



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

CENTER FOR DRUG EVALUATION AND RESEARCH

Office of Manufacturing and Product Quality  
Division International Drug Quality  
International Compliance Branch  
10903 New Hampshire Avenue  
Building #51, Room 4316  
Silver Spring, MD 20993

TELEPHONE: (301) 796-3254  
FAX: (301) 847-8742

January 30, 2015

Ms. Elena Borcova  
Member of the Management Board  
and Qualified Person  
OlainFarm  
5 Rupnicu Street  
Olaine, LV-2114, Latvia

Reference: FEI 3001672072

Dear Ms. Borcova:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your finished dosage, API drug substances and intermediates manufacturing facility in Olaine, Latvia by Investigator Angela E. Glenn during the period of September 15, 2014 to September 19, 2014.

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 practices (CGMPs).

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](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,

Concepcion Cruz  
Branch Chief (Acting)  
Division of Quality Surveillance Assessment

Enclosure: EIR

Sāņemts AS "Olainfarm"  
Datums 04.02.2015  
Nr. 535