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We Can't Wait: Obama Administration makes more progress to reduce, prevent drug shortages

In response to President Obama's Executive Order, FDA issues rule requiring manufacturers to report interruptions in production of critical drugs

Washington, DC - Today, in response to President Obama's Executive Order of Oct. 31, 2011, the Obama Administration is issuing an interim final rule that will help prevent prescription drug shortages.

The rule will require manufacturers that are the only producer of certain critical drugs to report to the Food and Drug Administration all interruptions in manufacturing of products. The rule builds on FDA's current work to ensure Americans have access to the medicine they need.

President Obama's Executive Order directed the Food and Drug Administration and Department of Justice to take action to help reduce and prevent drug shortages, protect consumers, and prevent stockpiling and exorbitant pricing of drugs in shortage. Early notification of potential drug shortages is an essential tool in helping FDA work with drug manufacturers, hospitals, doctors, and patients to prevent or mitigate a drug shortage before it becomes a crisis.

"The President made it clear that we can't wait to tackle this challenge and do all we can to prevent shortages of potentially life-saving medicines," said HHS Secretary Kathleen Sebelius. "Today's action is the latest in a series of proactive efforts we have undertaken to combat shortages of critical medicine the American people depend upon."

"Shortages delay or deny needed care for patients and FDA is committed to making sure that patients and health professionals have the drugs they need when they need them, said FDA Commissioner Margaret Hamburg, M.D. "We will continue to take steps such as issuing this interim final rule to prevent and reduce current and future disruptions in the supply of lifesaving medicines."

For more information on the rule, go to
http://www.hhs.gov/news/press/2011pres/12/20111215a_fda.html.

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