United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

WASHINGTON, DC 20510-6300

July 9, 2012

Dr. Margaret Hamburg
FDA Commissioner
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Hamburg,

As Chairman of the Senate Committee on Health, Education, Labor and Pensions (HELP) and a longtime supporter of patient access to homeopathic drugs, I am writing to clarify the intent of Title VII, Section 711 of the Food and Drug Administration Safety and Innovation Act (FDASIA).

As you know, on June 26, 2012, the Senate passed a final conferenced FDASIA bill by a bipartisan vote of 92-4. President Obama signed the bill into law on July 9, 2012. This law will provide the Food and Drug Administration (FDA) with the tools to review and approve drugs, medical devices, generic drugs, and biosimilars in a timely fashion. Section 711 of FDASIA establishes standards that drug importers must meet to ensure that drugs arriving in the United States from foreign facilities are safe and effective. Modernizing FDA's authority to protect consumers from drugs that transit an increasingly global supply chain will improve patient safety and level the playing field by holding foreign manufacturers to the same high standards met by domestic manufacturers.

However, it was not the HELP Committee's intent for Section 711 to mean that homeopathic drugs which lack an approved New Drug Application, but are marketed in accordance with the provisions in the current FDA Compliance Policy Guide (CPG) Sec. 400.400, will not be eligible for import. Indeed, the Committee does not intend that Section 711 will have any impact on the marketing of homeopathic products pursuant to FDA's enforcement discretion as set forth in CPG Sec. 400.400. For over 20 years FDA has appropriately exercised a policy of enforcement discretion with regard to the importation of homeopathic drugs that meet the provisions of CPG Sec. 400.400. Section 711 should not be read to alter this longstanding policy.

I respectfully request that FDA affirm the agency's understanding of the HELP Committee's intent that FDASIA Section 711 will not affect FDA's implementation of CPG Sec. 400.400.

Sincerely,

Tom Harkin
U.S. Senator