clinical trial.

BACKGROUND: Canagliflozin is a prescription medicine used with diet and exercise to lower blood sugar in adults with type 2 diabetes. It belongs to a class of drugs called sodium-glucose cotransporter-2 (SGLT2) inhibitors. Canagliflozin lowers blood sugar by causing the kidneys to remove sugar from the body through the urine. It is available as a single-ingredient product under the brand name Invokana and also in combination with the diabetes medicine metformin under the brand name Invokamet.

RECOMMENDATION: Health care professionals should follow the recommendations in the canagliflozin drug labels. Monitor patients for the signs and symptoms described above and advise patients to seek medical advice if they experience them.

Patients should not stop or change their diabetes medicines without first talking to their health care professional. Doing so can lead to uncontrolled blood sugar levels that can be harmful. Over time, this can cause serious problems, including blindness, nerve and kidney damage, and heart disease. Patients taking canaglifozin should notify their health care professionals right away if they notice any new pain or tenderness, sores or ulcers, or infections in their legs or feet.

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/ucm501565.htm