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FDA to make enforcement and compliance activities accessible online

New Web portal to include searchable database

The U.S. Food and Drug Administration today announced that it is disclosing more information about inspections and court actions, and now has a Web portal on its enforcement activities as part of Phase II of the agency's Transparency Initiative. These actions are being taken to make FDA's enforcement and compliance-related activities more accessible, downloadable, and searchable online.

The information includes a summary of the most common Inspectional Observations of objectionable conditions or practices made during inspections and a searchable Inspections Database that includes the names and addresses of inspected facilities, inspection dates, type of FDA-regulated products involved, and final inspectional classification.

By the end of 2011, FDA will also begin to disclose additional information about FDA evaluations of filers, expand disclosure of Untitled Letters, and in appropriate situations, support industry efforts during a food recall to inform consumers of products that are not subject to the recall.

Access to this information about FDA's enforcement and compliance activities will provide the following to the public and regulated industry:

- * More information about company practices that may jeopardize public health, as well as about companies that have had satisfactory FDA inspections.
- * Information about recall and enforcement activities that will help consumers make decisions about products.
- * Information about inspection results, which can be expected to create a greater incentive to bring practices into compliance with the law.
- * Information about food products that are not subject to a particular recall, which can help reduce consumer confusion.

FDA Commissioner Margaret A. Hamburg M.D. launched FDA's Transparency Initiative in June 2009 in response to the Obama administration's commitment to openness in government. After holding public meetings and inviting written comments, FDA issued a report proposing 21 actions to increase disclosures about agency activities. The actions announced today stem directly from that effort and are among the first of the proposals to be implemented.

For more information:

FDA's Transparency Initiative

<http://www.fda.gov/AboutFDA/Transparency/default.htm>

Inspections Database:

<http://www.fda.gov/ICECI/EnforcementActions/ucm222557.htm>

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.