US food and drug administration to Hold Public Hearing on Medication Guide Program

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April 12, 2007，The Food and Drug Administration (FDA) will hold a public hearing on June 12 and 13, 2007, to obtain feedback on FDA's Medication Guide program. Medication Guides are handouts given to patients by pharmacists each time certain prescription drugs and biological products are dispensed. Medication Guides contain FDA-approved patient information that could help prevent serious adverse events.

The goals of the public hearing include assessing the effectiveness of Medication Guides in communicating the risks of certain drug and biological products to consumers and identifying Medication Guide distribution challenges and solutions.

"We want to hear from manufacturers, distributors, pharmacies, health professionals, and patients about what concrete steps can be taken to ensure that consumers get the information they need to make informed decisions about the use of medicines," said Paul Seligman, M. D., Associate Director for Safety Policy and Communication at FDA's Center for Drug Evaluation and Research.

Under current rules (21 CFR part 208), Medication Guides are required if the FDA determines that the drug product has one or more of the following characteristics:

It is one for which patient labeling could help prevent serious adverse effects.

It has serious risk(s) (relative to benefits) of which patients should be made aware because information concerning the risk(s) could affect patients' decisions to use, or continue to use, the product.

The product is important to health and patient adherence to directions for use is crucial to the effectiveness of the drug.

In recent years, FDA's efforts to improve risk communication have included an increase in the number of Medication Guides. There are approximately 240 products with Medication Guides. In addition, it has become more common for Medication Guides to be required for entire classes of drugs (such as non-steroidal anti-inflammatory drugs, or NSAIDs).

The public hearing will be held on June 12 and 13, 2007, from 8:30 a.m. to 4:30 p.m. each day at the National Transportation and Safety Board Boardroom and Conference Center, 429 L'Enfant Plaza, SW, Washington, DC 20594 (Metro: L'Enfant Plaza Station on the Green, Yellow, Blue, and Orange Lines).

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