

# BI & DSI Expand their USAN/INN Generic Drug Naming Expertise

Brand Institute and Drug Safety Institute are proud to announce the additions of one USAN/INN nomenclature expert and one FDA nomenclature expert. Under Jerry Phillips, R.Ph., they will be dedicated to generic naming, research and regulatory submissions.



**Jerry Phillips, R.Ph.**

**President, DSI**

Mr. Phillips is extremely excited to accept the addition of Ms. Fuerst and Ms. Roberts to the Brand Institute and Drug

Safety Institute team to enhance our ability to expertly assist our clients with all of their regulatory and generic nomenclature needs.

Under the leadership of Jerry Phillips, R.Ph., who served 16 years with the Food and Drug Administration (FDA), Drug Safety Institute (DSI) continues to build a great track record with naming research and regulatory submissions.

The expansion of our generic drug expertise is the natural extension of our experience in the area of pharmaceutical nomenclature.



**Sophia V. Fuerst, M.S., M.B.A.**

**DSI Managing Director,  
USAN/INN Research: Chicago**

As prior Director of the United States Adopted Names (USAN) Program and Secretary of the USAN Council, Ms. Fuerst was

responsible for a specifically organized effort directed at producing simple, informative, and unique nonproprietary names for drugs and certain other related agents, based on a logical nomenclature classification. (see reverse)



**Khyati N. Roberts, R.Ph.**

**DSI Associate Director for  
Regulatory Affairs: Rockville**

Ms. Khyati Roberts, R.Ph., is a registered pharmacist with over 17 years of regulatory and private sector experience, including over 13 years at the FDA. At the FDA, Ms. Roberts held several key technical and management positions, including senior labeling reviewer and regulatory project manager for the Office of Generic Drugs, and the Deputy Director of the Office of Executive Programs, in the Center for Drug Evaluation and Research. (see reverse)

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**Sophia V. Fuerst, M.S., M.B.A.**

Ms. Fuerst came to the American Medical Association (AMA) in 1984 as an Editor for International Drug Names, and joined the USAN staff in 1986 as Assistant Secretary to the USAN Council. She left the USAN Program in late 1999 to become a consultant for the International Nonproprietary Names (INN) Programme at WHO in Geneva. She was asked to return as Director to the USAN Program in July 2000.

Ms. Fuerst represents the U.S. as a member of the INN Committee, is a member of the American Chemical Society (ACS) Committee on Nomenclature, Terminology, and Symbols, and a member of the Cosmetics, Toiletry, and Fragrance Association (CTFA) Nomenclature Committee. She has close liaisons with the Institute for Safe Medications Practices (ISMP), the Safe Medications Practices Consulting (SMPC), the USP, the APhA, the FDA, PhRMA, and other public and private institutions.

**Brand Institute is pleased to have worked on the following USAN/INN generic drug name development initiatives:**

**Khyati N. Roberts, R.Ph.**

During her tenure at the FDA, Ms. Roberts developed and implemented major new policies and regulations, including those associated with the FDA's patient safety, risk management, and pediatric initiatives. Ms. Roberts also served as the project manager for the Medication Errors Committee for several years and was responsible for reviewing and coordinating the review of all medication error reports and trade name reviews in the Center for Drug Evaluation and Research.

**USAN/INN generic regulatory submissions are complex procedures that involve creating names within specific generic name guidelines and navigating multiple regulatory agencies. By acquiring Ms. Fuerst, who has direct experience with the INN, USAN, WHO and the FDA, Brand Institute and Drug Safety Institute can greatly increase your chances for a successful submission.**

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