

Federal Regulation of Drugs and Pharmacy

PHA6274

Class Periods: Sundays, 7:00-9:00pm Eastern

Location: Zoom

Instructor:

Eli Phillips Jr.

Email: eliphillips@ufl.edu

Phone/Text: By Appointment

Office Hours: By appointment

Office Location: Virtual/Zoom

Erik Barbone

Phone/Text: By Appointment

Office Hours: By appointment

Office Location: Virtual/Zoom

Course Description

This course is designed to provide an understanding of the regulation of drug products by the US Food and Drug Administration. Among the topics we will explore include discussions of New Drug Applications, Abbreviated New Drug Applications and OTC monographs. We will also examine the areas of patent issues and market exclusivity within the context of FDA regulatory compliance.

Course Pre-Requisites / Co-Requisites

None

Course Objectives

1. List critical events in the evolution of U.S. drug laws.
2. Distinguish between drugs, dietary supplements, foods and medical devices.
3. Discuss the implications of “new drug” status.
4. Describe FDA practices and procedures.
5. Describe the process of drug discovery and testing.
6. List the criteria for IRB review of research with human subjects.
7. Explain the elements of an NDA and ANDA.
8. Describe the process of post-marketing surveillance.
9. List labeling requirements for drugs.
10. Discuss labeling and advertising regulations under the FDCA.
11. Describe Congressional oversight of FDA actions.
12. Understand the role of the FDA, the Courts and Congress in the regulation of drugs.

This syllabus is subject to change. The program will make every effort to post any updates promptly. However, students registered for the course should not rely on this document for course information, as changes will not be reflected immediately. Students should always refer to the Canvas course site as the authoritative source for course information.

Required Textbooks and Software

Hutt, Merrill and Grossman, Food and Drug Law Cases and Materials, 4th Edition. Foundation Press. (2014)

Recommended Materials

None

Course Schedule

Date	Topic
10/17	The Food and Drug Administration: Its Laws and Regulations
10/24	Statutory and Regulatory Framework
10/31	Enforcement
11/7	Investigational New Drug Applications(INDA) and Filing New Drug Applications (NDA)
11/14	Generic Drugs, and Marketing Exclusivity for NDA's
11/21	Product OTC and DESI II Drugs and Drug Labeling
11/28 (Thanksgiving)	NO CLASS
12/5	Intellectual Property for NDAs/ANDAs Marketing Exclusivity for New Drugs, Drug Master Files (DMF) and Compounding
12/12	FINAL Exam

Evaluation Methods

Case study assessments and the final project will be evaluating using the rubric provided in the syllabus Appendix.

Class participation will be evaluated based on contribution to class discussion. The instructor will call on individual students during synchronous class meetings. This strategy is intended elevate and advance the conversation, not to challenge the student with a question that is difficult to answer. Students are encouraged to be prepared for the discussion, but they should be comfortable responding to the question with another question or expressing points of ambiguity about the topic.

Evaluation of Grades

Assignment	Total Points	% of Final Grade
Weekly Assignment Papers - Grades are based on criteria for scoring following the assignment directions.	100 each	40%
Class Participation* - Class attendance and online activity will be used to gauge participation.	100 each	10%
Final Exam - This online exam is comprised of written (typed) responses to questions.	100	50%

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Attendance Policy

Students are expected to attend the synchronous class meetings every Sunday from 7-9 pm. Students who miss 30 minutes or more of the synchronous class meeting are considered absent. **Unexcused absences** from the synchronous class meetings carry a 4-percentage point (~1/2 letter grade) reduction in the final grade. **Excused absences** require a make-up paper to be submitted within 2 weeks of the missed class (unless the class is near the end of the semester and a shorter timeline will be required). Contact the instructor for specifics on the make-up paper. Absences are considered excused when the student (not a peer) has emailed the instructor before the synchronous class meeting begins and conveys why the student will miss class, such as illness, job conflict, and other emergencies. The instructor can be contacted via email (preferred) or text (listed above). Two or more excused absences will be addressed by the course coordinator and may result in an incomplete final grade for the course.

Make-up Policy

Assignments that are not submitted by the due date will be given a zero. Make up assignments are not usually given, but may be offered at the discretion of the course instructor after evaluation of the circumstances leading to the request.

Grading Policy

A	>92.500%
A-	89.500–92.499%
B+	86.500–89.499%
B	82.500–86.499%
B-	79.500–82.499%
C+	76.500–79.499%
C	72.500–76.499%
C-	69.500–72.499%
D+	66.500–69.499%
D	62.500–66.499%
D-	59.500–62.499%
E	<59.499%

More information on UF grading policy may be found at:

[UF Graduate Catalog](#)

[Grades and Grading Policies](#)

Students Requiring Accommodations

Students with disabilities who experience learning barriers and would like to request academic accommodations should connect with the [Disability Resource Center](#). It is important for students to share their accommodation letter with their instructor and discuss their access needs, as early as possible in the semester.

Course Evaluation

Students are expected to provide professional and respectful feedback on the quality of instruction in this course by completing course evaluations online via GatorEvals. [Click here for guidance on how to give feedback in a professional and](#)

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respectful manner. Students will be notified when the evaluation period opens, and can complete evaluations through the email they receive from GatorEvals, in their Canvas course menu under GatorEvals, or via ufl.bluera.com/ufl/. Summaries of course evaluation results are available to students here.

University Honesty Policy

UF students are bound by The Honor Pledge which states, "We, the members of the University of Florida community, pledge to hold ourselves and our peers to the highest standards of honor and integrity by abiding by the Honor Code. On all work submitted for credit by students at the University of Florida, the following pledge is either required or implied: "On my honor, I have neither given nor received unauthorized aid in doing this assignment." [The Honor Code](#) specifies a number of behaviors that are in violation of this code and the possible sanctions. Furthermore, you are obligated to report any condition that facilitates academic misconduct to appropriate personnel. If you have any questions or concerns, please consult with the instructor or TAs in this class.

Software Use

All faculty, staff, and students of the University are required and expected to obey the laws and legal agreements governing software use. Failure to do so can lead to monetary damages and/or criminal penalties for the individual violator. Because such violations are also against University policies and rules, disciplinary action will be taken as appropriate. We, the members of the University of Florida community, pledge to uphold ourselves and our peers to the highest standards of honesty and integrity.

Student Privacy

There are federal laws protecting your privacy in terms of grades earned in courses and on individual assignments. For more information, please see the [Notification to Students of FERPA Rights](#).

Recordings of weekly class sessions in Zoom are created for the purpose of course teaching and learning, as well as for use as a resource for students who miss a class session.

The use of video (or web camera) feature in Zoom is not a requirement, but rather is voluntary for meeting participants. For both the audio and video features in Zoom, you will have the option to Start or Stop these functions.

Students who participate with their camera engaged or who utilize a profile image are agreeing to have their video or image recorded. If you are unwilling to consent to have your profile or video image recorded, be sure to keep your camera off and do not use a profile image. Likewise, students who un-mute during class and participate orally are agreeing to have their voices recorded. If you are not willing to consent to have your voice recorded during class, you will need to keep your mute button activated and communicate exclusively using the "chat" feature, which allows students to type questions and comments live. As in all courses, unauthorized recording and unauthorized sharing of recorded materials is prohibited.

[Zoom Software Privacy Statement](#)

[Canvas \(by Instructure\) Privacy Policies](#)

Campus Resources:

Health and Wellness

U Matter, We Care:

If you or a friend is in distress, please contact umatter@ufl.edu or 352 392-1575 so that a team member can reach out to the student.

Counseling and Wellness Center: counseling.ufl.edu/cwc, and 392-1575; and the University Police Department: 392-1111 or 9-1-1 for emergencies.

Sexual Assault Recovery Services (SARS)

Student Health Care Center, 392-1161.

University Police Department at 392-1111 (or 9-1-1 for emergencies), or police.ufl.edu.

Academic Resources

E-learning technical support, 352-392-4357 (select option 2) or e-mail to Learning-support@ufl.edu.

Career Resource Center, Reitz Union, 392-1601. Career assistance and counseling.

Library Support, Various ways to receive assistance with respect to using the libraries or finding resources.

Teaching Center, Broward Hall, 392-2010 or 392-6420. General study skills and tutoring.

Writing Studio, 302 Tigert Hall, 846-1138. Help brainstorming, formatting, and writing papers.

Student Complaints Campus

On-Line Students Complaints