

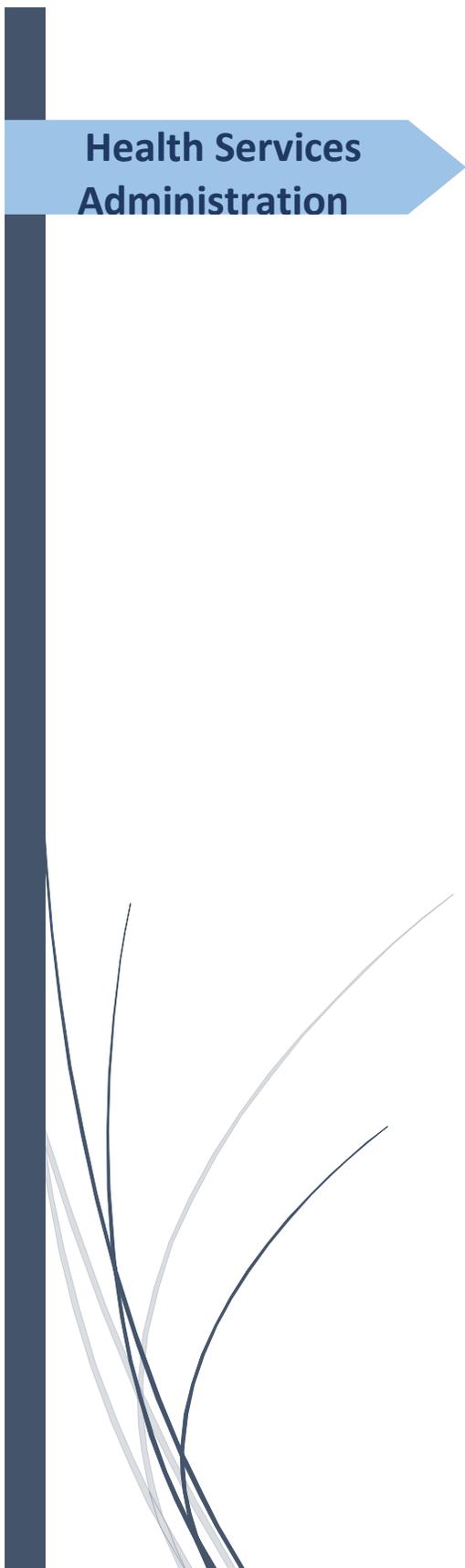
**Health Services
Administration**

**University of Wyoming
PHCY 5242
The Food and Drug
Administration
Spring 2022
Jan 16 to Feb 20**



UNIVERSITY
OF WYOMING

College of Health Sciences
School of Pharmacy



PHCY 5242 The Food and Drug Administration

Background:

The Food and Drug Administration is a two credit hour course. Before new drugs can be used in therapy, they must be approved by the federal Food and Drug Administration. The FDA has broad authority to develop and enforce standards related to the quality and safety of pharmaceutical products, as well as other articles used in patient care. This course provides an overview of the authority and responsibility of the FDA.

Course Description:

This is a survey course that examines the regulatory climate for FDA-regulated products, focusing primarily on drugs and biologics. Regulatory standards from cradle to grave are reviewed, starting with the discovery of new therapeutic modalities, through their approval, manufacturing, promotion, and distribution, to their use in the care of patients. The enforcement authority of the FDA is examined, with a particular focus on methods that promote safe and effective drug use through regulatory compliance.

Course Purpose:

The purpose of this course is to provide the foundational knowledge and skills necessary to establish regulatory compliance systems that will promote compliance with laws and regulations related to the quality and safety of pharmaceutical products.

COURSE OBJECTIVES:

Upon successful completion of this course, the student will be able to:

- List the characteristics of products regulated by the FDA, including drugs, “new” drugs, generics, biologics, dietary supplements, foods, and medical devices.
- Describe the process through which a drug or biologic sponsor obtains FDA approval to place the product into interstate commerce through a full NDA, ANDA, sNDA, 505(b)(2) submission, or a BLA.
- Discuss the misbranding standards that apply to the labeling and promotion of products regulated by the FDA.
- Discuss the limits of freedom of speech as applied to promotional statements made by representatives of a product that is being touted as a safe and effective therapeutic agent.
- Describe the regulatory requirements through which the FDA is responsible for the reduction of risk in the use of products that have been determined to be inherently safe and effective in premarketing studies, yet may nevertheless be used in unsafe or ineffective ways once they have been placed on the market.
- Discuss the indirect authority that the FDA has been given to regulate practices by state-licensed health care professionals who are responsible for the distribution and use of FDA-regulated products.
- Describe how the FDA uses its regulatory authority to develop and disseminate standards for the development, production, and distribution of pharmaceutical products, as well as the enforcement mechanisms available to the agency when standards have not been met.
- Discuss the challenge of high drug prices, and the opportunities available to the FDA to address the problem of drug affordability so that persons who need safe and effective drugs can overcome cost barriers and be given access to drugs they need.

COURSE LEARNING RESOURCES:

- Pre-Recorded Lecture
 - The Challenge of FDA Regulation
- Journal Articles
- Legal Case Studies

INSTRUCTOR AVAILABILITY/ CONTACT INFORMATION:

Dr. Eli Phillips, Jr. PharmD, JD

Email: ephill11@uwyo.edu

Office Hours: As arranged.

CLASS WEBSITE:

The WyoCourses site is accessible from the University website via WyoWeb. Class lectures and slide sets will be posted or linked on this site. Assignments will also be posted there (both by the instructor and the student). The student is expected to utilize the site and accept changes from this syllabus as amended on the site. You may not be able to see the course materials until two weeks prior to the course.

PLACE AND TIME OF CLASS SESSIONS:

This is a condensed course that will be taught over a five week period. The course will be taught in a blended fashion, with organized class sessions being combined with heavy reliance on an active discussion board. Live lectures will be held on Sunday evenings from 7p-9p ET (5p-7p Mountain Time). Learning materials will be posted on WyoCourses and may be accessed at any time. Participation in the discussion board is mandatory. Successful discussion board participation requires one original post and two responsive posts each week. There will be five exams that will start at 7am on Fridays and will end at noon on Sundays.

COURSE PROCEDURES:

All students will join the class at the same time (synchronous). Some activities, such as viewing recorded lectures can be done at the student's selected times (asynchronous). Opening and closing times for the modules, quizzes, or other activities will be posted and enforced.

A class session/assignment is the time that includes the live session, the pre-session work, and any immediate post-session work. For this class, a session/assignment will become available as noted in the Syllabus with due dates listed for each item.

Instructional procedures consist of pre-recorded lecture, discussion, participation exercises plus assigned readings and projects. The distance education model of this course requires some adaptation by the students and instructor from the traditional classroom setting. You may be recorded with your face and name. This recording will be placed on a password protected site, but no guarantees are made on its security.

Different people have different learning styles. Lecture where the instructor talks and students listen is passive on the part of the student. Discussion requires active participation on the part of the learner. In this class, some topics are appropriate for lectures; some are appropriate for discussion; and some will be conducted through active participation such as analysis of case studies and or discussion boards.

GENERAL REQUIREMENTS AND EXPECTATIONS:

Students should obtain the required textbook and complete assigned readings prior to the live online date listed in the course calendar. Students are encouraged to participate in live class sessions; active participation will also count towards your discussion board grade (see last page

of syllabus for Guideline for Evaluating Participation.

In order for a discussion or dialogue to be successful, students must have read the assigned readings, watched any video recording and have completed some assignments **before** joining class. Assignments will be clearly indicated whether due before or after the live session.

Whether a lecture or discussion, students should feel free to ask questions during class or on-line. If you have a question, other students may have the same question.

ATTENDANCE AND ABSENCE POLICIES:

Attendance at scheduled online classes through Big Blue Button is mandatory. The course coordinator will excuse students from class based on a valid reason. Classes will be recorded for later viewing (within two weeks) by students who have been excused from attendance. There is a requirement for weekly postings on the course discussion board. All postings must relate to the general course objectives. All students are expected to make weekly posts that are relevant to the course based on material that is being completed that week.

Participation is defined as asking questions, providing personal experience to the class, giving recommendations, etc. Comments can be either verbal or via chat.

Since some of the projects may be started in the live sessions, missing class can make projects much more difficult. Because of the multiple available times for posting assignments as well as for taking any quizzes or examinations, the need for an excused absence would be a rare event. Only rationale accepted by the University of Wyoming as an excused absence will be accepted. Any anticipated absence from the live sessions should be discussed in advance with the instructor.

CLASSROOM BEHAVIOR POLICY:

At all times, treat your presence in the classroom and your enrollment in this course as you would any professional activity. Act professionally, arrive on time, pay attention, complete your work in a timely and professional manner, and treat all deadlines seriously. All of us will be respectful of each other. Spirited debate and disagreement are to be expected in any graduate level course and all views will be heard fully, but at all times we will behave civilly and with respect towards one another. Personal attacks, offensive language, name-calling, and dismissive gestures are not warranted in a learning atmosphere. This is a safe environment and as the instructor, I have the right to dismiss anyone from the classroom, study sessions, electronic forums, and other areas where disruptive behavior occurs – there is zero tolerance on this issue.

Discrimination and harassment will not be tolerated in this class! Cases of academic dishonesty will be treated in accordance with UW Regulation 2-114. The penalties for academic dishonesty can include, at my discretion, an “F” on an exam, an “F” on the class component exercise, and/or an “F” in the entire course. Academic dishonesty includes plagiarism, which means anything that represents someone else’s ideas as your own without attribution. It is intellectual theft – stealing - and includes (but is not limited to) unapproved assistance on examinations, plagiarism (use of any amount of another person’s writings, blog posts, publications, and other materials without attributing that material to that person with citations), or fabrication of referenced information. Facilitation of another person’s academic dishonesty is also considered academic dishonesty and will be treated identically.

Such conduct is described within and will result in sanctions pursuant to the following School of Pharmacy and University policy and regulations:

University of Wyoming Code of Conduct
<http://www.uwyo.edu/dos/conduct/>

University of Wyoming Regulations
http://www.uwyo.edu/generalcounsel/_files/docs/UW%20Reg%20Updates%202016/UW%20Reg%206-802.pdf

DUTY TO REPORT:

While this is a safe environment and I want you all to feel comfortable coming to me with issues you may be struggling with or concerns you may be having, please be aware that I have some reporting obligations that are part of my faculty requirements at UW.

For example, if you inform me of an issue of sexual harassment, sexual assault, or discrimination I will keep the information as private as I can, but I am required to bring it to the attention of the institution's Title IX Coordinator. If you would like to talk to those offices directly, you can contact Equal Opportunity Report and Response (Bureau of Mines Room 319, 766-5200, report-it@uwyo.edu, www.uwyo.edu/reportit). Additionally, you can also report incidents or complaints to the UW Police Department. You can also get support at the STOP Violence program (stopviolence@uwyo.edu, www.uwyo.edu/stop, 766-3296) (or SAFE Project (www.safeproject.org, campus@safeproject.org, 766-3434, 24-Hour hotline: 745-3556).

Another common example is if you are struggling with an issue that may be traumatic or unusual stress. I will likely inform the Dean of Students Office or Counseling Center. If you would like to reach out directly to them for assistance, you can contact them using the info below or going to www.uwyo.edu/dos/uwyocares.

Finally, know that if, for some reason, our interaction involves a disruptive behavior or potential violation of policy, I must inform the Dean of Students, even when you and I may have reached an informal resolution to the incident. The purpose of this is to keep the Dean apprised of any behaviors (by students or faculty) and what was done to resolve them.

SUBSTANTIVE CHANGES TO THE SYLLABUS:

All deadlines, requirements, and course structure are subject to change if deemed necessary by the instructor. Students will be notified verbally in class or on our WyoCourses announcement page and/or via email of these changes.

STUDENT RESOURCES:

- DISABILITY SUPPORT SERVICES: udss@uwyo.edu, 766-3073, 128 Knight Hall, www.uwyo.edu/udss
- COUNSELING CENTER: uccstaff@uwyo.edu, 766-2187, 766-8989, 341 Knight Hall, www.uwyo.edu/ucc
- ACADEMIC AFFAIRS: 766-4286, 312 Old Main, www.uwyo.edu/acadaffairs
- DEAN OF STUDENTS OFFICE: dos@uwyo.edu, 766-3296, 128 Knight Hall, www.uwyo.edu/dos UW
- POLICE DEPARTMENT: uwpd@uwyo.edu, 766-5179, 1426 E Flint St, www.uwyo.edu/uwpd
- STUDENT CODE OF CONDUCT WEBSITE: www.uwyo.edu/dos/conduct

"If you have a physical, learning, sensory or psychological disability and require accommodations, please let me know as soon as possible. You will need to register with, and possibly provide documentation of your disability to Disability Support Services (DSS), room

109 Knight Hall. You may also contact DSS at (307) 766-3073 or udss@uwyo.edu. Visit their website for more information: www.uwyo.edu/udss."

COVID-19 POLICIES – during this pandemic, you must abide by all UW policies and public health rules put forward by the City of Laramie (or by Natrona County if at UW-Casper), the University of Wyoming and the State of Wyoming to promote the health and well-being of fellow students and your own personal self-care. The current policy is provided for review at: <https://www.uwyo.edu/alerts/campus-return/index.html>

As with other disruptive behaviors, we have the right to dismiss you from the classroom (Big Blue Button and physical), or other class activities if you fail to abide by these COVID-19 policies. These behaviors will be referred to the Dean of Students Office using the UWYO Cares Reporting Form for Student Code of Conduct processes (https://cm.maxient.com/reportingform.php?UnivofWyoming&layout_id=5).

Syllabus Changes: I will alert you to any possible course format changes in response to UW decisions about community safety during the semester.

HYFLEX, ZOOM, BIG BLUE BUTTON, AND WYOCOURSES EXPECTATIONS:

As with all UW coursework, this course will be educational and useful to you. I will respond to questions, concerns, and feedback in a timely manner.

Your responsibilities:

- Give and receive feedback from me and your classmates respectfully and constructively in all interactions. This includes in Big Blue Button chats, on WyoCourses boards, and within physical classroom spaces.
- Actively engage in civil discourse in a respectful manner. Use professional language in all course related forums.
- Communicate professionally. Whenever you send class-related email or messages, please include a clear, specific subject line and use the body of the email or message to explain the purpose for the email and any attached materials. Conduct yourself professionally.
- Meet assignment deadlines. We expect that you're interacting with course material multiple times during the week.
- Ask for help when you need it. For academic assistance for this course please contact me for available resources. For Dean of Students assistance please see: <https://www.uwyo.edu/dos/student-resources/covid-19-student-resources.html>
- Please let us know if you notice another student who needs help in our (anonymous) WyoCares referral option (<https://www.uwyo.edu/dos/students-concern/index.html>).

INFORMATION TECHNOLOGY (IT): If you have any IT related challenges, please contact the UWIT Service Center:

<https://uwyo.teamdynamix.com/TDClient/1940/Portal/Requests/ServiceDet?ID=8890>

COURSE STRUCTURE & OUTLINE:

This course is comprised of five modules, to be completed over a period of five weeks.

The five modules are:

- Classification of FDA Regulated Articles
- The Approval of New Drugs and Biologics
- Drug Labeling Requirements
- Pharmaceutical Quality
- Post-marketing Surveillance

COURSE SCHEDULE:**Week I: Classification of FDA Regulated Articles**

- Live class meets on January 23.
- Prior to Class on January 23:
 - Read monograph “Rx v. OTC Classification”
 - Read handout: “The Challenge of FDA Regulation”
 - Read Case Report: United States v. Hiland & Food Case Summaries
- One-page memorandum “Recall or Recondition” is due at 11:59pm on Thursday January 27, 2022.
Discussion Board is open all week and due 11:59p on Saturday January 29, 2022.
- Exam I opens on Friday (January 28, 2022) at 7am, closes on Sunday (January 30, 2022) at noon.

Week II: The Approval of New Drugs & Biologics

- Live class meets on January 30.
- Prior to Class on January 30:
 - Read monograph “The Food and Drug Administration Regulatory Role”
 - Read Case Report: Ancheff v. Hartford Hospital
- One-page memorandum “REMS or Withdraw”: is due at 11:59pm on February 3rd.
Discussion Board is open all week and due 11:59p on Saturday February 5th
- Exam II opens on Friday (2/4) at 7am, closes on Sunday (2/6) at noon.

Week III: Drug Labeling Requirements

- Live class meets on February 6
- Prior to Class on February 6:
 - Read monograph “Drug Labeling and Off-Label Use”
 - Read Case Report: United States v. Evers
- One-page memorandum “Off-label Incident” is due at 11:59pm on February 10.
Discussion Board is open all week and due 11:59p on 2/12.
- Exam III opens on Friday (2/11) at 7am, closes on Sunday (2/13) at noon.

Week IV: Pharmaceutical Quality

- Live class meets on February 13
- Prior to Class on February 13:
 - Read monograph “Compliance with Compounding Standards” & Contract Manufacturing Agreements: Quality Agreements
- One-page memorandum “Drug Shortages and Prices” is due at 11:59pm on February 17.
Discussion Board is open all week and due 11:59p on 2/19.
- Exam IV opens on Friday (2/18) at 7am, closes on Sunday (2/20) at noon.

Week V: Post-marketing Surveillance

- Live class meets on February 20.
- Prior to Class on February 20:
 - Read monograph “Postmarketing Surveillance and Risk Management”
- NO DISCUSSION BOARD IS DUE THIS WEEK.
- Exam V opens on Monday February 21 at 7am, closes on Friday February 24 at noon.

EVALUATION TECHNIQUES:

Class participation (discussion board)	20%
Exams	40%
Memoranda	40%

GRADING:

A:	90.0 – 100.0
B:	80.0 – 89.9
C:	70.0 – 79.9
D:	60.0 – 69.9
F:	<60.0

EXAMS/WRITTEN EXERCISES POLICY:

Inquiries regarding exams and written exercises should be directed to the course coordinator, preferably prior to the assessment, and always within a week following the assessment.

MAKE-UP EXAM POLICY:

Students who are excused from an exam may or may not be required to make up that assessment dependent on the faculty decision. The final grade will be calculated without consideration of the missed assessment. Students who are not excused from a missed quiz or exam will receive a grade of zero on that missed assessment. Any student who misses quizzes and/or exams of a sufficient number that indicate the student has not completed enough coursework to achieve the objectives of the course will be given an incomplete (I) grade for the course.

POLICY ON OLD EXAMS AND ASSIGNMENTS:

At the discretion of the instructor, exams and written exercises may be posted, with answers, to the course discussion board.