DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Tom Harkin
Chairman
Committee on Health, Education, Labor and Pensions
United States Senate
Washington, D.C. 20510-6300

AUG 10 2012

Dear Mr. Chairman:

Thank you for your letter of July 9, 2012, regarding the intent of the Senate Committee on Health, Education, Labor and Pensions that the Food and Drug Administration Safety and Innovation Act (FDASIA P.L.112-144), section 713,[1] will not affect the Agency's implementation of Compliance Policy Guide (CPG) sec. 400.400, *Conditions Under Which Homeopathic Drugs May Be Marketed.*

As you noted in your letter, FDASIA provides the Food and Drug Administration (FDA or the Agency) with important new authorities, including the authority under section 713, to establish standards that drug importers must meet to ensure that drugs arriving in the United States from foreign facilities are safe and effective. Regarding homeopathic drugs specifically, section 713 of FDASIA will not affect FDA's implementation of CPG 400.400, with regard to the importation of homeopathic drugs.

Thank you, again, for contacting us concerning this matter. Please let us know if you have further questions.

Sincerely,

Jeanne Ireland
Assistant Commissioner
for Legislation

[1] Although your letter references FDASIA section 711, based on the context, we believe you intended instead to refer to section 713, "Standards for Admission of Imported Drugs."