Regulatory Education for Industry (REdI): GENERIC DRUGS FORUM

Sheraton | Silver Spring, MD | April 22-23, 2015

April 22, 2015

Today's program will begin at:
8:20 AM (Eastern – UTC-4h)

Regulatory Education for Industry (REdI): GENERIC DRUGS FORUM

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Welcome

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Center for Drug Evaluation and Research

Regulatory Education for Industry (REdI):
GENERIC DRUGS FORUM

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Generic Drug Update

Ted Sherwood
Acting Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Welcome!

- **Thank you for your interest in generic drugs and the Regulatory Education for Industry (REdI) forum.**
- **This is the third "generics" meeting and the Center for Drug Evaluation and Research (CDER) hopes to continue holding these meetings.**

Forum Topics

- Generic Drug User Fee (GDUFA) implementation
- Patent listing and certification
- Office of Pharmaceutical Quality (OPQ)
- Pre-approval inspections
- Active Pharmaceutical Ingredients (APIs)
- Regulatory science

Today's Discussion

- Why should you be interested?
- What is a generic drug?
- Initiatives
- Tips
- Information sources

Brand vs Generic

Why Should You Be Interested?

- **Generic drugs represent 86% of all prescriptions filled in the U.S.***
- **Generic drug market is about $350 billion****
- **Use of generic drugs is increasing domestically and internationally**

* http://www.gphaonline.org/media/cms/GPhA_Generic_Cost_Savings_2014_IMS_presentation.pdf
** http://www.researchandmarkets.com/research/tvmk72/the_generic_drugs

Value of Generic Drugs

- **Reduce drug costs**
- **Increase access to drug products - improve national health**
- **Prevent drug shortages**
- **Increase adherence to therapy - improve health outcome**

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Definition of a Generic Drug

A drug product that is comparable to a brand/reference listed drug product in

- **dosage form;**
- **strength;**
- **route of administration;**
- **quality and performance characteristics;**
- **intended use.**

Brand Name Drug (NDA) Requirements

1. Labeling
2. Pharm/Tox
3. Chemistry
4. Manufacturing
5. Controls
6. Microbiology
7. Inspection
8. Testing
9. **Animal Studies**
10. **Clinical Studies**
11. **Bioavailability**

Generic Drug (ANDA) Requirements

1. Labeling
2. Pharm/Tox
3. Chemistry
4. Manufacturing
5. Controls
6. Microbiology
7. Inspection
8. Testing
9. **Bioequivalence**

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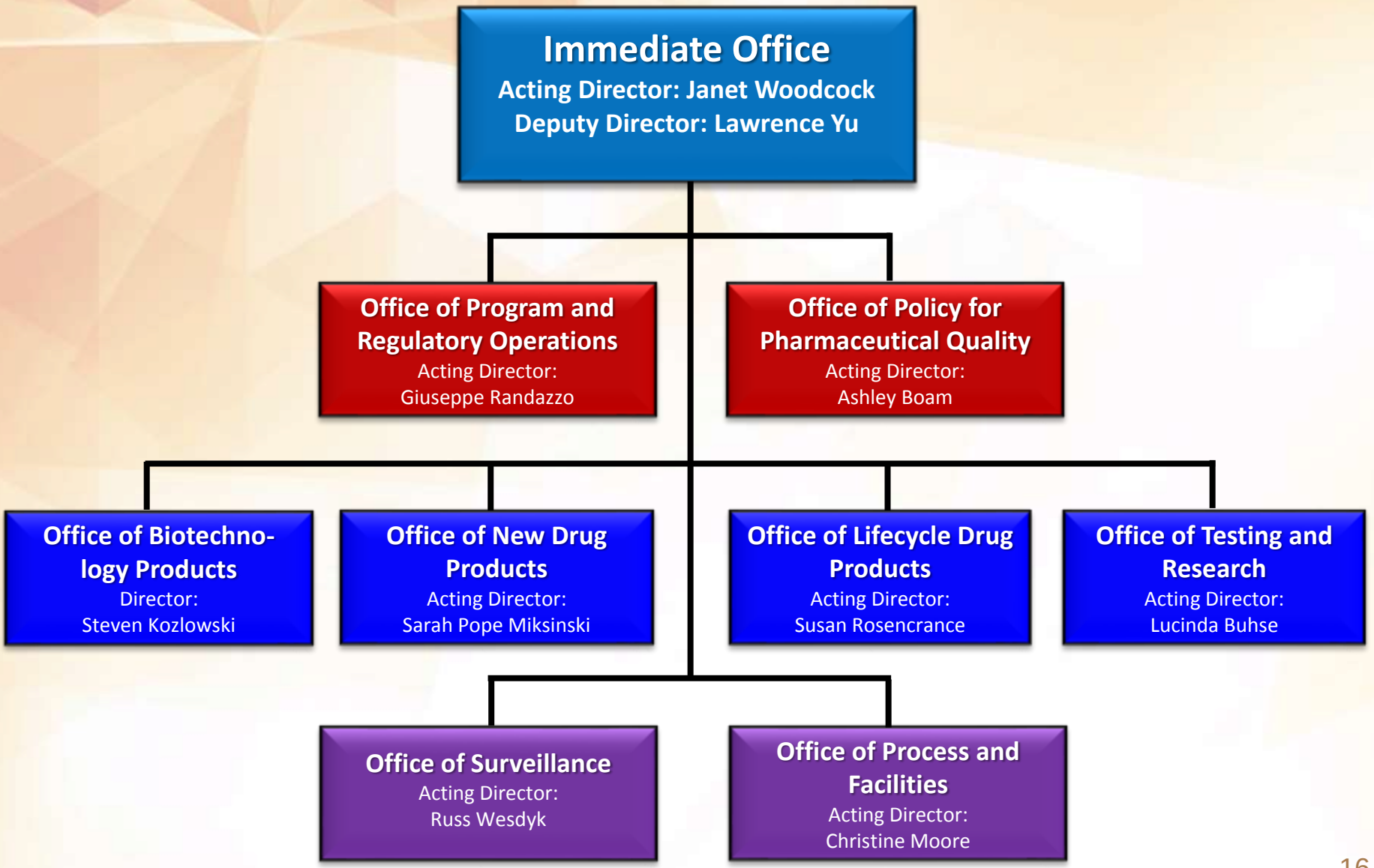
Build the Program

- Implementing a new program (GDUFA)
- Moved to White Oak
- Reorganized and became a Super Office
- New staffing infrastructure
- New IT platform
- New Office of Pharmaceutical Quality

Generic Drug Program

- Not just OGD
- All of CDER
- Other FDA units:
  - ORA
  - Office of the Commissioner
  - CBER, CDRH
- OGD is the interface for ANDA applicants to interact with the Generic Drug Program

Office of Pharmaceutical Quality



Hire & Train

- **In OGD, > 200 new FTEs in FY2014**
  1. **Reviewers**
  2. **RPMs**
  3. **Regulatory Science**
  4. **Policy staff**

  } **MOVE APPLICATIONS**

- **Train, train, train**
- **Repeat, repeat, repeat**

GDUFA Hiring Initiative:
http://www.fda.gov/AboutFDA/WorkingatFDA/GenericDrugUserFeeHiring/default.htm

Communications

- Filing Decision
- Target Action Dates (TADs)
- No Go
- Complete Responses (CR)
  - Post CR meetings

Communications (cont.)

- Information Requests (a.k.a. Real Time Communications)
- Easily Correctable Deficiencies
- Telephone Information Requests
- Launch Planning (a.k.a. Health of the Application)
- Go / Action Letter Expected
- Approvals / Tentative Approvals

Communications (cont.)

- **Controlled Correspondence**
  - **Year 3: 70% within 4 months (exceeding)**
  - **Year 4: 70% within 2 months**
  - **Year 5: 90% within 2 months**
  - **Extra month for clinical issues**

Filing Time Frames

- **Typical assessment time**
  - **Current/GDUFA Year 3 submissions: 27 days**
  - **Prior submissions: backlog is nearly eliminated**
- **Check-list:**
  http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM320405.pdf

Filing Time Frames (cont.)

- **Guidance on Refuse-to-Receive Standards:** http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM370352.pdf
- **Electronic format:**
  - **“highly recommend”**
  - **GDUFA review goals only apply to electronic ANDA submissions**

Review Time Frames

Application Year	Review and Act On:
3	60% of originals w/in 15 months & 1st major amendments w/in 10 months
4	75% of originals w/in 15 months & 1st major amendments w/in 10 months
5	90% of originals w/in 10 months & 1st major amendments w/in 10 months

Review Time Frames (cont.)

Applications	Review and Act On:
Backlog (pending on Oct 1, 2012)	90% by the end of FY 2017 (Sep 30, 2017)

- GDUFA Year 1 and 2 applications:
  - incorporated into the ANDA work plan
  - (eligible) PIV applications (and other priority applications) will be expedited

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- **Tips**
- Information sources

Tips

- **Submit a complete application – avoid "Refuse-to-Receive."**
- **Submit electronically.**
- **Assure Drug Master Files (DMFs) have undergone Completeness Assessments.**
- **Assure facilities are ready for inspection.**
- **Provide complete and timely responses.**

Tips (cont.)

- **Work with your Regulatory Project Manager (RPM).**
- **Watch for guidance updates.**
- **Make sure OGD has all legal documents.**
- **If Tentatively Approved*, make sure any changes are reported in a timely manner.**

*** meets FDA's requirements, but there is a patent and/or exclusivity protection**

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Office of Generic Drugs - Information

- **Your RPM**
- **Web page:** http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm119100.htm
- **Submission Requirements:** http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm120955.htm

Public Meetings

- **FY 2015 Regulatory Science Initiatives - June 5, 2015**
  - **Overview of regulatory science initiatives.**
  - **Opportunity for public input on research priorities.**
  - http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm436485.htm
  - **Watch for future meetings.**

Public Meetings (cont.)

- **GDUFA II June 15, 2015**
  - **Seeking participation (i.e., attendance and oral presentations)**
  - **If you wish to attend the meeting, please email your registration information to GenericDrugPolicy@fda.hhs.gov by June 1, 2015.**

GDUFA Info

1. **GDUFA website**
   http://www.fda.gov/gdufa

2. **GDUFA Goals/Commitment Letter**
   http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf

3. **1st GDUFA Report to Congress**
   http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/UCM384177.pdf

Feedback

- **Please provide your feedback on the surveys.**
- **CDER Small Business and Industry Assistance (SBIA) is a resource everyone should have – please take a business card from the exhibit table.**

OGD looks forward to receiving your applications!

Questions?

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