



March 22, 2010

Victoria A. Espinel
Office of Management and Budget
Intellectual Property Enforcement Coordinator
725 17th Street
Washington, DC 20503

Dear Ms. Espinel:

On behalf of the Lupus Foundation of America (LFA), we would like to acknowledge our support of the Food and Drug Administration's (FDA) current position on drug importation, shown below:

The United States Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. section 331) prohibits the interstate shipment (which includes importation) of unapproved new drugs. Thus, the importation of drugs that lack FDA approval, whether for personal use or otherwise, violates the Act. Unapproved new drugs are any drugs, including foreign-made versions of U.S. approved drugs, that have not been manufactured in accordance with and pursuant to an FDA approval.

While there have been no new approved drugs to treat lupus in more than 50 years, there have recently been several Phase III trials that may lead to the first new treatment for lupus. We feel it is imperative that people with lupus have access to the safest FDA regulated medications. Lupus is an acute and chronic autoimmune disease in which the immune system is unbalanced, causing inflammation and tissue damage to virtually any organ system in the body. Lupus can affect any part of the body, including the skin, lungs, heart, kidneys, and brain. The disease can cause seizures, strokes, heart attacks, miscarriages, and organ failure. An estimated 1.5 million Americans have a form of lupus. Lupus strikes mostly women of childbearing age; African Americans, Hispanics/Latinos, Asians and Native Americans are two to three times more likely to develop lupus - a disparity that remains unexplained.

The Lupus Foundation of America is the foremost national nonprofit voluntary health organization dedicated to finding the causes of and cure for lupus and providing support, service, and hope to all people affected by lupus. Research and education are at the heart of LFA's programs. The LFA has a nationwide network of nearly 300 chapters, branches, and support groups serving individuals with lupus, their families, and health professionals.

Thank you for the opportunity to submit comments. We congratulate the FDA on its oversight of importation and proper drug safety labeling. If you have any questions, please contact Julie Venners, Vice President for Government Relations, at 202-349-1150 or venners@lupus.org.

Sincerely,


Sandra C. Raymond
President and CEO