BioSpectrum the business of Bio & Health Sciences

Agilent announces resolution to FDA warning letter

23 April 2015 | News | By BioSpectrum Bureau

Agilent announces resolution to FDA warning letter

Agilent Technologies has announced that its subsidiary, Dako Denmark A/S, has received a close-out letter from the US Food and Drug Administration (US FDA) with respect to the warning letter issued Aug 21, 2013. The FDA informed Dako Denmark that it has completed its evaluation of Dako's corrective actions and that it appears Dako has addressed the violations contained in the warning letter.

The warning letter, issued by the FDA's Center for Devices and Radiological Health, focused on Dako's quality management processes for complaint handling, corrective and preventive actions, statistical techniques and process validation. The letter was the result of an inspection the FDA performed at Dako's facility in Glostrup, Denmark, in March 2013.

"We are pleased with this outcome. It underscores our commitment to maintaining a compliant and superior quality management system, and to delivering products that are of the highest quality," said Mr Mike McMullen, president and CEO, Agilent. â€ƒ