



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Sherrod Brown
United States Senate
Washington, D.C. 20510-3505

APR 20 2012

Dear Senator Brown:

Thank you for your letter of April 18, 2012, to the Food and Drug Administration (FDA or the Agency) expressing your concern about FDA's Compliance Policy Guide titled "Hospital Pharmacies- Status as Drug Manufacturer."

We appreciate your concern about shortage situations in which a hospital may want to repackage certain drug products and deliver them to affiliated hospitals within the same medical system. FDA uses all tools available to help prevent and help alleviate shortage situations when it is within our authority to do so. For your information, we have been actively reviewing our Compliance Policy Guide as it pertains to hospital pharmacies. It is our intention to provide guidance that clarifies the Agency's policy with respect to hospital pharmacies repackaging certain drugs and transferring them to affiliated hospitals in shortage situations. We are committed to assuring the availability of important drug products and at the same time assuring that the safety and effectiveness of the products will not be compromised.

FDA looks forward to continued work with Congress, hospitals, healthcare providers, and others who are working to help solve the drug shortage problem and maintain access to important drugs for all Americans.

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

Sincerely,

Jeanne Ireland
Assistant Commissioner
for Legislation