DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Slawomir Jeka, M.D., Ph.D.
Rodzinnych z Pryzchodnia
Specjalistyczna Szcztna 20
Toru, Poland 87-100
Poland

Dear Dr. Jeka:

This letter informs you of the findings of a U.S. Food and Drug Administration (FDA) inspection conducted at your site between 1/26/2015 and 1/29/2015. Investigator Marc A. Jackson, representing the FDA, reviewed your conduct of the following clinical investigations of the investigational drug infliximab (CT-P13) biosimilar, performed for Celltrion, Inc.:

- **Protocol # CT-P13 1.1**, entitled "A Randomized, Double-Blind, Parallel-Group, Phase 1 Study to Demonstrate the Equivalence With Respect to the Pharmacokinetic Profile of CT-P13 and Remicade in Patients With Ankylosing Spondylitis"; and

- **Protocol # CT-P13 3.1**, entitled "A Randomized, Double-Blind, Parallel-Group, Phase 3 Study to Demonstrate Equivalence in Efficacy and Safety of CT-P13 Compared With Remicade When Co-administered With Methotrexate in Patients With Active Rheumatoid Arthritis".

This inspection was conducted as a part of the FDA's Bioresearch Monitoring Program, which includes inspections designed to evaluate the conduct of FDA-regulated research to ensure that the data are scientifically valid and accurate, and to help ensure that the rights, safety, and welfare of the human subjects of those studies have been protected.

From our review of the establishment inspection report and the documents submitted with that report, we conclude you adhered to the applicable statutory requirements and FDA regulations governing the conduct of clinical investigations and the protection of human subjects.

We appreciate the cooperation shown to Investigator Jackson during the inspection. Should you have any questions or concerns regarding this letter or the inspection, please contact me by letter at the address given below.

Sincerely,

{See appended electronic signature page}

CDR LaKisha Williams-Patterson, USPHS
Regulatory Health Project Manager
Division of Clinical Compliance Evaluation
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
Building 51, Room 5374
10903 New Hampshire Avenue
Silver Spring, MD 20993-0000