DEPARTMENT OF HEALTH & HUMAN SERVICES

The Honorable Charles Grassley
Chairman
Caucus on International Narcotics Control
United States Senate
Washington, D.C. 20510-1501

JUN 1 5 2015

Dear Mr. Chairman:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity to testify at the May 5, 2015, hearing before the Senate Caucus on International Narcotics Control entitled "Improving Management of the Controlled Substances Quota Process." This letter is a response for the record to Question #2, posed by the Caucus, to FDA.

If you have further questions, please let us know.

Sincerely,

Thomas A. Kraus
Associate Commissioner
 for Legislation

Enclosure

cc: The Honorable Dianne Feinstein
 Co-Chair

We have restated your questions below in bold, followed by our responses.

2. Definition of a Drug Shortage

The report found that the agencies are unable to agree on how to define what a drug shortage is, which prevents them from effectively collaborating together.

a. How does the FDA define a drug shortage and why does it use this definition?

FDA uses the definition provided in the Federal Food, Drug, and Cosmetic Act (FD&C Act). Subsection 506C(h) of the FD&C Act defines a drug shortage as a period of time when "demand or projected demand for the drug within the United States exceeds the supply of the drug[.]"

b. How does the FDA determine the cause of a shortage?

The cause of the shortage is determined based on information received from the manufacturers as well as from other parts of FDA, such as field inspectors, and also from stakeholders such as health care professional associations. For example, a company may report increased demand as the reason for a shortage and from our contacts in health care professional associations, such as the American Society of Health-System Pharmacists, we may learn of a shift in the clinical use for the drug, which has caused the increased demand. When FDA is notified of a shortage or potential shortage, we reach out to manufacturers of the drug to find out whether they are experiencing any problems in meeting demand. We request that the manufacturers report reasons for any shortages they are experiencing, and we offer FDA assistance to help prevent or resolve the shortage. Additional information may come from several sources, including information provided by the manufacturers, market sales data we purchase, as well as from patient, pharmacist, physician and health care professional organization e-mails and phone calls reporting on the shortage and the impact it is having.

c. What steps does the FDA take to verify that a shortage exists?

Before concluding that a shortage exists, we apply a standard process which involves a careful review by our shortage staff of available data, which may include IMS Health market research; product manufacturers; internal FDA databases; reports from prescribers, patients, pharmacies, and other stakeholder organizations about supply disruptions; the American Society of Health-System Pharmacists, which also maintains drug shortages listing; and other federal agencies, such as the Drug Enforcement Administration (DEA), the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health (NIH). Steps that the Drug Shortage Staff may take to verify the presence or potential for a shortage include:

- Using a market research database to collect initial information to determine whether or not the current supply of product across manufacturers is stable.

- Contacting product manufacturer(s) to collect up-to-date inventory information, rate of demand (units/month), manufacturing schedules, and any changes in ordering patterns. Although manufacturers are generally not required to provide this information to FDA, voluntarily sharing this information greatly facilitates the management of shortages.
- Evaluating product inventory in the distribution chain to the extent possible. This information can help predict how quickly a shortage may develop (if at all).