August 19, 2014

Mr. Ilja Rodushkin
Laboratory Manager
ALS Scandinavia AB
Aurorum 10, SE-977 75 Lulea
Sweden

Reference: FEI 3007165135

Dear Mr. Rodushkin:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your control testing laboratory in Lulea, Sweden by Investigator Brian Nicholson during the period of May 15 to May 16, 2014. A Form FDA-483, Notice of Inspectional Observations was issued at the conclusion of the inspection.

We have also reviewed your company’s response dated June 5, 2014 with supportive documentation. Based on the profile class covered during the inspection, we are classifying your facility as acceptable. This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to assure continued compliance with current good manufacturing practice (CGMP).

Please be advised that all manufacturers must register annually as required by 21 C.F.R. § 207.40. Information on how to register is available at http://www.fda.gov/cder/drls/registration_listing.htm.

Additionally, we enclose a copy of the establishment inspection report (EIR). Releasing this EIR to you is part of FDA’s effort to make its regulatory process and activities more transparent to the regulated industry. It is being provided to you for information purposes only and may reflect some redactions made by the Agency in accordance with the Freedom of Information Act and 21 C.F.R. Part 20. Copies provided to other requestors may have additional redactions of trade secret and confidential commercial information.

If you have any questions regarding this letter, you may contact me at the above address or number.

Sincerely,

Xiaohui Shen
Compliance Officer
Division of International Drug Quality

Enclosure: EIR