

Food and Drug Law Fall 2009 – Syllabus

Frederick R. Ball

- Method of Instruction:

Lecture and class participation with weekly reading.
- Materials Required for the Course:

Food and Drug Law and Regulation from the Food and Drug Law Institute
- Topics to be Covered During the Semester:

A general overview of food and drug law.
- Criteria and Methods for Evaluating Students' Performance:

Students' grades will be based on class attendance, class participation, and a final paper, 15-20 pages, double spaced, fully Blue Booked. (10% of the grade will be based on class participation, 90% will be based on the final paper. Of that 90%, the student may choose to have between 10% and 45% based on an oral presentation to the class of the paper topic.)
- Contact Information:

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Office Hours: I will not have regularly scheduled office hours. However, if you e-mail me and/or call me I will set up a meeting with you at my offices at 190 S. LaSalle.
- Attendance Policy:

Class attendance is mandatory. If you miss a class, please speak to your fellow students about anything that you may have missed.

Week 1 – August 27, 2009

- I. Introduction
 - A. Goals
 - B. Guest Instructors

- C. Scheduling – 5:50 p.m. to 8:10 p.m. – no breaks
- D. Papers, Presentations, Grading
 - 1. September 10, 2009 – Possible late start or class on September 3
 - 2. November 5, 2009 – Early start at 4:30 p.m.
 - 3. November 12, 2009 – We may need to move this class

II. Overview of Regulatory Framework

- A. FDA
- B. DEA
- C. CMS
- D. State Boards
- E. Statutes
- F. Regulations
- G. Informal
 - 1. FDA CPGs
 - 2. DEA Fed. Reg.
 - 3. AG Rulings
 - 4. OIG Guidances
 - 5. Etc.

Week 2 – September 3, 2009

- I. How does all this play out in the real world?
 - A. *Washington Legal Found v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998)
 - B. *Thompson v. Western States Med. Ctr.*, 535 U.S. 357 (2003)
 - C. *United States v. Caputo*, 517 F.3d 936 (7th Cir. 2007)
 - D. *United States v. Caronia*, 576 F.Supp. 2d 385 (E.D.N.Y. 2008)
 - E. *Medical Ctr. Pharmacy v. Mukasey*, 536 F.3d 383 (5th Cir. 2008)

F. *United States v. Bader*, Case No. 07-cr-00338-msk (Order dated July 23, 2009)

Week 3 – September 10, 2009

- I. Basics of Food Law
- II. Cosmetics
- III. Veterinary Law

Week 4 – September 17, 2009

- I. Origins and Overview of the Organizational Structure of the FDA and the Regulation of Drugs
 - A. Landmark Legislative Enactments for Drug Regulation and Development of Today's Statutory Framework
 - 1. History
 - 2. Federal Food, Drug, and Cosmetic Act of 1938 (FDCA)
 - 3. The 1962 Drug Amendments/Kefauver-Harris
 - 4. Drug Price Competition and Patent Restoration Act of 1984
 - 5. Prescription Drug User Fee Act (PDUFA)
 - 6. Food and Drug Administration Modernization Act of 1997(FDAMA)
 - 7. Food and Drug Administration Amendments Act of 2007 (FDAAA)
 - B. Food and Drug Administration
 - 1. History
 - 2. FDA's Dual Mission -- The Dilemma
 - 3. The Food and Drug Administration Act of 1988
 - 4. FDA's Place in Government
 - 5. Responsibilities and Structure of Headquarters and the Field
 - C. Relevant Functions of Other Governmental Entities
 - 1. Congressional Oversight
 - 2. U.S. Department of Health and Human Services (HHS)

3. U.S. Department of Justice (DOJ)
4. The Securities and Exchange Commission (SEC)
5. Federal Trade Commission (FTC)
6. Government Accountability Office (GAO)
7. The States; State Attorneys General, State Boards of Pharmacy
8. U.S. Department of Homeland Security (DHS)

D. How FDA Regulates Compounding of Drugs by Pharmacies

Week 5 – September 24, 2009

I. FDA's Regulatory Processes

A. Sources of Legal and Regulatory Requirements and FDA Policies

1. Statutes; FDCA
2. Regulations
3. Federal Register (FR) Notices
4. Advisory Opinions and Preambles; Advisory Committees
5. Guidance Documents; Good Guidance Policy (GGP)
6. Compliance Policy Guides (CPGs)
7. Staff Manuals, Guides and Programs
8. Miscellaneous Publications
9. Enforcement Actions and Letters
10. Citizen Petition Responses
11. Informal Statements and Advice
12. FDA's Website

B. Non-FDA/External Requirements and Pronouncements/ Standards

1. International Conference on Harmonization (ICH)
2. United States Pharmacopeia (USP)

- C. Participating in FDA Policymaking
 - 1. Citizen Petitions
 - 2. Rulemaking Comments and Hearings
 - 3. Judicial Review
- D. Product Specific Regulatory Proceedings
 - 1. Informal Adjudications
 - 2. Regulatory Hearings
 - 3. Formal Adjudications
 - 4. Judicial Review

Week 6 – October 1, 2009

- I. The New Drug Approval Process: Basic Concepts and Regulatory Approval Pathways
 - A. What is a Drug?
 - 1. Statutory and Regulatory Definitions
 - 2. The Key Principle - Intended Use
 - 3. Drugs vs. Other Regulated Products
 - 4. Combination Products
 - B. What is a New Drug?
 - 1. The Key Principle – “Old” vs. “New”
 - 2. Old Drug/New Drug vs. Rx/OTC
 - 3. Drug Substances vs. Drug Products
 - C. Legal Standard for Approval of New Drugs
 - 1. Effectiveness - Substantial Evidence (SE)
 - 2. Adequate and Well Controlled Studies
 - 3. Safety - Balancing Risk and Initial Benefit
 - 4. Drugs for Serious or Life-Threatening Illnesses

- D. New Drug Approval Pathways
 - 1. Full New Drug Applications (NDAs)
 - 2. Abbreviated NDAs (ANDAs)
 - 3. Paper NDAs/505(b)(2) Applications
 - 4. Bioterrorism Review Pathways

Week 7 – October 8, 2009

- I. The New Drug Approval Process: New Drug Research and Development
 - A. Preclinical Testing/Investigation
 - 1. “Good Laboratory Practice” (GLP) Regulations
 - B. Clinical Testing/Investigation and Good Clinical Practice (GCP) Requirements
 - 1. Investigational New Drug (IND) Applications
 - 2. Phase I, Phase II, Phase III
 - 3. Meetings with FDA
 - 4. Role of the Protocol
 - 5. Informed Consent
 - 6. Institutional Review Boards (IRBs)
 - 7. Obligations of Sponsors and Investigators; Role of Contract Research Organizations (CROs)
 - 8. Clinical Holds
 - 9. Use of Foreign Studies
 - 10. Exemptions from the IND Requirement
 - C. Pediatric Testing Requirements
 - 1. Pediatric Research Equity Act of 2003 (PREA) – FDAAA Reauthorized
 - 2. Expanded Access Programs
 - D. Treatment INDs and Emergency Use

- E. Fast Track Review/Accelerated (Conditional) Approval
 - 1. Use of Surrogate Endpoints, Post-Approval Restrictions and Other Clinical Trial Design Issues
 - 2. Rolling Submissions
- F. Orphan Drugs
 - 1. Designation
 - 2. FDA Assistance in Study Design
- G. Clinical Trials Registry
 - 1. FDAMA Section 113
 - 2. FDAAA Title VIII
 - 3. Medical Publisher/State Policies
- II. The New Drug Approval Process: NDA Submission and Review
 - A. Content and Organization of a Full NDA
 - 1. Safety and Effectiveness Data
 - 2. Chemistry, Manufacturing, and Controls (CMC) Information
 - 3. Packaging
 - 4. Proposed Labeling
 - 5. Patent Information
 - 6. Drug Master Files (DMFs)
 - 7. Certifications and Disclosures
 - 8. Use of the Common Technical Document
 - B. The Review Process
 - 1. User Fees and Goals (PDUFA)
 - 2. The Review Clock and the Impact of PDUFA
 - 3. Interacting with FDA
 - 4. Special Issues

- C. Responses to FDA Adverse Decisions
 - 1. Right to a Hearing on Refusal to Approve an Application
 - 2. Judicial Review of Refusal to Approve an Application
 - 3. Judicial Review of Approval of a Competitor's Application
 - 4. FDA and CDER Ombudsman
- D. Post-Approval Study and Surveillance Requirements
- E. Critical Path Innovations

Week 8 – October 15, 2009

Guest Lector Dr. Robert Gould – The Generic Pathway

Week 9 – October 22, 2009

- I. Post-Approval Issues
 - A. Annual Reports
 - B. Adverse Drug Experience (ADE) Reports
 - C. FDA Drug Safety Activities
 - D. Post-Approval Changes and Supplemental NDAs (sNDAs) and ANDA's
 - E. Grounds for Withdrawal of Approval
 - F. Sale/Transfer of NDAs/ANDA's
 - G. Post-Approval Safety Issues
 - 1. Postmarket Studies
 - 2. Change in Label Safety Information
 - 3. Risk Evaluation and Mitigation Strategies (REMS)
 - 4. Penalties for Noncompliance
 - H. Medicare, Medicaid and Reimbursement Issues

- I. PDMA/Pedigrees/Authentication
 - 1. Drug Distribution Issues
 - 2. Track and Trace Technologies

Week 10 – October 29, 2009

- I. Over-the-Counter (OTC) Drugs
 - A. Rx vs. OTC Status
 - 1. Statutory Definition; Examples
 - 2. Durham-Humphrey Amendment of 1951
 - B. The OTC Review and the Monograph Process
 - 1. Legal Nature and Basis
 - 2. Scope of the Review
 - 3. Completing and Amending the Monograph
 - 4. Monograph Requirements
 - 5. Marketing New Dosage Forms under the OTC Review
 - 6. New OTC Drug Labeling Requirements
 - 7. Time and Extent Application (TEA)
 - C. Rx-to-OTC Switches
 - 1. By Monograph
 - 2. By NDA
 - 3. The Switch Regulation
 - 4. Non-Patent Exclusivity
 - 5. “Forced” OTC Switches
 - 6. Partial OTC Switches, e.g. “Plan B”
 - 7. “Behind-the-Counter” OTC Drugs

Week 11 – November 5, 2009

- I. Regulation of Drug Manufacturing
 - A. Establishment Registration and Drug Listing
 - B. Adulteration
 - 1. Current Good Manufacturing Practices (cGMPs)
 - 2. Departure from Compendial or Represented Standards
 - 3. Insanitary Conditions
 - C. Inspections
 - 1. Inspection Process and Procedure
 - 2. Search Warrants
 - 3. Photographs and Recordings
 - 4. Affidavits and Declaration
 - 5. Pre-Approval Inspections (PAIs)
 - D. Responding to 483 Observations – Closing an Inspection
 - 1. Establishment Inspection Report (EIR)
 - E. Field Alert Reports
 - F. Product Recalls/Market Withdrawals
- II. Regulation of Drug Marketing
 - A. Key Principles of Advertising and Promotion
 - 1. Basic Definition and Concepts of Labels, Labeling, Advertising
 - 2. Intended Use and the New Drug Approval Requirement
 - 3. Misbranding
 - 4. Division of Drug Marketing, Advertising, and Communications (DDMAC)
 - B. Prescription Drug Promotion and Advertising
 - 1. Promotional Labeling versus Advertisements

2. Conformance with Approved Labeling
 3. Fair Balance
 4. Brief Summary for Advertisements
 5. Comparative Claims
 6. Pharmacoeconomic/healthcare economic/outcomes information
 7. Patient Reported Outcomes
 8. Direct-to-Consumer (DTC) Advertisements
 9. Interactions with SEC – Reporting and Disclosures
 10. Use of Internet
- C. Off-Label Information and Other Current Issues
1. Washington Legal Foundation (WLF) vs. Henney and the Dissemination of Information on Off-Label Uses
 2. Disease and Help Seeking Ads
 3. Pre-Approval Promotion and Advertising
 4. Scientific and Educational Activities
 5. Use of Medical Science Liaisons (MSLs); Unsolicited Requests for Information by Medial Professionals
- D. OTC Drugs
- E. Drug Sampling
- F. Anti-Kickback Statute
- G. False Claims Act
- H. Other Considerations – the States, Product Liability, the Lanham Act
- I. PhRMA Code
- J. Corporate Compliance Programs

Week 13 – November 12, 2009

- I. Import and Export Requirements and International Issues
 - A. Imports
 - 1. Importation from Foreign Sources; Canada
 - 2. Import for Export (IFE)
 - 3. Foreign Establishment Inspection/FDA Foreign Offices
 - 4. Import Detentions and Refusals
 - 5. Alerts
 - B. Exports
 - 1. Exporting Unapproved Drugs and Vaccines
 - 2. NDA-Approved Product
 - 3. Exports for Investigational Use; FDA’s Office of International Programs
 - C. International Harmonization
 - D. Counterfeit Drugs
 - E. Role of U.S. Department of Homeland Security (DHS)/Customs and Border Protection (CBP)
 - 1. Compliance with FDA and CBP Regulations
 - F. Drugs and Vaccines for Emergency Use; Personal Use
 - G. Enforcement Discretion Related to Canadian Drugs
- II. Violations and Enforcement
 - A. The Interstate Commerce Element
 - B. Prohibited Acts
 - C. Enforcement Tools and Procedures
 - 1. Warning Letters (WLs) and Untitled Letters
 - 2. Use of Media/Publicity
 - 3. “Voluntary” Recalls

4. Civil Penalties/Disgorgement
5. Seizure Actions
6. Suits for Injunctions, Consent Decrees
7. Criminal Prosecutions
8. How FDA Decides an Enforcement Action
9. Debarment

Week 14 – November 19, 2009

Paper Presentations

Week 15 – December 3, 2009

Paper Presentations

All papers are due no later than December 10, 2009.

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