

COURSE SYLLABUS

FOOD AND DRUG LAW

HARVARD LAW SCHOOL
WINTER TERM 2018

Peter Barton Hutt

January 2, 2018

All references to the Casebook are to Hutt, Merrill, and Grossman, Food and Drug Law (4th edition 2014).

All materials in the Casebook titled as “Comment” or “Notes” are optional reading.

The projected course schedule is approximate, not rigid. The course may fall behind the projected schedule, usually by no more than one day, but all of the assigned reading will eventually be covered.

I. Introduction to FDA

January 2: History of food and drug regulation.
History of FDA.
Structure of statute.
Reading: Casebook Chapter 1

II. Jurisdiction and Enforcement

January 3: Jurisdiction.
Prohibited acts.
Factory inspection.
Judicial enforcement.
Informal enforcement.
Import and export.
Reading: Casebook pages 271-289
1439-1485
163-270

III. Regulation of Human Food

January 4: Definition of food.
Categories of food.
Scope of labeling.
Misbranding.
Food identity.
Reading: Casebook pages 77-88
92-98
101-109
151-162
317-403

January 8: Nutrition claims.
Food fortification.
Dietary supplements.
Structure/function and disease claims.
Reading: Casebook pages 353-355
403-469

January 9: Sanitation.
Safety.
Reading: Casebook pages 469-639

IV. Regulation of Human Drugs

January 10: Morning
Definition of drug.
History.
OTC drugs.
Investigational new drugs.
New drug applications.
Reading: Casebook pages 77-78
89-101
957-990
641-751

January 10: Afternoon
Labeling.
Advertising.
Reading: Casebook pages 751-775
834-957

January 11: Control of prescribing.
Impact of 1962 Amendments
Reading: Casebook pages 775-834
996-1044

V. Regulation of Animal Feed and Drugs

January 12: Animal feed.
Animal drugs.
Reading: Casebook pages 1045-1121

VI. Regulation of Human Biological Drugs and Biotechnology

January 16: History.
Definition of biological product.
Biologics.
Organs and tissues.
Immunization.
Biotechnology.
Reading: Casebook pages 77-78
135-139
1123-1192

VII. Regulation of Human Medical Devices

January 17: History.
Definition of medical device.
Labeling.
The 1976 Amendments.
Substantial equivalence.
Premarket approval.
Postmarket regulation.
Reading: Casebook pages 77-79
89-101
1193-1254

January 18: General controls.
Radiation devices.
Reading: Casebook pages 1254-1300

VIII. Regulation of Human Cosmetics and Carcinogens

January 19: History.
Definition of cosmetic.
Adulteration.
Misbranding.
Voluntary regulation.
Hair dyes.
Color additives.
Reading: Casebook pages 77-78
92-98
109-121
1301-1350
1373-1438

* * *

All materials in the Casebook titled as “Comments” or “Notes” are optional reading unless otherwise designated in this Syllabus.

* * *

All course papers are due at any time between noon on Friday, January 20, 2018, and 5:00 p.m. on Monday, April 2, 2017. Extensions will be liberally granted upon request. Combined (Option 1) papers are due on or before May 1 of your 3L year. An electronic version must be sent to Mr. Hutt at his office in Washington (phutt@cov.com) and will be acknowledged by return email.