IMMUNE DEFICIENCY FOUNDATION URGES FDA TO EXEMPT IMMUNOGLOBULIN FROM BIOSIMILARS PATHWAY

Baltimore, MD – (May 16, 2012) – In an effort to voice concern on biosimilar pathways for patients with primary immunodeficiency diseases (PIDD), the Immune Deficiency Foundation (IDF) offered oral testimony at last week’s U.S. Food and Drug Administration (FDA) public hearing on draft guidance of biosimilar products. IDF urged the FDA to exempt immunoglobulin (Ig) therapies from the biosimilar pathways in order to protect the safety of patients with PIDD.

PIDD occurs in people born with an immune system that is either absent or hindered in its ability to function, causing an array of illnesses. Many of these patients require Ig therapy, a biologic medicine, for long-term management. Ig therapies are derived from human blood product, or plasma, and can differ in terms of processing and end composition.

“The FDA should restrict Ig therapies from the biosimilar pathways until the science advances significantly,” said Marcia Boyle, president and founder, IDF. “Patients with primary immunodeficiency diseases depend on frequent antibody replacements with Ig therapy in order to fight infections.”

The FDA recognizes each Ig brand as unique with no generic equivalent— Ig products are not clinically interchangeable. Current science cannot demonstrate that two products will provide the exact same clinical results for a large number of patients or that switching patients from one product to another will pose no additional risks.

Boyle’s testimony urged the FDA to follow the example set by the European Medicines Agency and exempt Ig therapy from the biosimilars pathway, or to at the least require that biosimilar products undergo clinical trials to determine whether a proposed interchangeable therapy will offer patients the same clinical outcome. Additionally, Boyle requested that the FDA prohibit automatic substitution of a biosimilar with an original biologic.

“We believe the FDA’s foremost responsibility is to ensure that biosimilars are manufactured and prescribed safely,” said Boyle. “All medicines must be thoroughly tested and meet the highest safety standards set by the FDA.”

About the Immune Deficiency Foundation
The Immune Deficiency Foundation is the national patient organization dedicated to improving the diagnosis, treatment and quality of life of persons with primary immunodeficiency diseases through advocacy, education, and research. www.primaryimmune.org.