

March 15, 2010

Janet Woodcock, MD  
Director  
Center for Drug Evaluation and Research, FDA  
White Oak Bldg. 51, Rm. 6133, Mail Code: HFD-001  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Dr. Woodcock,

As you know, it is estimated that as many as several thousand unapproved drugs are in the marketplace today in the United States. While we at MANA very much appreciate the hard work your agency has already done to remove a number of these drugs from pharmacy shelves, I feel it necessary to encourage the acceleration of your efforts at fixing this important problem as too many unapproved drugs still remain available for purchase today.

Few know the dangers of unapproved drugs better than those who work at the FDA. Between the risks consumers face posed by the insufficiently tested drugs themselves and those posed by the possibility of adverse drug to drug interactions (enhanced by the insufficient labeling common to unapproved drugs), little more need be said.

Adding to the problem is the fact that even well-meaning physicians continue to write scripts for unapproved drugs falsely characterizing these drugs as “generics” and leaving the patients they care for at risk.

The FDA acknowledged the importance of removing unapproved drugs from the marketplace in 2006 when it announced the “Unapproved Drugs Initiative,” and has done important work to start addressing the problem. That being said, too many of these drugs remain available today as only approximately 400 of the estimated thousands of unapproved drugs have been removed from the market since 2006.

It is clear that the FDA has a difficult task at hand, but the removal of all unapproved drugs from the marketplace is an important and commendable goal that must be achieved as soon as possible. Doing so will not only encourage other companies to pursue the proper measures necessary to win FDA approval for their own products, but more importantly, will assure that no more unnecessary harm is brought to the unknowing purchasers of unapproved drugs in this country.

Our organization’s purpose is to work towards a better quality of life for Latinas and the Latino community as a whole, but the existence of unapproved drugs on the marketplace endangers all Americans, making their removal from our pharmacies an even more important goal. We at MANA would like to offer your agency our assistance and support to help you achieve our shared goal of a marketplace that is free of dangerous, unapproved drugs.

Thank you for your time and consideration.

Sincerely,



Alma Morales Riojas  
President and CEO