CDER 2016 Actions and 2017 Priorities

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2016 ACCOMPLISHMENTS
CDER Operates Multiple Large Programs

• New drug regulatory program (Dr. Jenkins)
• Generic drug regulatory program
• Biosimilar drug regulatory program
• Marketed drug safety surveillance
• Marketed drug quality oversight
• Compounded drug quality and safety
• Drug shortage program
• Drug supply chain oversight:
  – Track and trace
  – Imports (with ORA)
  – Unapproved drugs
2016 Generic Drug Program

- FDA meeting all GDUFA goals; current review goal 10 mths
- Successful implementation of “Panorama” for generic drug review program
- OGD has approved about 70 first-time generics, including drugs for many important indications, in the program
- Highest number of approvals and tentative approvals on record in 2016
  - 651 approved
  - 184 TA’d
- GDUFA commitment: take first action on 90% of ANDAs and PASs in “backlog”
  - Achieved this summer, more than one year ahead of schedule
  - Exceeded goal of 90%
Generic Drugs: Guidance

• In 2016, OGD issued 126 new and 73 revised product-specific recommendations (PSRs)
• Many involved complex dosage forms such as inhaled powders, nasal sprays, topical products and ophthalmics
• These PSRs are very helpful to industry: data from Oct 2014 thru Jan 2015 show that 70% of bioequivalence studies submitted were found approvable on the first cycle
Generic Drugs: Advice

• Since beginning GDUFA, industry has submitted over 5,400 “controlled correspondences”, by which they seek written advice on an issue from the FDA
• 2016 saw 1,883 of these
• FDA is meeting goals for responding
• This advice improves application quality and it is hoped will decrease cycles
Generic Drugs: Regulatory Science

• FDA funding research with significant impact on generics:
  – Testing mechanisms to determine bioequivalence for certain dosage forms that currently require clinical equivalence studies
  – Bioequivalence studies in patient groups (e.g., people with epilepsy) where treating physicians had skepticism about use of generics
Biosimilars Program

• Continue to approve biosimilar drugs: currently 4 approved
• Eight firms have publicly announced submission of a total of 12 351(k) applications
• “Biosimilars Development Program” contains 66 projects
• CDER has interacted with sponsors of biosimilars to 21 different reference products
• Still working on certain guidances
Drug Safety Operations

• Sentinel system has been integrated into routine postmarketing safety activities
• Modernized adverse event intake and triage operations to make them virtually paperless (involving more than 1.5 million reports)
• Consolidated human factors studies for drug-device combo products in OSE/CDER
• Established a lead for opioid safety in OSE
• Working on “IMEDS” initiative: a Reagan-Udall Foundation portal for external use of Sentinel infrastructure
Drug Quality Program

• Have successfully developed a reliable inventory of world-wide facilities producing drugs for the US and have implemented risk-based inspection program

• Negotiating, with Global Operations Office, a Mutual Reliance Agreement with Europe on facility GMP inspections

• OPQ Office fully functional after massive reorganization

• Stimulating advanced manufacturing and emerging technologies (continuous manufacturing, 3D printing, etc)
Compounding Program

Since enactment of the DQSA on November 27, 2013, FDA has:

• Conducted approximately 425 inspections of compounders.
• Overseen over 90 recall events by compounders, and requested numerous compounders to cease operations
• Issued over 130 warning letters; one addressed violations identified at four facilities
• Issued over 30 letters referring findings from inspections of pharmacies that compounded their drugs in accordance with the conditions of section 503A to the states
• Obtained 4 civil consent decrees of permanent injunction
• Sought several criminal prosecutions

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Other compounding actions

• Issued over 20 guidance documents
• Issued final rule and proposed rule describing additions and modifications to the Withdrawn or Removed List (503A and 503B)
• Solicited nominations for 503A and 503B bulks lists and for drugs that are difficult to compound under sections 503A and 503B
• Held 6 meetings of the Pharmacy Compounding Advisory Committee
• Held 4 sets of listening sessions with over 75 stakeholders
• Held 4 intergovernmental working meetings with the states
Inspection observations

• Continue to identify insanitary conditions at many of the compounding facilities inspected
  – Dog beds and hairs in close proximity to sterile compounding room
  – Dead bugs in ceilings
  – Renovations being made without evidence of controls to prevent contamination
  – Compounding by personnel with exposed skin
Progress on 2016 Priorities

• Have negotiated PDUFA, GDUFA, and BSUFA programs with industry and expecting them to be presented to Congress within required timeframes
• Have also made significant progress on OTC monograph reform and accompanying use fee program
• Implemented Opioid Action Plan activities
• Have met all goals of Sunscreen Innovation Act; have issued 4 final guidances and one final rule
• Patient-focused drug development: more than 20 total meetings; external groups also holding these
Progress on 2016 Goals

- Drug-resistant organisms:
  - Discussion of novel trial designs
  - Relevant provisions in “21\textsuperscript{st} Century Cures”
- Combination product review: formation of Combination Product Council (Agency Level) and significant policy progress
- ICH: Successful progress of re-engineered organization
- Biomarker qualification: progress with external stakeholders on evidentiary criteria
CDER 2017 Priorities

• Development and implementation of 5 year plan for process automation
  – Staged implementation of “Pharmaceutical Platform” now being used for generic drug review process
  – Formalization of IT governance
  – Formalization of data standards governance

• Successful re-authorization of 3 existing user fee programs

• Participate in process to evaluate modernization of OTC monograph process and potential user fee program support
CDER 2017 Priorities

• Continue to modernize facility assessment
  – Work with ORA on “PAG” agreements and their re-organization
  – Continue work on mutual reliance with EU

• Implement drug provisions of the 21st Century Cures Act

• Continue work on all fronts with respect to prescription opioid abuse
CDER 2017 Priorities

• Hiring: still many hundreds of positions below ceiling but making progress
• Continued implementation of recent statutes and user fee agreements
• Continued attention to designated “breakthrough therapies”
• Work with CBER and CDRH on implementation of “Oncology Center of Excellence”
CDER 2017 Priorities

• “Evidence Generation”
  – Recent article on “Real World Evidence” by FDA authors in NEJM offering a framework for thinking about regulatory use
  – Series of workshops with Duke Margolis Center for Health Policy on technical topics related to use of data collected in clinical practice to inform regulatory decisions
  – Multiple internal activities at FDA and with NIH intended to advance the field
Summary

• CDER made significant progress on its 2016 priorities
• 2017 will bring a new set of challenges
• Continued user fee (or other) support will be needed for program to meet its many obligations
• Planning to implement more automation and process re-engineering to improve efficiency