From:	Board of Pharmacy
To:	PHARM-GENERAL@DCALISTS.CA.GOV
Cc:	Pharmacy_Subscriberlist@DCA
Subject:	FDA MedWatch - Mass Spectrometers by Sciex: Safety Communication - Incorrect Assignment of Test Results
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Mass Spectrometers by Sciex: Safety Communication - Incorrect Assignment of Test Results

Including:
Sciex API 3200 LC/MS/MS System, 3200MD QTRAP LC/MS/MS System, Triple Quad 4500 LC/MS/MS System, and the QTRAP 4500 LC/MS/MS equipped with:

- the Analyst Software Versions 1.6.1 and 1.6.2, and
- the MultiQuant Software Versions 3.0, 3.0.1, and 3.0.2.

AUDIENCE: Risk Manager, Laboratory, Pharmacy
ISSUE: The FDA is alerting lab staff and health care professionals about a software defect in Sciex mass spectrometers. This software defect may cause the devices to incorrectly assign results to samples analyzed. Sciex notified the FDA that, under certain conditions, the defect in the software versions identified above may lead the devices to display results that do not match the specimens tested. This is of concern because health care professionals may make inaccurate clinical diagnoses or inaccurate medical treatment decisions for patients by relying on incorrect results from the devices. A potential inaccurate clinical diagnosis or treatment decision may lead patients to experience serious adverse health consequences.
The mass spectrometers manufactured by Sciex are medical devices specified either for clinical diagnostic use or for research use only (RUO). RUO devices are typically in a development stage and must be labeled "For Research Use Only. Not for use in diagnostic procedures."
The company has sent Urgent Medical Device Correction Letters and issued two voluntary recalls for the mass spectrometers for clinical use. However, there may be customers of the RUO version of the mass spectrometers that are using them for clinical purposes. Since Sciex has not notified its customers of the RUO version about the issues associated with the software defect in the instruments, we are concerned that these customers, which include clinical laboratories, may be unaware of the issue and its potential impact on results generated by the device.
BACKGROUND: Mass spectrometers are devices used in lab settings to identify inorganic or organic compounds (e.g. lead, mercury, drugs, proteins, and peptides) in human specimens. The devices separate isotopes, molecules, and molecular fragments according to their mass through electric and magnetic fields. Health care professionals may use the results to aid in their clinical diagnosis or to help evaluate possible treatment decisions.
RECOMMENDATION: FDA recommends the following:

- Determine if your facility owns and uses one of the mass spectrometers equipped with the software listed above;
- Contact Sciex for necessary software corrections; and
- If necessary, laboratories should follow CLIA requirements to investigate and take appropriate corrective action when errors have been known, or are suspected to have occurred.

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 Safety Communication, at:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm518907.htm