ICH for Generic Drugs
– The FDA's Perspective

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Introduction

- Global harmonization for generic drugs or ICH for generic drugs is NOT a new concept
  - WHO report in 2001*
  - Prior exploration from generic drug industry and association

- FDA is taking a strategic approach to exploring and studying this opportunity by leveraging ICH reform initiated at the end of 2015
  - Established a unique global affair function at OGD at the end of 2015
  - Exploring ICH for generic drugs as part of global strategy development for US generic drug program;
  - Enhanced our participation and interaction with IGDRP,
  - Participating at ICH M9 guidance development
  - Submitted a generic drug specific topic to ICH to better understand the opportunities and challenges
  - Developing the reflection paper

* The impact of Implementation of ICH Guidance in Non-ICH Countries, Report of a WHO meeting, Geneva, 13-15 September 2001

Global Public Health Benefits

- Generic drugs comprise a significant market share of all prescribed medicine worldwide*
  - 89 percent in the United States
  - 56 percent in Europe
  - 60 percent in Japan
  - 84 percent in Mexico

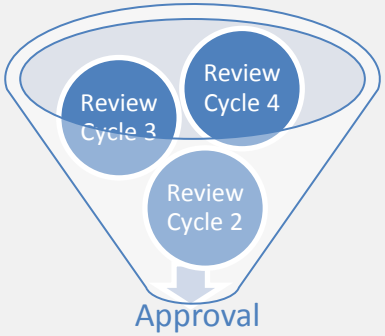
- Generic drugs improves global public health by providing more affordable, high quality alternatives to brand names drugs
  - Essential medicines for developing countries;
  - Access and affordability though free market competition in developed countries
  - Increased compliance with therapy**

* http://www.gphaonline.org/media/generic-drug-savings-2016/index.html ; http://www.medicinesforeurope.com/wp-content/uploads/2016/05/4.-Generic-Medicines_On-Generic-Medicines.pdf ; http://www.prnewswire.com/news-releases/overview-of-japanese-generic-drug-market-2016-market-size-primary-makers-market-trends-and-updated-situation-on-biosimilars-and-authorized-generics---research-and-markets-300348466.html ; http://www.sealeassociates.com/wp-content/uploads/Update-on-the-Pharmaceutical-Industry-in-Mexico-June-2016_2.pdf

** Gagne JJ et al: Comparative effectiveness of generic and brand-name statins on patient outcomes: a cohort study. Ann Intern Med. 2014 Sep 16;161(6):400-7

US Generic Drug Program Perspective

Timely Access to Affordable and Quality Medicines



Inefficient Use of FDA Resource

Two Impacts

One Challenge

Sites	Exclusively in the US
API Site 	3%
Finished Product Site 	24%
Clinical BE Site 	14%
Bioanalytical Site 	9%

Global Distribution

Source Data:
1. Janet Woodcock, M.D. Testimony before the Senate Committee on Health, Education, Labor, and Pensions January 28, 2016 ; http://www.fda.gov/NewsEvents/Testimony/ucm484304.htm
2. Courtesy of Drs. Julia Luan and Jason Woo: FDA Internal analysis on unique original ANDA applications that were received in FY 2015 (n=400).

ICH is Uniquely Positioned

- ICH Improves Regulator and Industry Efficiency AND Cross-Regulator Efficiency in Collaboration
  - Leverage on 25 years of experience in developing global drug development guidance for new drugs;
  - Replace bilateral arrangements with more cohesive focus of global pharmaceutical regulatory harmonization work in one venue

- ICH reform in 2015 opened the door for more involvement from regulators around the world and wider inclusion of global industry sectors affected by ICH harmonization

How and Where to Get Started ?

- Consistent scientific approach to define:
  - Generic drug
  - Bioequivalence (BE)
  - Pharmaceutical equivalence (PE)
  - Pharmaceutical alternative
  - Pharmaceutical “identity”
  - Substitutability
  - Interchangeability

How and Where to Get Started ?

- Potential scientific areas for harmonization
  - Standards to determine BE
  - Alternative approaches to in vivo pharmacokinetic studies in humans to demonstrate BE, such as the modelling methodologies
  - Waivers for BE studies for certain classes of drug products
  - Principles for biowaivers for additional drug strengths
  - The concept of global reference standard

- BUT the key question: Are WE Ready?
  - New drug vs generic drug perspectives
  - Regulators and generic drug industry participation
  - Need for pre-alignment mechanism