Regulatory Education for Industry (REdI): GENERIC DRUGS FORUM

DoubleTree by Hilton
Silver Spring, MD
April 13 - 14, 2016

FDA

Center for Drug Evaluation and Research
FDA

WEDNESDAY, APRIL 13

7:30am	Registration Opens	
8:20 - 8:30am	Welcome Description: Forum Welcome and opening remarks.	**Brenda Stodart, Pharm.D.** *Captain, United States Public Health Service* *Program Director* *CDER Small Business and Industry Assistance (CDER SBIA)* *Division of Drug Information (DDI)* *Office of Communications (OCOMM)* *Center for Drug Evaluation and Research (CDER)|FDA*
8:30 - 9:00am	Keynote: Update on GDUFA Implementation Description: • Overview of GDUFA program • Update on progress with implementing GDUFA at FDA	**Kathleen Uhl, MD** *Director* *Office of Generic Drugs (OGD)|CDER|FDA* 
9:00 – 10:00am	GDUFA Regulatory Science Update Description: The purpose of this presentation is to provide an annual update about Office of Generic Drugs' GDUFA Regulatory Science Research Program. In this presentation, the Office of Research and Standards (ORS) which is tasked to implement the GDUFA regulatory science program will be briefly introduced. 2016 GDUFA regulatory science priorities, recent advancements in regulatory science and their impact on generic drug development, review, and public confidence on generic drugs will be discussed. In addition, how to interact with ORS for pre-ANDA submission activities will be discussed.	**Wenlei Jiang, PhD** *Deputy Director (Acting)* *Office of Research and Standards* *OGD|CDER|FDA* 
10:00 - 10:15am	BREAK	
10:15 - 11:15am	Fundamentals of Bioequivalence Description: To explain the concept of bioequivalence, the regulations regarding the bioequivalence of generic drugs, and the review process by which OGD determines whether a proposed generic drug product meets applicable standards.	**Trueman W. Sharp, MD, MPH** *Deputy Director (Acting)* *Office of Bioequivalence|OGD|CDER|FDA* 

11:15 - 12:15pm	How to use the Inactive Ingredient Database (IID) Description: The goal of this presentation is to explain how the IID works, to address misconceptions and common questions about the IID and to provide guidance to applicants on the best to way reference IID data in applications.	**Susan Zuk, MS** *CDER Excipient Working Group Lead* *Division of Regulations, Guidance, and Standards (DRGS)* *Office of Policy for Pharmaceutical Quality (OPPQ)* *Office of Pharmaceutical Quality (OPQ)|CDER|FDA* 
12:15 - 1:30pm	Networking Lunch at the Savor	Special lunch buffet (inclusive with beverage) made specially by the chef for purchase on your own.
1:30 - 2:30pm	How an ANDA Gets Reviewed Description: Our goal is to give the attendees an overview of the review of an application within the Office of Generic Drugs. We will hit upon the different disciplines that interact with the application and the roles of the RPM within OGD and RBPM within OPQ.	**Kevin Denny, PharmD** *Lieutenant Commander, United States Public Health Service* *Regulatory Project Manager* *Office of Regulatory Operations (ORO)* *OGD|CDER|FDA* **Craig Kiester, RPh, MS, RAC** *Commander, United States Public Health Service* *Branch Chief (acting)* *Regulatory and Business Process Management I, Branch II* *Office of Program and Regulatory Operations (OPRO)* *OPQ|CDER|FDA* 
2:30 - 2:45pm	BREAK	
2:45 – 3:45pm	Question-based Review (QbR) in an Integrated Review Approach Description: To describe how the Quality Overall Summary can be a useful tool under the new Team base, Quality Assessment Paradigm	**Damaris Maldonado, BS** *Drug Product Quality Reviewer* *Office of Lifecycle Drug Products, OPQ, CDER, FDA*

3:45 - 4:45pm	Division of Microbiology Assessment: Who we are, what we do and our recommendations to industry

Description: As the title indicates, the goal of this talk is to serve as an introduction of the OPF's Division of Microbiology Assessment to the industry to describe our current organization structure, product quality microbiology assessment of applications and our recommendations to industry to improve submissions and provide transparency regarding expectations

Lynne Ensor, PhD.
Acting Director
Division of Microbiology Assessment
Office of Process and Facilities|OPQ|CDER|FDA

Pre-Approval Inspections

Description: This presentation will describe management of pre-approval inspections within the Office of Process & Facilities.

Robert Iser
Acting Director
Office of Process and Facilities|OPQ|CDER|FDA

4:45pm	ADJOURNMENT
4:45 - 7:00pm	Networking Opportunity: NETWORKING HAPPY HOUR IN THE SAVOR LOUNGE

The Savor lounge offers a comfortable atmosphere to network with peers. Happy Hour specials will be available. Please come and enjoy!

THURSDAY, APRIL 14

7:30am	Registration Opens
8:20 - 8:30am	**Welcome** Description: Welcome and overview of CDER SBIA **Brenda Stodart, PharmD** *Captain, United States Public Health Service* *Program Director* *CDER Small Business and Industry Assistance (CDER SBIA)* *Division of Drug Information (DDI)* *Office of Communications (OCOMM)* *Center for Drug Evaluation and Research (CDER)|FDA*
8:30 – 9:30am	**Overview of Controlled Correspondence Process Controlled Correspondence** Description: The goal of this presentation is for the audience to have a better understanding of the controlled correspondence process and what is required when submitting a controlled correspondence. **Marissa McNall, PharmD** *Office of Regulatory Operations* *Office of Generic Drugs (OGD)|CDER|FDA*  **Content and Format for Accurate Submissions** Description: The presentation will focus on providing guidance, strategies, and examples of how to properly complete and communicate submissions related to ANDA files to increase the efficiency of routing and proper identification by review staff. **Thomas Hinchliffe, PharmD** *Commander, United States Public Health Service* *Regulatory Affairs Coordinator* *Generic Drug Regulatory Affairs Team* *OGD|CDER|FDA* 
9:30 - 10:30am	**ANDA Submissions – Refuse-to-Receive and eCTD considerations** Description: To educate industry on the most prevalent reasons for a refuse to receive determination and eCTD standards that will become requirements as of May 2017. **Johnny Young, MA** *Director (Acting)* *Division of Filing Review (DFR)* *ORO|OGD|CDER|FDA* **Julia Lee, PharmD** *Deputy Director (Acting)* *Division of Filing Review* *ORO|OGD|CDER|FDA*
10:30 - 10:45am	BREAK

10:45 - 11:45am	Current Trends in Labeling and Best Practices Description: This presentation will provide a brief overview of the labeling review process, give insight into the labeling reviewer's primary areas of focus, and recommend best practices for submitting a quality labeling submission	**Lillie Golson, PharmD** *Captain, United States Public Health Service* *Acting Deputy Director* *Division of Labeling Review* *OGD|CDER|FDA* 
12:15 - 1:30pm	Networking Lunch at the Savor Restaurant	(Guest Pays for Own Food & Beverage)
1:00 - 2:00pm	Entering the Home Stretch: GDUFA I Entering its Final Year Description: As we prepare to enter the fifth and final year of GDUFA I, we will recap how GDUFA I is structured and address some of the more commonly-heard questions, including the logistics of how and when fees are set. There will be a discussion of how companies can seek a re-examination of user fee determinations, and we will briefly look at the next steps in moving forward to GDUFA II.	**Donal Parks, MBA, MPM** *Director* *Division of User Fee Management and Budget Formulation* *Office of Management|CDER|FDA* *CDER, FDA* 
2:00 - 2:15pm	BREAK	
2:15 - 3:15pm	Common errors and opportunities to improve FDA submissions and communications Description: We will present an outline and examples of errors we have received in the past The goal is to communicate and make applicants aware of common errors in an effort to improve future FDA submissions	**Giuseppe Randazzo, MS** *(Acting) Director, Office of Program and Regulatory Operations (OPRO)* *Office of Pharmaceutical Quality |CDER|FDA* **Lieutenant Geoffrey Wu** *Associate Director for Science and Communication, Office of Lifecycle Drug Products (OLDP)* *Office of Pharmaceutical Quality (OPQ), CDER* 
3:15pm	ADJOURNMENT	

SPEAKER BIOGRAPHIES

Kevin Denny, PharmD
Lieutenant Commander, United States Public Health Service
Regulatory Project Manager
Office of Regulatory Operations (ORO)
OGD|CDER|FDA

LCDR Kevin Denny is an acting Team Leader in the Division of Project Management in the Office of Generic Drugs at the Food and Drug Administration (FDA). He has been with the FDA for the last two years currently working at the White Oak Campus in Maryland. Kevin graduated from Idaho State University, with a Doctor of Pharmacy degree in 2001. Kevin is currently working on a Master's of Science in Health Sciences in Regulatory Affairs degree from George Washington University.

Lynne Ensor, PhD.
Acting Director
Division of Microbiology Assessment
Office of Process and Facilities|OPQ|CDER|FDA

Dr. Lynne Ensor currently serves as the Division Director (Acting) for the Division of Microbiology Assessment (DMA) in the Office of Pharmaceutical Quality's Office of Process and Facilities. Currently DMA is responsible for the product quality microbiology assessment of new, generic and biologic drug products, with an emphasis on sterile drug manufacture. During Lynne's 18 years of regulatory experience at the FDA, she worked the vast majority of them in the Office of Generic Drugs, followed by a detail to the Office of Pharmaceutical Science briefly prior to the creation of the Office of Pharmaceutical Quality.

Dr. Ensor serves on several committees overseeing the creation and stand-up of CDER's Office of Pharmaceutical Quality and the initial implementation of the Generic Drug User Fee Act. Lynne earned her B.S. in Biology and Ph.D. in Microbiology from the University of Maryland, College Park. In addition to her regulatory experience at FDA, Lynne served as a clinical medical technologist at Roche Biomedical Laboratories, a post-doctoral research fellow at the University of Maryland at Baltimore's School of Medicine, and a script consultant for the Discovery Channel.

Lillie Golson, PharmD
Captain, United States Public Health Service
Acting Deputy Director
Division of Labeling Review
OGD|CDER|FDA

Lillie Golson currently serves as Acting Deputy Director of the Division of Labeling Review (DLR) in the Office of Generic Drugs (OGD) in the Center for Drug Evaluation and Research at the Food and Drug Administration. This division is responsible for the review and approval of labeling for Abbreviated New Drug Applications. CAPT Golson began her career with OGD in 1995 and has held the positions of Labeling Reviewer, Team Leader, and Acting Supervisor. She received her PharmD from the University of Florida and is a Captain in the U.S. Public Health Service Commissioned Corps.

Craig Kiester, RPh, MS, RAC
Commander, United States Public Health Service
Branch Chief (acting)
Regulatory and Business Process Management I, Branch II
Office of Program and Regulatory Operations (OPRO)
OPQ|CDER|FDA

CDR Craig Kiester is a graduate of Duquesne University, with a Bachelor of Science in Pharmacy and a Master of Science in Health Science from Trident University. Prior to joining the FDA, he worked in home infusion pharmacy, most recently as an Operations Manager. He started his career with the United States Public Health Service when he came to the Office of Generic Drugs as a Chemistry Project

Manager. In addition, he has held positions as a Regulatory Review officer and a Microbiology Project Manager within the Office of Generic Drugs. Currently he is an Acting Branch Chief in the Office of Product Quality, for the project management staff responsible for the review of the quality portion of original ANDA's.

Thomas Hinchliffe, PharmD
Commander, United States Public Health Service
Regulatory Affairs Coordinator
Generic Drug Regulatory Affairs Team
OGD|CDER|FDA

CDR Thomas Hinchliffe currently serves as a Regulatory Affairs Coordinator on the Office of Generic Drugs Immediate Office Generic Drug Regulatory Affairs Team, working closely with leadership teams on ad hoc and long-term projects, providing oversight and outreach, strategic liaison, and integration of cross-OGD and cross-Center regulatory programs and initiatives. Prior to this, CDR Hinchliffe served as a special assistant to the OGD Director, leading the initial implementation efforts in OGD for the various changes required as a result of the Generic User Fee Amendment of 2012 (GDUFA). From 2002 to 2012, CDR Hinchliffe served as a ANDA/Chemistry Project Manager in the OGD Review Support Branch. CDR Hinchliffe obtained his Doctor of Pharmacy degree from the University of Pittsburgh, College of Pharmacy.

Robert Iser
Acting Director
Office of Process and Facilities|OPQ|CDER|FDA

Bob joined the FDA in 2003. He is currently the acting Director of the Office of Process & Facilities (OPF), a part of the new Office of Pharmaceutical Quality (OPQ). Prior to the formation of OPQ, Bob was acting Associate Director for Policy Development in the Office of Pharmaceutical Science. He was also a Division Director and CMC Team Leader in the Office of Generic Drugs.

Prior to joining the FDA, Bob spent seven years in the pharmaceutical industry with industrial experience related to management of quality systems, analytical method development, and support of manufacturing process development, scale-up and validation.

Wenlei Jiang, PhD

Deputy Director (Acting)
Office of Research and Standards
OGD|CDER|FDA

Dr. Wenlei Jiang is the Acting Deputy Director of the Office of Research and Standards in the Office of Generic Drugs. She provides oversight on Generic Drug User Fee Act (GDUFA) regulatory science research activities to help develop ANDA review standards and ensure the therapeutic equivalence of generic drug products. She has been mainly responsible for developing bioequivalence standards of generic complex drug products such as liposomes and nano drug products, revising ANDA review policy of narrow therapeutic index drugs, and initiating post-market generic drug research including generic substitution studies in patient populations, generic drug surveillance method development, and patient perception about generic drug usage.

Previously, Dr. Jiang worked in the Division of Chemistry, OGD to review the chemistry and manufacturing control (CMC) sections of ANDAs. Prior to joining FDA, she was at Novartis Pharmaceutical Corporation where her responsibilities included formulation development of conventional liquid and solid dosage forms, as well as parenteral drug delivery systems. She received her PhD in Pharmaceutics and Pharmaceutical Chemistry from The Ohio State University in 2001.

Craig Kiester, RPh, MS, RAC
Commander, United States Public Health Service
Branch Chief (acting)
Regulatory and Business Process Management I, Branch II
Office of Program and Regulatory Operations (OPRO)
OPQ|CDER|FDA

CDR Craig Kiester is a graduate of Duquesne University, with a Bachelor of Science in Pharmacy and a Master of Science in Health Science from Trident University. Prior to joining the FDA, he worked in home infusion pharmacy, most recently as an Operations Manager. He started his career with the United States Public Health Service when he came to the Office of Generic Drugs as a Chemistry Project Manager. In addition, he has held positions as a Regulatory Review officer and a Microbiology Project Manager within the Office of Generic Drugs. Currently he is an Acting Branch Chief in the Office of Product Quality, for the project management staff responsible for the review of the quality portion of original ANDA's.

Julia Lee, PharmD
Deputy Director (Acting)
Division of Filing Review
ORO|OGD|CDER|FDA

Acting Deputy Director, Division of Filing Review since February 2015. Team Leader, Division of Filing Review from November 2015 to February 2016. Acting Team Leader, Division of Filing Review from July 2014 to November 2105. Regulatory Filing Reviewer in the Office of Generic Drugs/Division of Labeling and Program Support from October 2012 to July 2014. Prior to working at the Agency, she was a retail pharmacist at Walgreens. She has also worked in the Chesapeake-Atlantic node of the Pediatric Emergency Care Applied Research Network as a clinical research assistant. She received her Doctorate of Pharmacy at the University of Maryland, Baltimore, School of Pharmacy and her Bachelor of Science at The George Washington University.

Damaris Maldonado, BS
Drug Product Quality Reviewer
Office of Lifecycle Drug Products,
OPQ, CDER, FDA

Damaris Maldonado joined the Agency in 2000 as a Review Chemist in the Office of Generic Drugs after 15 years of manufacturing experience in Boehringer Mannheim and Johnson & Johnson. She has served as Team Leader as well as an active member of FDA initiatives related to Risk Assessment and Surveillance. She is a Certified Quality Engineer and Quality Auditor and holds a BS in Chemistry from the University of Puerto Rico.

Marissa McNall, PharmD
Office of Regulatory Operations
Office of Generic Drugs (OGD)|CDER|FDA

Marissa McNall has been with the Office of Generic Drugs since 2014. She started in the Immediate Office, Communication Staff and is currently in the Office of Regulatory Operations, Immediate Office as a Controlled Correspondence Coordinator for OGD. She assures that controlled correspondences are routed to the appropriate office for review. Marissa has a Bachelor of Arts degree in Psychology and a Doctor of Pharmacy degree.

Donal Parks, MBA MPM
Director
Division of User Fee Management and Budget Formulation
Office of Management
CDER|FDA

Donal directs the user fee collections staff at CDER's Office of Management. This staff is responsible for collecting user fees under the Generic Drug User Fee Amendments (GDUFA) and the Biosimilars User Fee Act (BsUFA), both of which were authorized in the FDA Safety and Innovation Act as signed by the President on July 9, 2012.

Before joining the FDA as an operations research analyst in 2008, Donal worked for the District of Columbia Office of the Chief Financial Officer, on Capitol Hill for the Chief Administrative Officer of the House of Representatives, and for a private consulting firm specializing in public health-related outsourcing work. He earned graduate degrees in finance (MBA) and in public-sector financial management (MPM) from the University of Maryland at College Park in 1995, and an undergraduate degree in Foreign Service from Georgetown University in 1988.

Trueman W. Sharp, MD, MPH
Deputy Director (Acting)
Office of Bioequivalence|OGD|CDER|FDA

Trueman Sharp MD MPH is currently serving as the Deputy Director (Acting) in the Office of Bioequivalence in the Office of Generic Drugs. Prior to this, he was a clinical reviewer in the Division of Clinical Review in the Office of Bioequivalence. Dr. Sharp came to the FDA after a career in the U.S. Navy where he held a number of positions in clinical medicine and research, focusing on the development of drugs and diagnostics for tropical infectious diseases. He is a graduate of the University of Virginia School of Medicine and the University of Washington School of Public Health, and is board certified in General Preventive Medicine and Public Health.

Brenda Stodart, Pharm.D.
Captain, United States Public Health Service
Program Director
CDER Small Business and Industry Assistance (CDER SBIA)
Division of Drug Information (DDI)
Office of Communications (OCOMM)
Center for Drug Evaluation and Research (CDER)|FDA

CAPT Brenda Stodart is currently the Program Director for the Center for Drug Evaluation and Research's (CDER's) Small Business and Industry Assistance (SBIA). Prior to her current position, CAPT Stodart was a Senior Regulatory Management Officer in the Office of Regulatory Policy (ORP). Before ORP, CAPT Stodart served as a Senior Health Promotion Officer in the Division of Drug Information for 9 years. CAPT Stodart received her BS in Pharmacy from Howard University and her PharmD from the University of Arkansas Medical Sciences. CAPT Stodart has had experience in hospital and retail pharmacy before joining the FDA.

Kathleen Uhl, MD
Director
Office of Generic Drugs (OGD)|CDER|FDA

Kathleen Uhl, MD currently serves as the Director for the Office of Generic Drugs in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA). This office is responsible for the review and approval of Abbreviated New Drug Applications (ANDAs) and is largely tasked with implementing the Generic Drug User Fee Amendments (GDUFA).

Dr. Uhl began her career with FDA in 1998 as a medical officer in the Office of Clinical Pharmacology and has served in numerous positions at FDA, including the Assistant Commissioner for Women's Health and the Director of FDA's Office of Women's Health and the Deputy Director of the Office of Medical Policy in the CDER. She received her undergraduate degree from Temple University and her medical degree from the Medical College of Pennsylvania, with subsequent fellowship training in medical research and clinical pharmacology at the Uniformed Services University. She retains faculty appointments as Professor in Family Medicine and Internal Medicine at the Uniformed Services University and is a retired officer of the US Public Health Service Commissioned Corps

Lieutenant Geoffrey Wu

Associate Director for Science and Communication, Office of Lifecycle Drug Products (OLDP)
Office of Pharmaceutical Quality (OPQ), CDER

Geoffrey Wu, Ph.D., is a scientist officer in the United States Public Health Service. He is currently the Associate Director for Science and Communication in the Office of Lifecycle Drug Products, Office of Pharmaceutical Quality (OPQ), CDER. He is also a current member on the OPQ Emerging Technology Team (ETT). Geoff has been deeply involved, leading or co-leading regulatory review and research for controlled correspondences, ANDAs, and supplemental ANDAs in the past five years. Geoff has training and education in pharmacy, pharmaceutical science, protein chemistry, polymer chemistry, and process analytical technology. He received his Ph.D. degree in Pharmaceutics and Pharmaceutical Chemistry from University of Utah, and B.S. in pharmacy and M.S. in pharmaceutics for Peking University, China.

Johnny Young, MA

Director (Acting)
Division of Filing Review (DFR)
ORO|OGD|CDER|FDA

Acting Director, Division of Filing Review since September 2014. Acting Deputy Director, Division of Filing Review from August to September 2014. Regulatory Filing Reviewer in the Office of Generic Drugs/Division of Labeling and Program Support from May 2007 to August 2014. Prior to that, he was in retail pharmacy practice for 18 years. He has a BS in Pharmacy from the University of MD; a BA in English Literature from the University of MD, Baltimore County; and a Liberal Arts Masters from St. John's College in Annapolis.

Susan Zuk, MS

CDER Excipient Working Group Lead
Division of Regulations, Guidance, and Standards (DRGS)
Office of Policy for Pharmaceutical Quality (OPPQ)
Office of Pharmaceutical Quality (OPQ)|CDER|FDA

Susan holds a BS in Chemistry from Syracuse University and a MS in Biotechnology from Johns Hopkins University. During her 16 years with the FDA, she has served as Chemistry Reviewer, Team Leader and Acting Deputy Director in the Office of Generic Drugs. She has served as Acting Branch Chief of the Division of Internal Policies and Procedures (DIPAP) in the OPQ Office of Policy for Pharmaceutical Quality (OPPQ). She is the current leader of the Excipient Working Group. In this role, she is responsible for overseeing the IID project. Susan has served on many FDA committees and working groups related to product safety and quality.