

DSI Name Research & Submission Strategies Show Positive Results



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Under the leadership of Jerry Phillips, R.Ph., the Drug Safety Institute (DSI) continues to build a great track record with naming research and regulatory submissions. Jerry Phillips, who served 16 years with the Food and Drug Administration (FDA), was formerly the Associate Director for the Office of Drug Safety and Director for the Division of Medication Errors and Technical Support (DMETS).

DSI, a subsidiary of Brand Institute, addresses risk assessment and management issues associated with nomenclature, labeling, and packaging of healthcare products. DSI's name evaluation process parallels that of the FDA and other international regulatory agencies. DSI's methodology utilizes a multifactorial approach that includes a computer analysis emulating the FDA's Phonologic and Orthographic Computer Analysis (POCA).

Brand Institute and Drug Safety Institute are pleased to have worked on the following recent brand development initiatives:

Name Submission Strategies

General Guidelines

- Submit data to regulatory agencies as soon as possible after nomenclature safety research is completed
- Submit custom-tailored DSI FDA and/or EMEA reports rather than entire study
- We recommend that a new study be conducted on data more than one year old
- File trademark application with local trademark authorities as soon as possible

FDA

- Submit a DSI FDA Report as early as Phase II of an IND
- Submit 1 or 2 name candidates (designate primary and alternate)
- Initial review upon submission. Final review 90 days prior to NDA approval.

EMEA

- Submit a DSI EMEA Report as early as 12 months, but no later than 4 months prior to the submission of the MAA (Marketing Authorization Application)
- Submit up to 3 name candidates

ACOMPLIA 	AGILECT 	APOKYN 	CAMPRAL 	CODEPREX
DEPODUR 	ENJUVIA 	EVOCLIN 	FEMTRACE 	SANCTURA
SCULPTRA 	TRUVADA 	TYSABRI 	VIDAZA 	VIVAGLOBIN

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