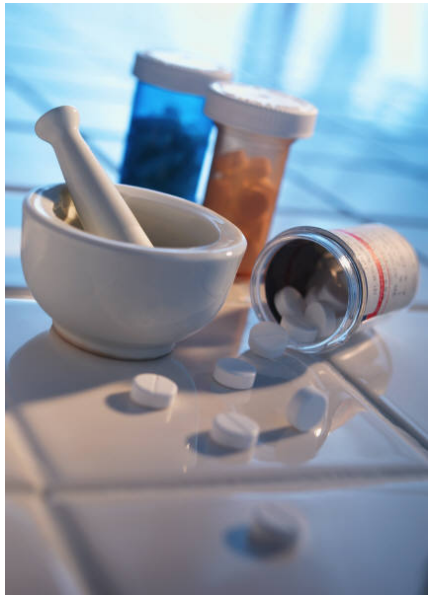
Introduction to the Regulatory Process in the USA



Hanan Ghantous Ph.D., DABT

The opinions expressed by Dr. Ghantous in this presentation do not reflect official support or endorsement by the Food and Drug Administration

Agenda

- Overview of FDA/CDER
- Laws and Regulations
- Drug Development Process
- IND
- NDA
- Generic Drugs
- BLA
- FDA Website

Overview of FDA/CDER

FDA Mission Statement

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

HHS/FDA

CDER (Center for Drug Evaluation and Research)

CBER (Center for Biologic Evaluation and Research)

CDRH (Center for devices and Radiological Health)

CFSAN (Center for Food Safety and Applied Nutrition)

CVM (Center for Veterinary Medicine)

CTP (Center for Tobacco products)

NCTR (National Center for Toxicology Research)

CDER Mission Statement

- Promote and protect public health by assuring that safe and efficacious drugs are available to Americans
- CDER accomplishes this mission by reviewing data that sponsors submit to support the safe and efficacious use of new drugs in humans

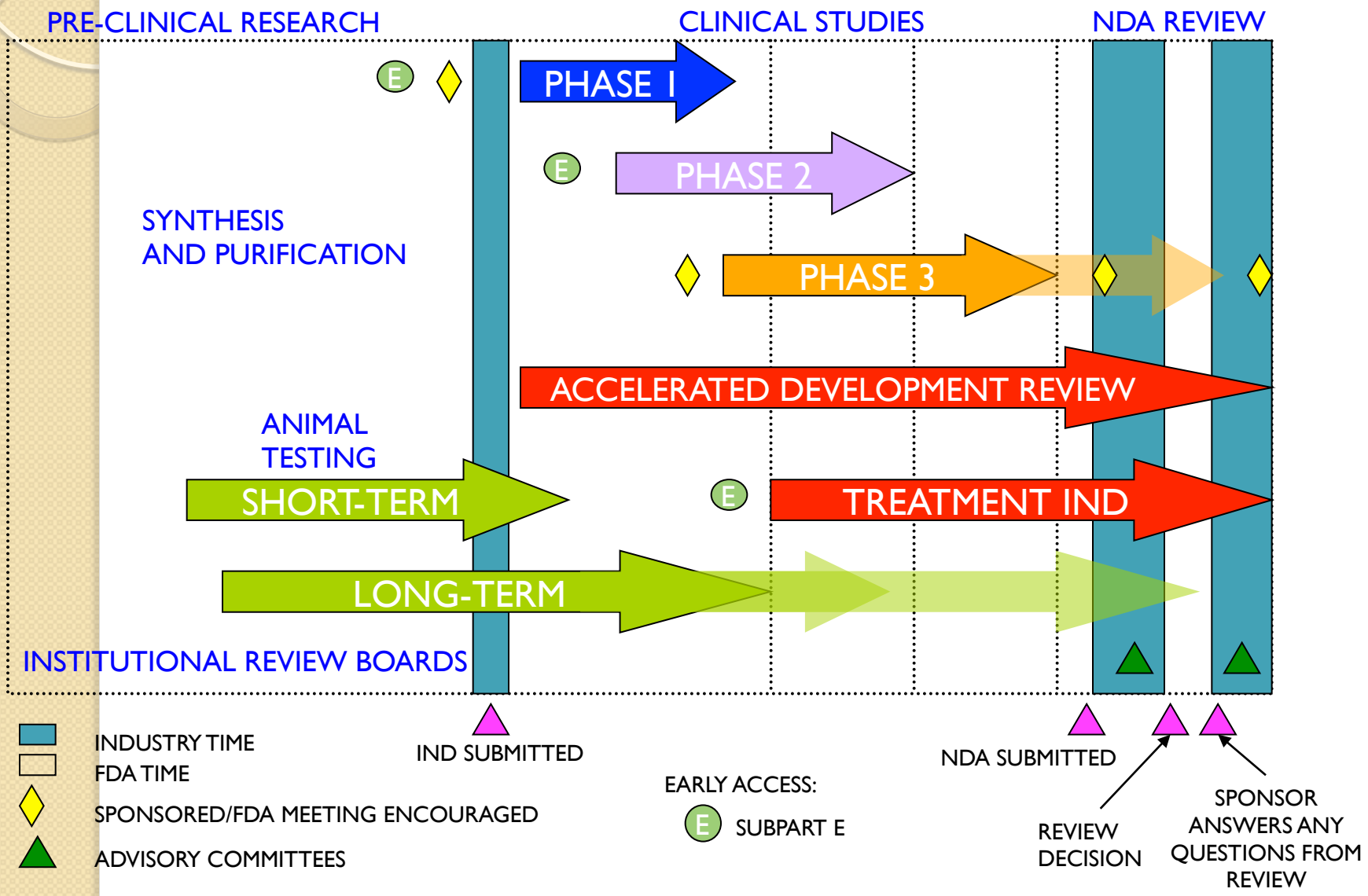
CDER Review Divisions/OND

- ***Office of New Drugs Immediate Office***
- ***Office of Hematology and Oncology Products***
- ***Office of Drug Evaluation I***
  - Division of Cardiovascular and Renal Products
  - Division of Neurology Products
  - Division of Psychiatry Products
- ***Office of Drug Evaluation II***
  - Division of Anesthesia, Analgesia and Addiction Products
  - Division of Metabolism and Endocrinology Products
  - Division of Pulmonary, Allergy, and Rheumatology Products

CDER Review Divisions/OND Cont'd

- ***Office of Drug Evaluation III***
  - Division of Gastroenterology and Inborn Errors Products
  - Division of Dermatology and Dental Products
  - Division of Bone, Reproductive and Urologic Products
- ***Office of Drug Evaluation IV***
  - Division of Medical Imaging Products
  - Division of Nonprescription Clinical Evaluation
  - Division of Nonprescription Regulation Development
- ***Office of Antimicrobial Products***
  - Division of Anti-Infective Products
  - Division of Antiviral Products
  - Division of Transplant and Ophthalmology Products

Drug Development 101



Clinical Development

- **PHASE 1**
  - First in Human
  - Safety and Tolerability
  - Pharmacokinetics
  - Normal and Targeted Populations
- **PHASE 2**
  - Proof of Concept
  - Dose Ranging
  - Safety/PK in Special Populations and Risk Factors
- **PHASE 3**
  - Large, Multi- centered
  - Usually Placebo- Controlled
  - Usually replicated
  - Primary data to support marketing approval in NDA
- **NDA/BLA,APPROVAL**
- **PHASE 4**
  - Adverse Event Reporting and Surveillance
  - Development of New Indications and Dosage Forms

Phase 1, 2, and 3 Trials

Phase 1:

- Safety and pharmacokinetics
- Generally 20 to ~80 subjects
- Closely controlled


Phase 2:

- Efficacy and safety
- Usually no more than several hundred subjects
- Closely controlled



Phase 3:

- Efficacy and safety
- Several hundred to several thousand subjects

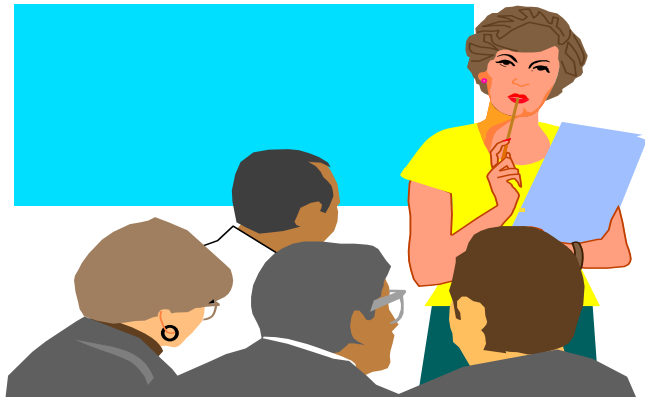
Drug Law

- Federal Food, Drug and Cosmetic Act of 1938
  - Sulfanilamide and diethylene glycol
- Drug Amendments Act of 1962
  - Thalidomide and birth defects
- PDUFA- Prescription Drug User Fee Act of 1992 (1997, 2002, 2007, 2012)
  - Collect user fees to fund the new drug approval process
- FDAMA- Food and Drug Modernization Act of 1997
  - 6 months pediatric exclusivity
  - Fast track
- FDAAA- FDA Amendments Act of 2007
  - REMS- Risk Evaluation Mitigation Strategy
  - SLC- Safety Labeling Changes
- FDASIA- Food and Drug Administration Safety and Innovation Act of 2012

Where Does FDA Get Authority to Regulate?

- Laws passed by congress
- CFR- Code of Federal Regulations
- Manual of Policies and Procedures (MaPPs)
- Guidance for Industry

Pre-IND



Pre-IND
Before Submitting an IND, Sponsors…

- Conduct nonclinical pharmacology/toxicology studies
- Define chemical properties of the drug
- Develop clinical protocol(s)

Pre-IND Meetings

- Avoid premature submission of INDs
- Avoid unnecessary nonclinical studies
- Resolve potential safety issues
- Discuss the contents of IND and overall drug development plan
- Provide regulatory guidance and answer appropriate questions

Suggested Contents of Pre-IND Briefing Packages

- Background information on the drug
- Chemical description of the drug product
- Chemistry, manufacturing, and controls
- Summaries of available nonclinical toxicology results and outlines of proposed studies
- Brief description of proposed clinical protocols and final clinical use
- List of specific questions to be discussed at the pre-IND meeting

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To Maximize Benefit from a Pre-IND Meeting

- Hold the meeting early in the development process
- Submit a complete briefing package on the proposed drug product
- Submit specific questions and/or concerns regarding the nonclinical development of the drug
- Include pharmacologists and toxicologists who are involved in the nonclinical development of the drug

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IND
Investigational New Drug

IND: A Request to Start Clinical Trials

- Commercial IND - pharmaceutical companies whose ultimate goal is to obtain marketing approval for new products
- Investigator IND (Research IND) – submitted by physicians who initiates and conducts an investigation
- Single-Patient IND – a submission that is meant to treat only one patient

IND Types Cont'd

- Treatment IND – experimental drugs showing promise in clinical testing for serious or life-threatening conditions
  - Criteria to meet:
    - Intended to treat a serious or life-threatening disease
    - No comparable drug or other therapy available to treat that stage of the disease in the intended population
    - Drug under investigation in a controlled clinical trial or all clinical trials have completed
    - Sponsor of the controlled clinical trial is actively pursuing marketing approval with due diligence
      - Treatment protocol submitted by an IND sponsor
      - Treatment IND submitted by a licensed practitioner (Single Patient IND) or a commercial sponsor
- Emergency IND (EIND)

Emergency IND (EIND)

- Emergency situation that does not allow time for submission of IND which is generally reserved for life-threatening situation in which no standard acceptable treatment is available
- IND number provided by phone
- Drug can be shipped and administered prior to submission of application to FDA
- One patient per IND

IND Review

- 21 CFR 312.22
- FDA's primary objectives in reviewing an IND are, in all phases of the investigation, to assure the safety and rights of subjects and in Phase 2 and Phase 3, to help assure that the quality of the scientific evaluation of drugs is adequate to permit an evaluation of the drug's effectiveness and safety
- 21 CFR 312.23 (content and format)
  - Cover Sheet (Form FDA 1571)
  - Form 3674
  - A Table of Contents
  - Introductory Statement and General Investigational Plan
  - Investigator's Brochure
  - Protocols – a protocol for each planned study
  - Chemistry, Manufacturing and Controls Information
  - **Pharmacology and Toxicology Information**
  - Previous Human Experience with the Investigational Drug
  - Additional Information

Types of Non-clinical Studies for Safety Assessment

GLP

- Safety pharmacology
- Pharmacokinetics
- ADME (absorption, distribution, metabolism, elimination)
- General toxicology
- Local Tolerance
- Genotoxicity
- Carcinogenicity
- Reproductive toxicology
- Special studies

Institutional Review Boards (IRBs)

- IRB definition – any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects.
- IRBs ensure that:
  - Informed consents is obtained and the documents meet regulatory requirements
  - Risk to subjects are minimized
  - Risk to subjects are reasonable in relation to anticipated benefits
  - Adequate study monitoring for safety
  - Adequate protection of subject privacy
  - Rights and welfare of vulnerable subjects are protected

Informed Consent

- Obtained for every subject except where there is an exception (emergency, DOD use)
- Offered in manner to minimize possibility of coercion
- Presented in understandable language
- Contains no language that waives subject's rights to release anyone from liability or negligence

The First 30 Days

- Study cannot proceed until 30 days from FDA receipt (new INDs and reactivated INDs only)
- 30 day safety review
- Internal meeting before the 30 days to review the application together to determine whether the proposed study is safe to proceed
- Decision: safe to proceed or clinical hold?

Clinical Holds

- Grounds for imposing a clinical hold differ based on phase of IND development
  - Phase 1 – Human subjects at unreasonable and significant risk, unqualified investigator, IB misleading, erroneous or incomplete, or insufficient information to assess risk
  - Phase 2 or 3 – any reasons cited above and protocol deficient in design to meet stated objective
- Can be imposed at any time
- Unless accompanied by a clinical hold, agency comments to an IND sponsor are advisory
- Partial clinical hold vs. full clinical hold

Types of IND Submissions

- New protocol
- Protocol amendment
- Information amendment
- Safety reports (initial and follow-up)
- Annual Reports
- Meeting request
- Special Protocol Assessment (SPA)
  - Clinical
  - Stability
  - Carcinogenicity

How Do Submissions Get to the Reviewers?

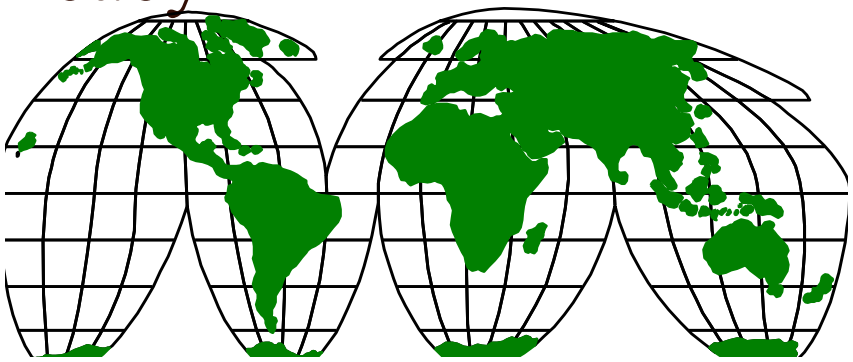
- Amendment arrives at Central Document Room (electronic or paper)
- Amendment sent to Division/Project Manager
- Amendment given to Team Leaders
- Amendment assigned to Primary Reviewers

The Review Team

- Division Director
- Team Leaders from each of the review teams
  - Clinical Reviewer (Medical Officer)
  - Pharmacology/Toxicology Reviewer
  - Product Quality Reviewer
  - Clinical Virology Reviewer (in some divisions)
  - Clinical Pharmacology Reviewer
  - Biometrics Reviewer
  - Regulatory Project Manager

The ICH Process

- Established in 1990 to improve efficiency of the new drug approval process in Europe, Japan, and the United States
- Regulators and industry representatives from all three regions participated
- The harmonized topics are safety, quality, and efficacy



NDA
New Drug Application

NDA: A Request to Market the Drug

NDA Consists of:

- Clinical safety and efficacy data
- Clinical pharmacokinetic data
- Nonclinical pharmacology/toxicology data
- Chemistry data
- Package labeling
- Administrative information (e.g. patent information, debarment certification)

NDA Types

- Type 1: New Molecular Entity (NME)
- Type 2: New Active Ingredient (e.g. new salt)
- Type 3: New Dosage Form
- Type 4: New Combination
- Type 5: New Formulation or New Manufacturer
- Type 6: New Indication, Same Manufacturer (no longer used)
- Type 7: Drug Already Marketed, but Without Approved NDA
- Type 8: Rx to OTC

Types of NDAs

- 505(b)(1) - applicant own or have a right of reference to all of the investigations relied upon by the application to support approval of the NDA
- 505(j) - generic application
- 505(b)(2) – an NDA that relies for approval on investigations not conducted by or for the applicant and for which the application does not have a right of reference

Office of Generic Drugs (OGD) Mission:

- To ensure through a scientific and regulatory process, that generic drugs are safe and effective for the American public.

Did you know that generic drugs...

- Are safe and effective alternatives to brand name prescriptions?
- Can help both consumers and the government reduce the cost of prescription drugs?
- Represent greater than 80% of the total prescriptions dispensed in the US?
- Save consumers 30% to as much as 80% over brand medicines?

Major Responsibilities of OGD

Implement GDUFA and Meet the GDUFA Goals

- Review and Approve Abbreviated New Drug Applications (ANDAs)/Supplements
- Provide Regulatory/Technical Guidance to Industry (Controlled Documents)
- Address Scientific Issues Concerning Generic Drug Products (Citizens' Petitions, etc.)
- Educate & Train a Diverse Staff in Latest Scientific, Regulatory, and Review Technologies
- Educate American Public about FDA Approved Generic Drug Products
- Monitor Performance of Generic Drugs in Marketplace

What are the requirements for a generic drug?

- Same active ingredient(s)
- Same route of administration
- Same dosage form
- Same strength
- Same conditions of use
- Compared to reference listed drug (RLD) - (brand name product)

Brand Name Drug vs. Generic Drug Review Process

Brand Name Requirements	Generic Requirements
1. Chemistry	1. Chemistry
2. Manufacturing	2. Manufacturing
3. Testing	3. Testing
4. Labeling	4. Labeling
5. Inspections	5. Inspections
6. Animal Studies	
7. Clinical Studies	6. Bioequivalence
8. Bioavailability	

NDA vs. ANDA Review Process

- NDA Review = Lower volume, but higher complexity
- (Pre-Clinical, Clinical Trials, etc.)
- ANDA Review = Higher volume, but generally lower complexity (Safety & Efficacy already established)
- Volume is Comprised of Total Number of Applications,
- Supplements (CBE, PAS), DMF Completeness Assessments,
- This number is over 15,000.

Generic Drug User Fee Amendments (GDUFA) Overview

5 Year Program with $299 million, inflation adjusted, per year

FDA commits to program enhancements and performance goals.

- Review Goals apply to ANDAs, amendments, prior approval supplements (PAS), and drug master files (DMF)

- Ten-month review cycle for 90% of Original ANDAs in year 5 (FY 2017)
- Six-month review cycle for 90% of PAS's with no inspection need beginning FY 2015
- Act on 90% of the backlog (ANDAs and PAS) by end of FY2017

- DMF Type II completeness assessment requirement

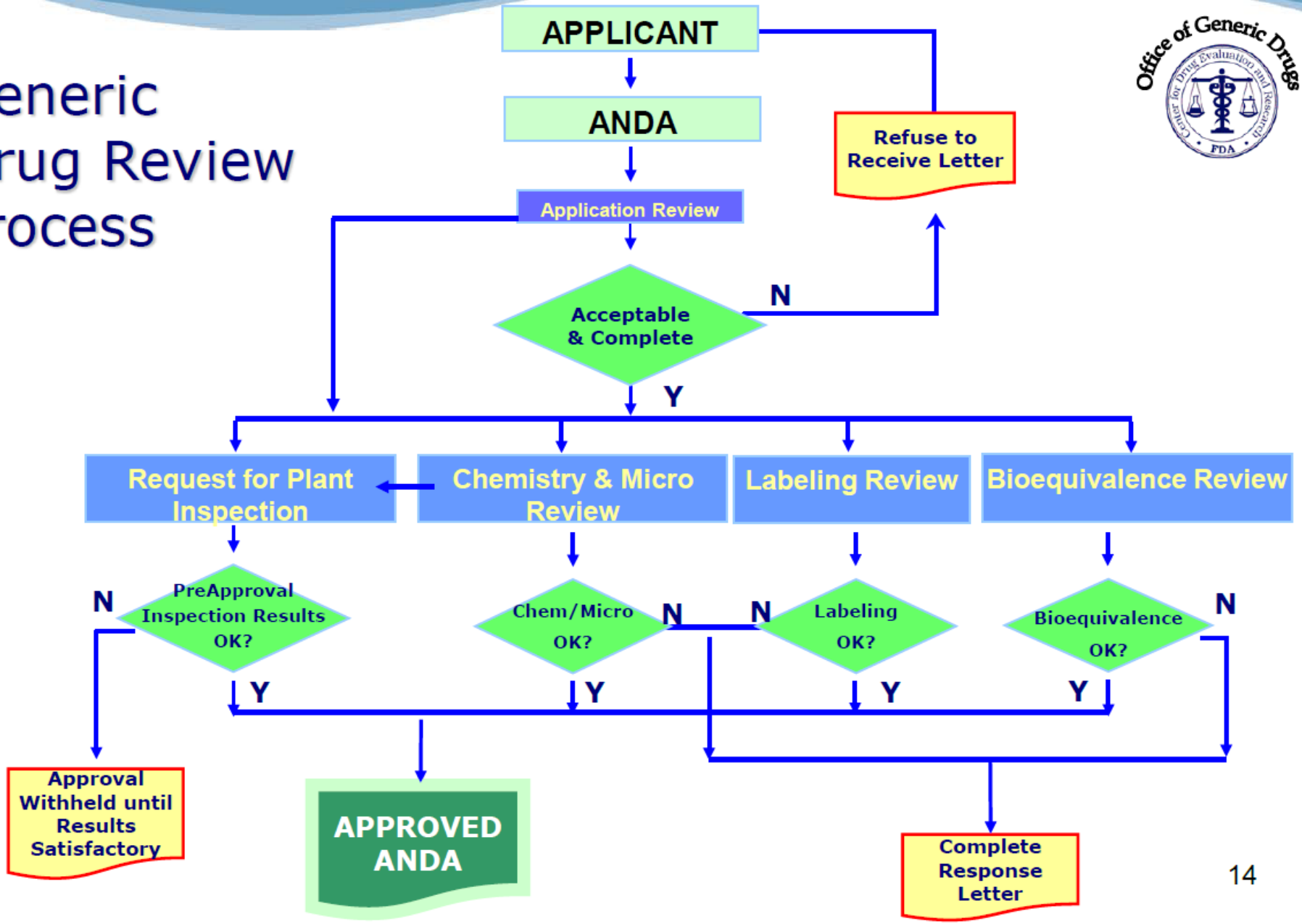
- Issue Complete Response (CR) letters

- Provide prompt communication of easily correctable deficiencies

- Perform division-level deficiency reviews

Huge priority for OGD and requires substantial process changes for both FDA and industry

Generic Drug Review Process



Research Initiatives by OGD Scientific Staff

Respond to Scientific Challenges

Regulatory Science

Develop Bioequivalence Methodology for:

- MDIs (master data index)
- Topicals
- Injectable Suspensions, etc.
- Work with Office Testing & Research in developing/hiring expertise
- External Contracts

"Orange Book"

Approved Drug Products with Therapeutic Equivalence Evaluations

All FDA approved drug products listed

(New drugs, Over-the-Counter and Generic)

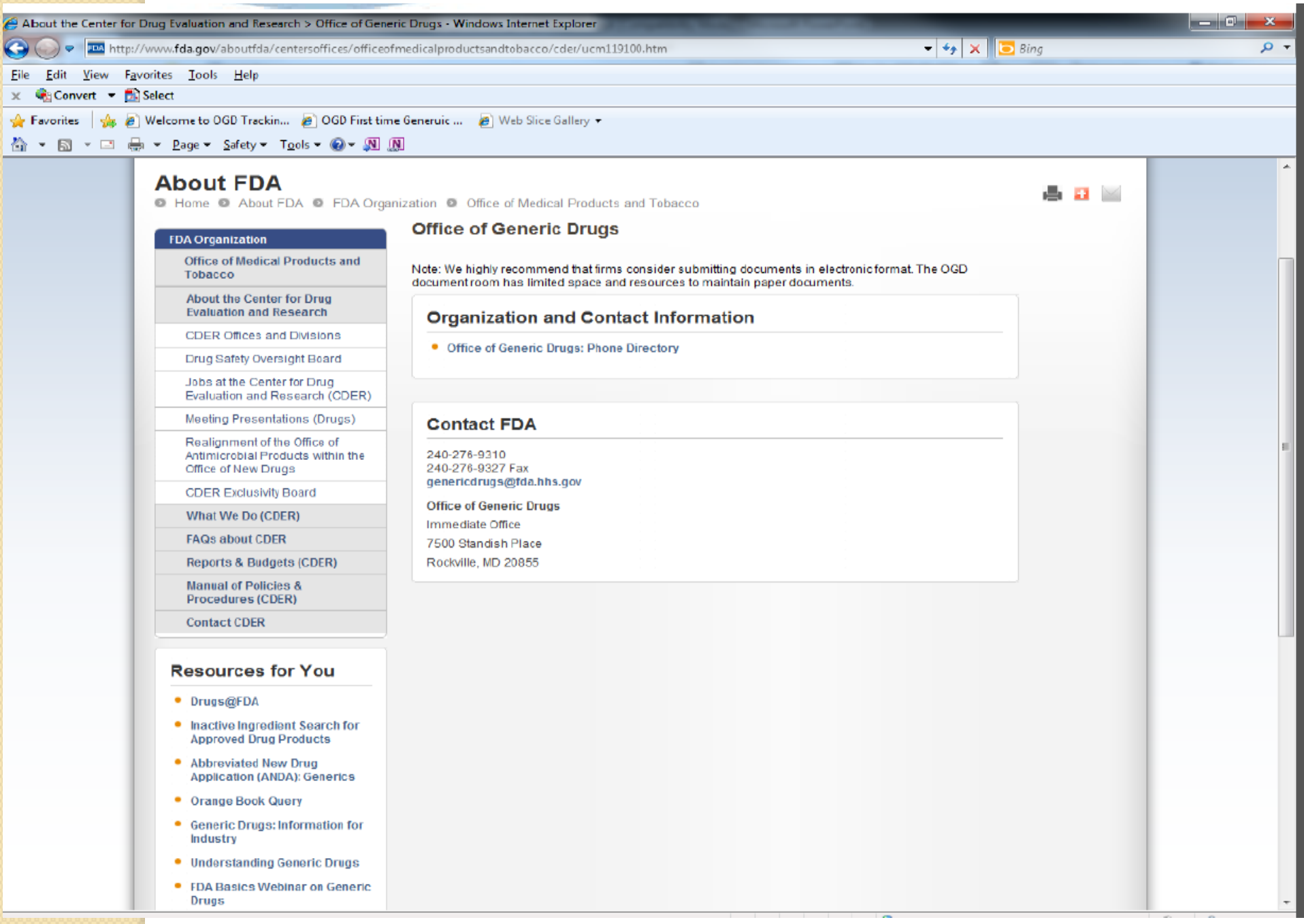
Therapeutic equivalence codes

"A" = Substitutable

"B" = Inequivalent, NOT Substitutable

Expiration date: for patents and exclusivity

Reference Listed Drugs (brand drugs) identified for generic companies to compare with their proposed products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http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm119100.htm
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Office of Medical Products and Tobacco
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Drug Safety Oversight Board
Jobs at the Center for Drug Evaluation and Research (CDER)
Meeting Presentations (Drugs)
Realignment of the Office of Antimicrobial Products within the Office of New Drugs
CDER Exclusivity Board
What We Do (CDER)
FAQs about CDER
Reports & Budgets (CDER)
Manual of Policies & Procedures (CDER)
Contact CDER
Resources for You
Drugs@FDA
Inactive Ingredient Search for Approved Drug Products
Abbreviated New Drug Application (ANDA): Generics
Orange Book Query
Generic Drugs: Information for Industry
Understanding Generic Drugs
FDA Basics Webinar on Generic Drugs
Office of Generic Drugs
Note: We highly recommend that firms consider submitting documents in electronic format. The OGD document room has limited space and resources to maintain paper documents.
Organization and Contact Information
Office of Generic Drugs: Phone Directory
Contact FDA
240-276-9310
240-276-9327 Fax
genericdrugs@fda.hhs.gov
Office of Generic Drugs
Immediate Office
7500 Standish Place
Rockville, MD 20855

Review Generic Drugs

FDA-approved generic drugs must have

- same active ingredient(s)
- same labeled strength
- same dosage form
- same administration

The drug company must show the generic drug is "bioequivalent"to the brand-name drug

- active ingredient works in the same way
- active ingredient works in the same amount of time

Generic Drugs

The generic drug's labeling must be basically the same as that of the approved brand-name drug.

The drug company must:

- fully document the generic drug's chemistry, manufacturing steps, and quality control measures
- detail each step of the process

Generic Drugs

The raw materials and the finished product must meet USP specifications,if these have been set.

USP-United States Pharmacopeia

The drug company must:

- show that its generic drug maintains stability as labeled before it can be sold
- continue to monitor drug's stability

Generic Drugs

The drug company must:

- comply with federal regulations for current good manufacturing practices
- give a full description of the facilities it uses to manufacture, process, test, package, label, and control the drug

Inspection at the proposed manufacturing site ensures that the firm:

- is capable of meeting commitments of the application
- can manufacture the product consistently

FDA Requirements for Brand-Name and Generic Drugs

	Brand Name Drug	Generic Drug
For reformulations of a brand-name drug or generic versions of a drug, FDA reviews data showing the drug is bioequivalent to the one used in the original safety and efficacy testing.	✓	✓
FDA evaluates the manufacturer's adherence to good manufacturing practices before the drug is marketed.	✓	✓
FDA reviews the active and inactive ingredients used in the formulation before the drug is marketed.	✓	✓
FDA reviews the actual drug product.	✓	✓
FDA reviews the drug's labeling.	✓	✓
Manufacturer must seek FDA approval before making major manufacturing changes or reformulating the drug.	✓	✓
Manufacturer must report adverse reactions and serious adverse health effects to the FDA.	✓	✓
FDA periodically inspects manufacturing plants.	✓	✓
FDA monitors drug quality after approval.	✓	✓

Biologics

- Biological Product- “A virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypepetide), or analogous product, applicable to the prevention, treatment, or cure of a disease or condition of human beings”
- Therapeutic biological products were transferred from CBER to CDER in 2003

Therapeutic Biologic Products

- Monoclonal antibodies of *in vivo* use
- Proteins intended for therapeutic use that are extracted from plants, animals or microorganisms, including recombinant versions
- Cytokines, growth factors, enzymes, immunomodulators and thrombolytics
- Other non-vaccine therapeutic immunotherapies

Current Biologic Laws

- Public Health Service Act (1994)
  - Section 351- Licensure of biological establishments and products
- Federal Food, Drug and Cosmetic (FD&C) Act (1938, 1962, 1997, 2007)
  - Which interprets that “biological products” are also “drugs”
- Patient Protection and Affordable Care Act
  - Biologics Price Competition and Innovations Act of 2009

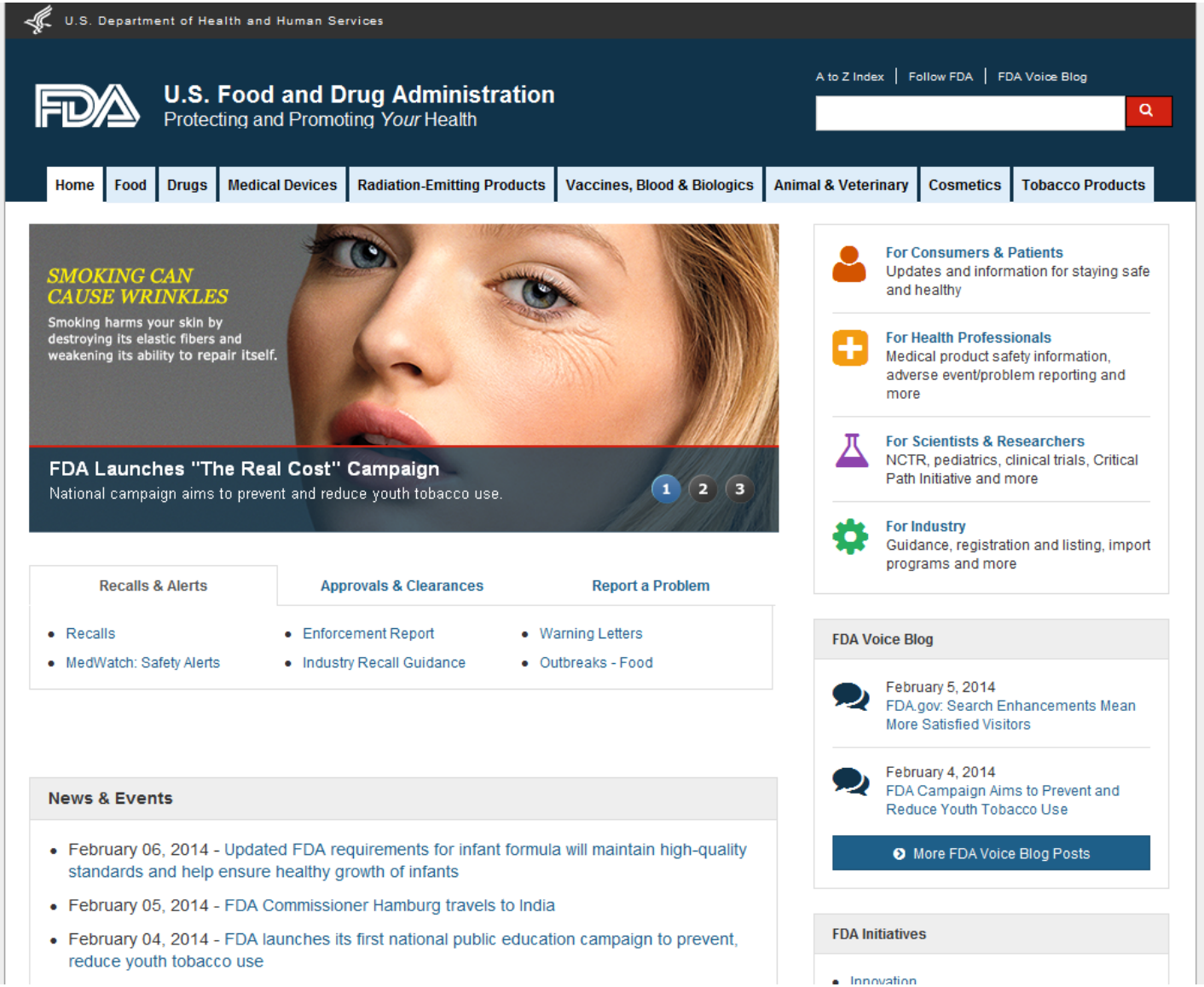
How Does a Biologic License Get Approved?

- The secretary shall approve a biologics license application:
  - On the basis of a demonstration that
    - Product is safe, pure and potent
    - The facility(ies) meet standards designed to assure that it continues to be safe, pure, and potent

User Fee

- PDUFA 1992, 1997 (PDUFA II), 2002 (PDUFA III), 2007 (PDUFA IV) and PDUFA V (2012). Authorizes FDA to collect fees from companies that produce certain human drug and biological products.
- User fee is required to submit clinical information to the FDA for review (NDA, BLA, sNDA and sBLA)
- Fees (Fiscal Year 2014):
  - Original application: $2,169,100
  - Supplemental application: $1,084,

WWW.FDA.GOV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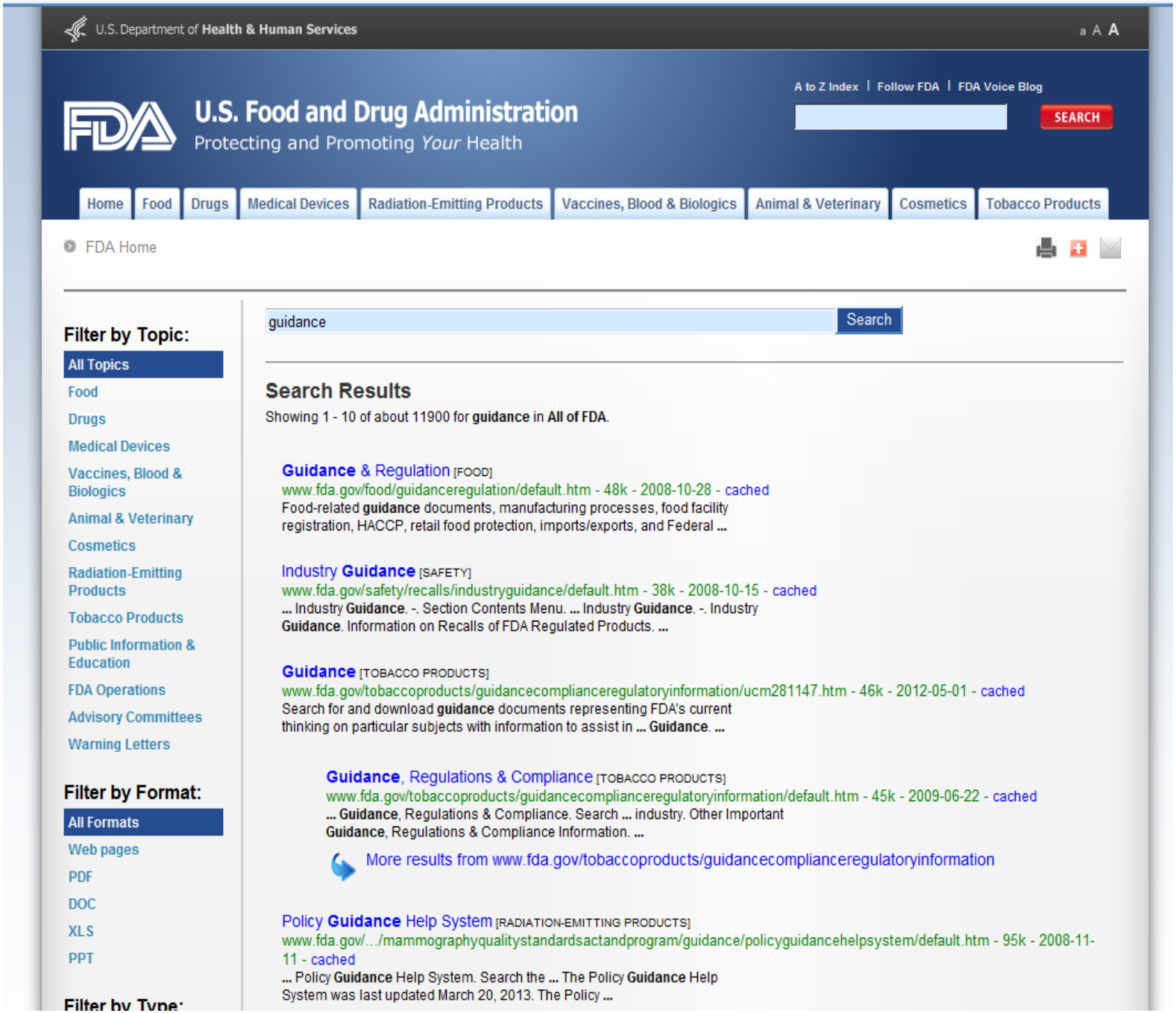
Tobacco Products
SMOKING CAN CAUSE WRINKLES
Smoking harms your skin by destroying its elastic fibers and weakening its ability to repair itself.
FDA Launches "The Real Cost" Campaign
National campaign aims to prevent and reduce youth tobacco use.
1 2 3
For Consumers & Patients
Updates and information for staying safe and healthy
For Health Professionals
Medical product safety information, adverse event/problem reporting and more
For Scientists & Researchers
NCTR, pediatrics, clinical trials, Critical Path Initiative and more
For Industry
Guidance, registration and listing, import programs and more
Recalls & Alerts
Approvals & Clearances
Report a Problem
Recalls
MedWatch: Safety Alerts
Enforcement Report
Industry Recall Guidance
Warning Letters
Outbreaks - Food
FDA Voice Blog
February 5, 2014
FDA.gov: Search Enhancements Mean More Satisfied Visitors
February 4, 2014
FDA Campaign Aims to Prevent and Reduce Youth Tobacco Use
More FDA Voice Blog Posts
News & Events
February 06, 2014 - Updated FDA requirements for infant formula will maintain high-quality standards and help ensure healthy growth of infants
February 05, 2014 - FDA Commissioner Hamburg travels to India
February 04, 2014 - FDA launches its first national public education campaign to prevent, reduce youth tobacco use
FDA Initiatives
Innovation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Search Results
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Guidance & Regulation [FOOD]
www.fda.gov/food/guidanceregulation/default.htm - 48k - 2008-10-28 - cached
Food-related guidance documents, manufacturing processes, food facility registration, HACCP, retail food protection, imports/exports, and Federal ...
Industry Guidance [SAFETY]
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... Industry Guidance. -. Section Contents Menu. ... Industry Guidance. -. Industry Guidance. Information on Recalls of FDA Regulated Products. ...
Guidance [TOBACCO PRODUCTS]
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Policy Guidance Help System [RADIATION-EMITTING PRODUCTS]
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Drugs

Navigate the Drugs Section

Emergency Preparedness
Bioterrorism, drug preparedness and natural disaster response

Drug Approvals and Databases
Drug-Related Databases from FDA; Information on Drug Approvals

Drug Safety and Availability
Medication Guides, Drug Shortages, Drug Safety Communications and Other Safety Announcements

Development & Approval Process (Drugs)
Conducting Clinical Trials, Types of Drug Applications,

Guidance, Compliance & Regulatory Information
Guidance for Industry, Warning Letters, Postmarket Surveillance Programs, Rules and Regulations

News & Events
What's New on This Site, Drug Approval Listing, Meetings and Conferences

Science & Research (Drugs)
Research by FDA Staff to Evaluate and Enhance the Safety of Drug Products

Resources for You
For Consumers, Health Professionals, Industry

Spotlight

- Compounding
- Drug Shortages
- Drug Information (Drugs@FDA)
- Orange Book Search
- National Drug Code Directory

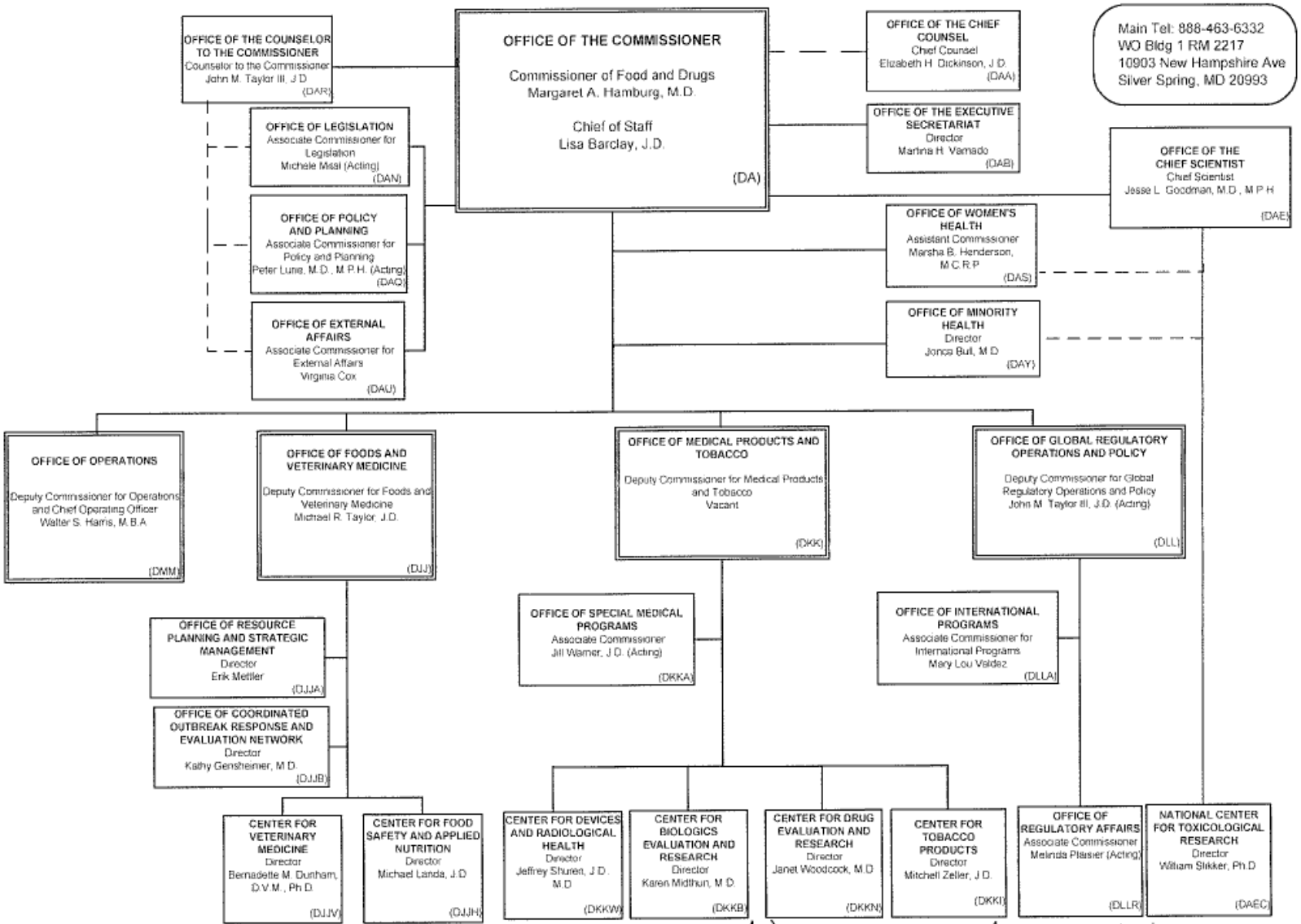
Recalls & Alerts

- Drug Recalls
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program
- Recalls, Market Withdrawals, & Safety Alerts

Approvals & Clearances

- This Week's Drug Approvals
- Drug and Biologic Approval and IND Activity Reports
- Search Drug Approvals by Month Using Drugs@FDA

FOOD AND DRUG ADMINISTRATION



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and Principal Delegation Control Officer

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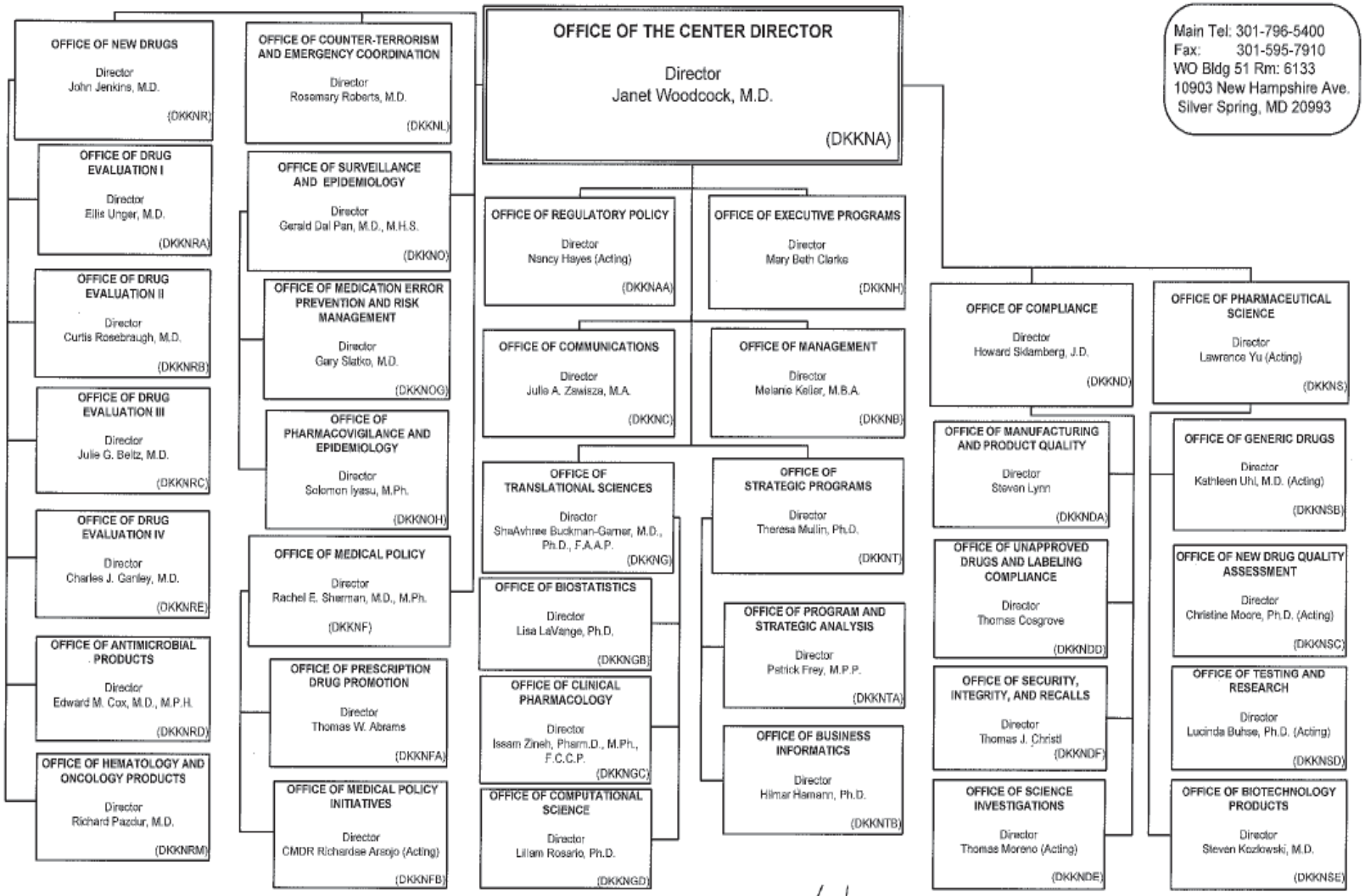
FOOD AND DRUG ADMINISTRATION
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
CENTER FOR DRUG EVALUATION AND RESEARCH



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Principal Delegation Control Officer

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The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is unique in bringing together the regulatory authorities and pharmaceutical industry of Europe, Japan and the US to discuss scientific and technical aspects of drug registration. Since its inception in 1990, ICH has evolved, through its ICH Global Cooperation Group, to respond to the increasingly global face of drug development, so that the benefits of international harmonisation for better global health can be realised worldwide. ICH's mission is to achieve greater harmonisation to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner. Download the ICH 20th Anniversary Publication

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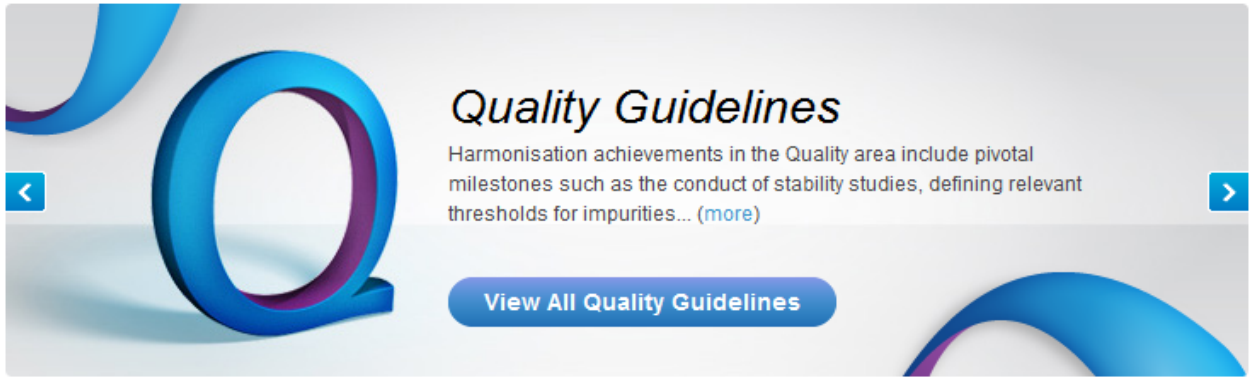

ICH Training

DIA ICH training E2 Pharmacovigilance Guidelines

28-29 November 2013, Zagreb, Croatia

DIA ICH training E2 Pharmacovigilance Guidelines

22-23 September 2013, Muscat, Sultanate of Oman

China ICH Study Group workshop on the ICH E11 Guideline

China ICH Study Group workshop on ICH M Guidelines

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by responding to one of our consultations. Your contribution will then be considered by the relevant ICH Working Group.

Draft Guidelines
Q&A Documents

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