BRANDNEWS

Brand Institute is proud to have partnered with 900+ healthcare companies on over 3,300 pharmaceutical brand names, highlighted by these most recent name approvals from the FDA

PLEASE BE SAFE AND THANK YOU FOR MAKING
BRAND INSTITUTE THE WORLD'S #1 NAMING COMPANY!

February 5, 2021	January 22, 2021	January 21, 2021
Breyanzi™ (lisocabtagene maraleucel) suspension for IV infusion BRISTOL MYERS SQUIBB	Lupkynis™ (voclosporin) capsules 7.9 mg AURINIA PHARMACEUTICALS	CABENUVA cabotegravir 200 mg/mL; rilpivirine 300 mg/mL extended-release injectable suspensions VIIV HEALTHCARE
January 21, 2021	**December 22, 2020**	**December 16, 2020**
VOCABRIA cabotegravir VIIV HEALTHCARE	ORGOVYX™ (relugolix) 120 mg tablets MYOVANT SCIENCES	Margenza™ (margetuximab-cmkb) MACROGENICS
December 14, 2020	**December 3, 2020**	**December 1, 2020**
KLISYRI™ tirbanibulin ointment ATHENEX	orladeyo™ (berotralstat) capsules 150 mg BIOCRYST	Hetlioz LQ (tasimelteon) capsules VANDA PHARMACEUTICALS
November 25, 2020	**November 25, 2020**	**November 23, 2020**
DANYELZA™ (naxitamab-gqgk) Y-MABS THERAPEUTICS	IMCIVREE™ (setmelanotide) injection RHYTHM PHARMACEUTICALS	OXLUMO™ (lumasiran) for injection 94.5 mg/0.5 mL ALNYLAM PHARMACEUTICALS

DRUG SAFETY INSTITUTE (DSI) NAMING & LABELING EXPERT SPOTLIGHT

Todd Darwin Bridges, R. Ph.

Global President
Drug Safety Institute

Mr. Bridges joined DSI – Rockville in May 2018 as Global President. Prior to joining DSI, Mr. Bridges was the Director of the Division of Medication Error Prevention and Analysis (DMEPA) in the Office of Surveillance and Epidemiology at the U.S. Food and Drug Administration (FDA). He has more than thirteen years of DMEPA experience with three of those years as the Director of DMEPA. As Director of FDA's DMEPA, Mr. Bridges supervised the review of approximately 500 proprietary names each year, and since joining DSI has overseen 1119 brand naming projects.

As Director of DMEPA, Mr. Bridges was responsible for supervising the premarket review and approval of proposed proprietary/ brand drug names, labels/labeling, packaging, product design, United States Adopted Names, biological product proper name suffixes, and human factors studies in order to reduce the potential for medication errors with products regulated by the Center for Drug Evaluation and Research (CDER). DMEPA conducts review and analysis of post-marketing medication errors submitted to CDER to determine if regulatory action such as label/labeling revisions, names change, product redesign, or post-marketing communications to stakeholders is needed. DMEPA also works with external stakeholders, regulators, and researchers to better understand the causes of medication errors and the effectiveness of interventions at preventing them, and provides guidance to the pharmaceutical industry on drug development considerations from a medication errors perspective.

Mr. Bridges has contributed to FDA policy and guidances related to medication errors, represented FDA as a member of the National Coordinating Council for Medication Error Reporting and Prevention as well as the Joint Commission's Patient Safety Advisory Group, and was responsible for establishing FDA's ongoing membership with the International Medication Safety Network. In addition to his FDA experience, Mr. Bridges has thirteen years of pharmacy practice and supervisory experience prior to joining FDA. He has also received specialty training in medication error prevention and analysis from the Institute for Safe Medication Practices.

Mr. Bridges earned a B.S. in Pharmacy from Virginia Commonwealth University's Medical College.

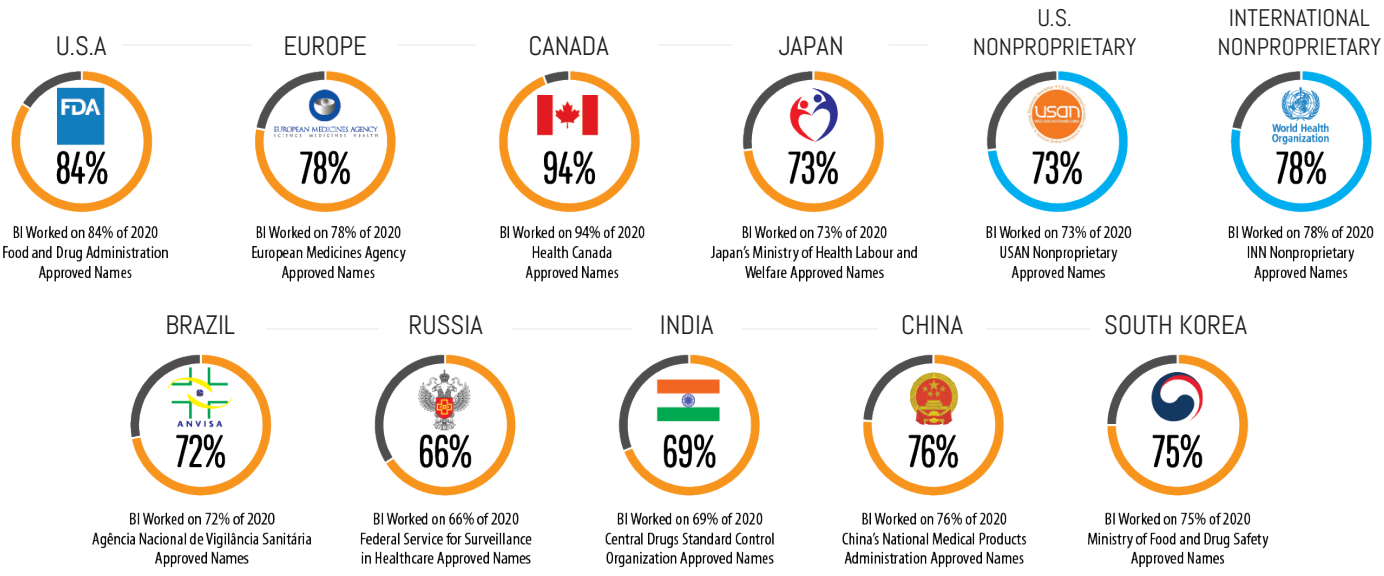
Nora Roselle, Pharm.D.

President, U.S. Regulatory Affairs
Drug Safety Institute

Dr. Roselle joined DSI - Rockville as Managing Director of U.S. Regulatory Affairs in 2007, promoted in 2012 to Vice President, Global Regulatory Affairs and most recently promoted to President, U.S. Regulatory Affairs. Prior to DSI, she served as an officer (LCDR) in the U.S. Public Health Service. She joined the U.S. Food and Drug Administration (FDA) in 2001 as a Safety Evaluator in the Division of Medication Errors and Technical Support (DMETS), in the Office of Drug Safety (ODS), renamed the Office of Surveillance and Epidemiology (OSE), now known as the Division of Medication Error Prevention and Analysis (DMEPA). DMEPA is responsible for the approval of manufacturer's drug/biologic brand names and human factors/ medication error evaluation of drug and drug/device labeling, packaging, and product design to reduce medication errors.

As Team Leader, Dr. Roselle managed DMETS safety evaluators, proprietary (brand, line extension, and combination product) name reviews, labeling and risk management consults. Dr. Roselle has published several articles on medication errors. Two of her most widely known name safety articles include "Metadate ER or Metadate CD?; Drug Topics 2004,Oct 11:62,64" and "Confusion between Methylphenidate and Methadone, Patient Care 2003, Jan 15:76." Dr. Roselle earned a Doctor of Pharmacy from the University of Maryland (with Honors) and a B.S. in Biology with a Chemistry Minor from the University of Akron (Cum Laude).

BRAND INSTITUTE'S 2020 GLOBAL SHARE OF MARKET NAME APPROVALS



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