DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

December 8, 2009

The Honorable Sam Brownback
United States Senate
Washington, DC 20510

Dear Senator Brownback:

Thank you for your letter requesting our views on the amendment filed by Senator Dorgan to allow for the importation of prescription drugs. The Administration supports a program to allow Americans to buy safe and effective drugs from other countries and included $5 million in our FY 2010 budget request for the Food and Drug Administration (FDA or the Agency) to begin working with various stakeholders to develop policy options related to drug importation.

Importing non-FDA approved prescription drugs presents four potential risks to patients that must be addressed: (1) the drug may not be safe and effective because it was not subject to a rigorous regulatory review prior to approval; (2) the drug may not be a consistently made, high quality product because it was not manufactured in a facility that complies with appropriate good manufacturing practices; (3) the drug may not be substitutable with the FDA-approved product because of differences in composition or manufacturing; and (4) the drug may not be what it purports to be, because it has been contaminated or is a counterfeit due to inadequate safeguards in the supply chain.

In establishing an infrastructure for the importation of prescription drugs, there are two critical challenges in addressing these risks. First, FDA does not have clear authority over foreign supply chains. One reason the U.S. drug supply is one of the safest in the world is because it is a closed system under which all the participants are subject to FDA oversight and to strong penalties for failure to comply with U.S. law. Second, FDA review of both the drugs and the facilities would be very costly. FDA would have to review data to determine whether or not the non-FDA approved drug is safe, effective, and substitutable with the FDA-approved version. In addition, the FDA would need to review drug facilities to determine whether or not they manufacture high quality products consistently.

The Dorgan importation amendment seeks to address these risks. It would establish an infrastructure governing the importation of qualifying drugs that are different from U.S. label drugs, by registered importers and by individuals for their personal use. The amendment also sets out registration conditions for importers and exporters as well as inspection requirements and other regulatory compliance activities, among other provisions.

We commend the sponsors for their efforts to include numerous protective measures in the bill that address the inherent risks of importing foreign products and other safety concerns relating to the distribution system for drugs within the U.S. However, as currently written, the resulting structure would be logistically challenging to implement and resource intensive. In addition,

there are significant safety concerns related to allowing the importation of non-bioequivalent products, and safety issues related to confusion in distribution and labeling of foreign products and the domestic product that remain to be fully addressed in the amendment.

We appreciate your strong leadership on this important issue and would look forward to working with you as we continue to explore policy options to develop an avenue for the importation of safe and effective prescription drugs from other countries.

Sincerely,

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs