Dear Manufacturer:

The FDA is contacting all drug manufacturers to express our concern about the rising incidence of drug shortages in the United States, particularly those involving drugs for which no good alternative therapies exist, and the serious impact these shortages have for patients and health care providers. The number of drug shortages annually has tripled from 61 in 2005 to 178 in 2010. Some of these shortages delay or deny needed care for patients since they involve critical drugs used to treat cancer, to provide required nutrition, or to address other serious medical conditions.

Today, we released a report (INSERT LINK) about this serious public health issue, emphasizing that its root causes are complex, as is the path to resolving them. A significant number of drug shortages are the result of manufacturing quality problems. In fact, in 2010, 54% of drug shortages were caused by manufacturing quality issues. The American public counts on companies like yours to ensure drug quality and safety, so that patient care is not compromised.

The public also relies on you to assure an adequate, predictable supply of those drugs. While a number of companies are in the process of expanding capacity to address this issue, another important factor in many of the recent shortages appears to be an increase in demand that exceeds current manufacturing capacity. Finally, recent reports in the press and at public workshops (such as the one held by FDA's Center for Drug Evaluation and Research in September 2011) from medical societies, patient advocate groups, and patients themselves describe the serious negative impact that drug shortages can have on patients.

Some drug shortages cannot be predicted or avoided, but many can be anticipated in advance of a crisis. We believe that effective communication and early notification from manufacturers to the FDA about matters that could result in a product shortage can have a significant, positive impact on the incidence and duration of shortage situations. This year alone, early notification by manufacturers allowed the FDA to help prevent 99 drug shortages.

For certain sole source drugs, section 506C of the Federal Food Drug and Cosmetic Act requires you to notify us of any manufacturing discontinuance at least 6 months prior to the date of the discontinuance. Given the current crisis of drug shortages in the United States, we remind you of your obligation to report such discontinuances as required by section 506C. In addition, we encourage you to provide voluntary notifications beyond those currently required by the statute and regulation as soon as you become aware of the possibility of a shortage. This would include potential shortages in drugs not covered by Section 506C and the risk of shortages created by events such as:

- interruptions or other adjustments in manufacturing that may adversely affect market supply;
- delays in acquiring critical raw materials or components;
- production problems that occur during or after manufacturing that could result in supply disruptions;
- import delays; and
- unexpected increases in demand.

To provide additional clarity, FDA intends to issue guidance that more specifically identifies the requested information on potential supply disruptions and discusses opportunities to enhance collaboration and communication to prevent and reduce the adverse impact of drug shortages.

If you anticipate a potential supply disruption to prescription drugs that are used in the treatment of serious medical conditions or for which there is no alternative available therapy, please notify FDA by sending an email to our Drug Shortage staff at drugshortages@fda.hhs.gov or visit www.fda.gov/Drugs/DrugSafety/DrugShortages. Our Drug Shortage staff will work with you and other appropriate parties to take all measures possible to mitigate the effect of drug shortages on patient needs. FDA staff are available to discuss contingency plans for additional manufacturing sites, production lines and suppliers to help prevent shortages.

We are committed to continuing to identify the problems that lead to drug shortages and to establishing processes to resolve and avoid critical shortages in the future. We seek your commitment to do the same. Clear, ongoing, and timely communications between the FDA and industry are essential to preventing many drug shortages, mitigating those that cannot be avoided, and facilitating the resolution of ongoing shortages. When you notify us of potential disruptions, we can work with you to resolve quality or manufacturing problems to ensure continued patient access to safe and effective medicines. There is no single or simple solution that can resolve the drug shortage problem, but we look forward to working with manufacturers, distributors, Congress, and other stakeholders to develop approaches, such as early notification, that are multifaceted, sustainable, and assure that disruptions to patient care are minimized.

We thank you for your assistance in this effort.

Sincerely,

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