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DSI Participates in FDA Meeting on Naming, Labeling and Packaging

On June 24-25, 2010 the FDA held a public meeting in College Park, Maryland soliciting panelist and public comments for Developing Guidance on Naming, Labeling, and Packaging Practices to Reduce Medication Errors. There were four panel discussions that discussed the following: (1) Container/ Carton Labeling, (2) Safety Testing of Container/ Carton Labeling, (3), Packaging and (4) Naming. After each panel discussion, there was an open public hearing. A draft Guidance is expected to be released by the end of the year.

Jerry Phillips, the President and CEO of the Drug Safety Institute, was the only person who provided comments on all four topics discussed at the FDA public meeting. Mr. Phillips was the former Associate Director of the Office of Drug Safety and Acting Director of the Division of Medication Errors and Technical Support (DMETS, now called DMEPA). Specific recommendations were provided on how to safely label and package pharmaceuticals and how to evaluate whether the labeling and packaging is safe. When it came to naming, Mr. Phillips outlined the many challenges the Industry faces when developing a trademark for a pharmaceutical. He suggested that FDA consider:

1. Harmonization with the European Medicines Agency (EMA) on USAN/INN Stem issues.
2. Collaboration on an ICH Guideline that would develop a standardized global approach to name safety testing and evaluation.
3. Allowing the incorporation of the dosage form (e.g. nasal) in the development of a trademark.
4. Considering a one-time only review of a proposed trademark, similar to the EMA, where the trademark could be tentatively approved in the Investigational New Drug (IND) application. Once approved, other trademarks could not be confusingly similar in sound and/or look. FDA was encouraged to also consider the US Patent and Trademark Office (USPTO) filing and acceptance dates for pending trademarks at FDA.
5. Developing a coherent policy on modifiers with a proposed testing methodology to evaluate the safe use of the modifier.

For further information, please contact your local Brand Institute sales team or call 305-374-2500.

FDA Former Official



Jerry Phillips, R.Ph. President & C.E.O., Drug Safety Institute

Mr. Phillips was formerly the FDA Associate Director for Medication Error Prevention in the Office of Drug Safety (ODS), renamed the Office of Surveillance and Epidemiology (OSE), and the Acting Director of the FDA's Division of Medication Errors and Technical Support (DMETS now called DMEPA) a Division that he helped create.

He has been the FDA representative and Chair of the National Coordinating Council for Medication Error Reporting and Prevention, an expert member on the USP Nomenclature Expert Committee, and a collaborator with many international regulatory authorities and agencies.

Mr. Phillips oversees all proprietary & nonproprietary strategy, naming, safety research, labeling, risk management, name submissions, rebuttals, and special consults for DSI.

Mr. Phillips earned his B.S. in Pharmacy from the University of Houston and completed an ASHP hospital pharmacy residency at the U.S. Public Health Service hospital in Staten Island, N.Y.