

# BI & DSI Can Now Help You Create Nonproprietary (USAN/INN) Names

**With the recent addition of Sophia Fuerst as Drug Safety Institute's Managing Director of Nonproprietary Names, Brand Institute and Drug Safety Institute can now provide our pharmaceutical and biotechnology clients with the following nonproprietary (USAN/INN) naming services:**

- USAN/INN Name Creation
- USAN/INN Name Safety Evaluation
- USAN/INN Name Rejection Rebuttals
- USAN/INN Name Submission Strategies
- USAN/INN Name Stem/Substem Architecture
- USAN/INN Name Submission Form Packets

**To inquire about our services, please call: 1-800-5-BRANDS 272637**



BI and DSI are proud to welcome the former Director of the American Medical Association's United States Adopted Names Division and U.S. representative at the World Health Organization's International Nonproprietary Names (INN) Expert Committee to our team.

**Sophia Fuerst, M.S., M.B.A.**  
*DSI Managing Director, Nonproprietary Names*

"With 20 years experience in the nonproprietary name field, which many see as a "black box," I can assist Brand Institute and Drug Safety Institute in the development of nonproprietary names that will be found acceptable to the USAN and INN, and with the added value of risk assessment used by DSI to ensure that the names are not only logically derived, but will not cause medication errors due to nomenclature issues."

- Sophia Fuerst

## Sophia Fuerst, M.S., M.B.A.

*DSI Managing Director, Nonproprietary Names*

- 21 years with the American Medical Association (AMA) with emphasis on medication safety, non-proprietary drug nomenclature, biotechnology, and international harmonization
- 19 years with the United States Adopted Names (USAN) Council; Director of the USAN program from July 1, 2000, to March 2005
- Former consultant to the Secretariat of the World Health Organization (WHO)
- Former U.S. representative to WHO's International Nonproprietary Names (INN) Expert Committee
- Member of the American Chemical Society (ACS) Committee on Nomenclature, Terminology, and Symbols

### DEVELOPING NONPROPRIETARY (USAN/INN) NAMES

"The names submitted on a new entity USAN application have an 85% chance of rejection or modification, and INN submissions have over a 90% chance of rejection."

- Sophia Fuerst

Nonproprietary name development and submission to USAN/INN can frustrate your resources and delay your product's release date. Drug Safety Institute can help avoid regulatory rejection by creating, evaluating, and assisting sponsors with submitting USAN/INN nonproprietary name safety research proactively.

### USAN/INN NAME STALEMATES

If you are in a stalemate with USAN/INN, Drug Safety Institute can provide strategic regulatory advice on resolving the conflict.

### GAINING USAN/INN NAME NEW STEM APPROVAL

USAN/INN new stem approval is extremely difficult, but Drug Safety Institute's experienced professionals can assist. We will be glad to provide a proposal outlining the ways that Drug Safety Institute can help you avoid rejection.

### FOR USAN/INN NAME SUBMISSIONS, TIMING IS EVERYTHING

Exactly how long it takes for a USAN to be adopted greatly depends on the timing of the submission to USAN. Submissions are routed on a regular basis to the USAN Council members. When a name is unanimously accepted, it is forwarded to the manufacturer for consideration.

A USAN can be applied for after an IND is in place, beginning as early as Phase I. However, it is important to note that the USAN Council generally meets in early-to-mid February and early-to-mid July. USAN submissions received up to a month before the meetings will probably be discussed at that meeting. It is advantageous for a manufacturer to submit before these deadlines - the turn-around time is much quicker as a unanimous decision is needed for approval of a name, and all Council members are in attendance. The USAN Council will cite reasons for acceptance/rejection of the submitted name, and additional balloting may be required. After a name is agreed upon by the manufacturer and the USAN Council, it will be forwarded to the INN for international review.

An INN can also be applied for after an IND is in place, beginning as early as PHASE I, but the timing of the INN submission is even more crucial. The INN generally meets in April and October/November. The cutoff date for submissions is strictly adhered to, and currently is two months prior to the Consultation. If the cutoff date is missed, the submission is assigned to the next meeting or pINN List, which means seven or eight months before the manufacturer is notified of the decision, and even longer delays may ensue.

Drug Safety Institute recommends for sponsors to proactively submit USAN/INN nonproprietary name safety research to USAN and INN.

### BRAND INSTITUTE IS PLEASED TO HAVE WORKED ON THE FOLLOWING RECENT NONPROPRIETARY (USAN/INN) NAMES:

ALAFORMIN

ATILMOTIN

GANTACURIUM

AMGEN®

Baxter

Avera™  
Pharmaceuticals, Inc.