



USC Department of Regulatory
and Quality Sciences

MPTX 514: Regulation of Foods and Dietary Supplements

Term: Summer, 2022

Instructors: Roger Clemens, DrPH, USC School Pharmacy
Mary Hardy, MD, Former Medical Director of the Simms/Mann-UCLA Center for Integrative Oncology

Guest Instructors: Joseph Betz, PhD – Office of Dietary Supplements
Mark Blumenthal, PhD – American Botanical Council
Tod Cooperman, MD – Consumer Lab
Johanna Dwyer, DSc, RD – Office of Dietary Supplements
Holly Johnson, PhD – American Herbal Products Association
Joy Joseph, Joys Quality Management
Adam Kuszak, PhD – Office of Dietary Supplements
Narain Naidu, PhD – enNTech
Peter Pressman, MD – Polyscience Consulting / University of Maine
Jay Sirois, PhD – Consumer Health Products Association
Michael Smith, ND – Carolinas Natural Health Center

Course Units: 3 units

Course Registration: Section: 48814

Course Time/Dates: 9 am – 5 pm (Pacific); May 21, June 12, June 26, July 10, July 24, 2022

Classroom: Center for Health Professions (CHP), Room Assignment Posted Weekly

Department Office: 1540 Alcazar Street CHP 140, Los Angeles, CA 90033

Office Hours: By appointment only (in-person and virtual meetings are encouraged)

Contact Info: Email: clemens@usc.edu
Office: 323-224-2124
Cell: 818-624-2616

Recommended Preparation:

Undergraduate degree in pharmacy, medical or independent health sciences, engineering or equivalent mix of post-secondary training and industry experience.

Introduction and Purposes

The growing importance of “healthy foods” in today’s society has resulted in a growth of regulations governing foods, functional foods and dietary supplements. These rules vary substantially amongst different countries of the world. Students will examine the differing rules governing traditional foods, functional foods and dietary supplements in the US and other countries. They will consider the impact of recent scientific advances, social pressures, and political agendas on the development of domestic and international regulatory policies. The regulation of foods and herbs/botanicals in other countries will be examined and the relative merits of different systems will be analyzed and debated.

Learning Objectives

By the end of the course, students will be expected to demonstrate the following knowledge and skills:

- Assess and apply required information for labeling of human foods and foods for companion animals
- Describe the basic supporting principles for NDI and GRAS determination and notification processes
- Explain the features that differentiate dietary supplements from foods and drugs (see CFRs)
- Formulate appropriate claims for dietary supplements and functional foods, recognizing the limits to which claims language must adhere
- Write a draft test plan to evaluate the safety of a new dietary supplement and explain the safe of such substance (see NDIN final guidance, Federal Register, 2016)
- Design a label for a food and for a dietary supplement
- Describe a testing approach to characterize a botanical product and explain how to find and negotiate with a third-party testing laboratory
- Describe the roles of the FDA and FTC in enforcement actions against companies that violate labeling and advertising rules
- Identify three key pressures on the policy arena that will probably change the laws governing foods and dietary supplements over the next several years, such as standards of identity, updates in DSHEA 1994, and cannabis legislation

Students will work in teams to develop appropriate testing plans, documentation, and advertising for a range of food-related products. Some parts of the course will be taught through case studies presented by the students. An emphasis will be placed on relatively informal lecture formats in which students are encouraged to ask and answer questions throughout the didactic sessions. As part of a novel strategy to meet the needs of part-time as well as full-time students, the course will be taught in a condensed period of five (5) full days in the summer term; lecture-discussions will occupy a total of approximately 40 face-to-face hours.

Class Topics/ Discussion Items

These and related topics are indicated below.

1. Introduction to cGMP for Dietary Supplements
2. Overview of New Dietary Ingredient Process
3. Examination of Generally Recognized As Safe Criteria
4. Synopsis of Key Regulatory Concepts and Terms
5. Assessment of Dietary Supplements in Primary Care Settings
6. Appraisal of Dietary Supplements in Alternative and Integrative Medicine
7. Analysis of Dietary Supplements and SARS-CoV-2
8. Summary of Safety of Dietary Supplement Ingredients
9. Outline of Adverse Effects of Dietary Supplements
10. Assessment of Dietary Supplements Health Claims
11. Inspection of Differences between Dietary Supplements and OTC Drugs
12. Initiation to USP Dietary Supplement Verification Program
13. Summation of Consumer Lab Testing
14. Primer on Nutrition and Toxicology of Dietary Supplements
15. Exploration of Office of Dietary Supplements: Mission and Operations
16. Review of Dietary Supplements Value among Healthy Aging
17. Prospectus on Next Generation of Clinical Assessment and Dietary Regulations

Course Requirements and Grades:

Assignment	Title	DUE Date	Percent of Grade
1	Deliverable #1 – Critical assessment of dietary supplement advertisements and marketing’s (written and oral)	Posted on Blackboard Oral due Sunday, June 26, 2022 Written Due Monday, June 27, 2022 (NLT 9 am)	25%
2	Deliverable #2 - Assessment of three AAFCO presentations by Dr. Dzanis	URLs to be provided Written Due on Monday, July 11 (NLT 9 am)	5%
2	Deliverable #3 – Critical analysis of filed legal complaints pertinent to dietary supplements (written)	Posted on Blackboard Due Monday, August 8, 2022 (NLT 9 am)	25%
4	Deliverable #4 - Worksheet summary from Sunday, July 24, 2022, presentations	Worksheet provided on Blackboard Due on Friday, August 12 (NLT 9 am)	15%
5	Deliverable #5 - Course Exam: Take Home	Posted on Blackboard Due Friday, August 19 (NLT 9 am)	30%
Extra Credit			
6	Extra Credit - Assessment of Food Evolution video (~92 min) that addresses GMO (technology, production, labeling, disputed cases)	URL to be provided Written Due on Friday, August 12 (NLT 9 am)	30 pts

Deliverable #1 will be evaluated on both the presentation to the class and the written submission to the instructors. The presentation in class will be marked by both the class members and the instructors using the appended evaluation sheet. The written submissions will be evaluated on the basis of:

- Clarity of presentation
- Appropriate identification and description of problem to be solved
- Correct identification of regulatory issues

- Appropriateness of solutions to the problem
- Appropriate use of source materials collected as a reference list

All other deliverables will be evaluated on the student's ability to provide cogent and critical assessments of the respective topics and final exam.

Distance Students:

Please contact Erin Chow at erinchow@usc.edu with any questions and for testing arrangements.

ALL STUDENTS:

All submissions are to be entered in to <http://blackboard.usc.edu>, emailed to Erin Chow at erinchow@usc.edu and to Dr. Clemens (clemens@usc.edu) to ensure confirmation of receipt. Be sure to see the accompanying Getting Started sheet for directions.

Please format MS Word file titles with your last name, initial, course number and assignment number, for example: Brown_C_514_A1.docx. **Be sure to include your name, the course number and title at the beginning of the text itself.**

If applicable, provide details of accessing course if not in a traditional classroom setting.

Attendance and Conduct:

The Student Handbook, SCampus, and University Catalogue provide guidance regarding academic policies and procedures. Students should regard the program as a part of their professional development in which courtesy and responsibility are significant factors in success. Thus, students are expected to communicate absences from class and are expected to attend all examinations and class presentations by themselves and their colleagues. Under normal circumstances, papers and exams must be completed on the day that they are scheduled for submission. Failure to make appropriate arrangements in case of justifiable delay will result in a penalty of 10% in the assignment mark.

Textbooks and Reference Materials

Useful Professional Reference: Fortin, ND. Food Regulation – Law, Science, Policy, and Practice, 2nd edition Wiley Press, 2017; Available on Amazon (~\$130); 3rd edition available on Amazon (~\$160)

Supplementary Readings

All supplementary readings for each course session will be posted on Blackboard.

Statement on Academic Conduct and Support Systems

Academic Conduct:

Plagiarism – presenting someone else’s ideas as your own, either verbatim or recast in your own words – is a serious academic offense with serious consequences. Please familiarize yourself with the discussion of plagiarism in SCampus in Part B, Section 11, “Behavior Violating University Standards” policy.usc.edu/scampus-part-b. Other forms of academic dishonesty are equally unacceptable. See additional information in SCampus and university policies on [Research and Scholarship Misconduct](#).

Students and Disability Accommodations:

USC welcomes students with disabilities into all of the University’s educational programs. The Office of Student Accessibility Services (OSAS) is responsible for the determination of appropriate accommodations for students who encounter disability-related barriers. Once a student has completed the OSAS process (registration, initial appointment, and submitted documentation) and accommodations are determined to be reasonable and appropriate, a Letter of Accommodation (LOA) will be available to generate for each course. The LOA must be given to each course instructor by the student and followed up with a discussion. This should be done as early in the semester as possible as accommodations are not retroactive. More information can be found at osas.usc.edu. You may contact OSAS at (213) 740-0776 or via email at osasfrontdesk@usc.edu.

Support Systems:

Counseling and Mental Health - (213) 740-9355 – 24/7 on call
studenthealth.usc.edu/counseling

Free and confidential mental health treatment for students, including short-term psychotherapy, group counseling, stress fitness workshops, and crisis intervention.

National Suicide Prevention Lifeline - 1 (800) 273-8255 – 24/7 on call
suicidepreventionlifeline.org

Free and confidential emotional support to people in suicidal crisis or emotional distress 24 hours a day, 7 days a week.

Relationship and Sexual Violence Prevention Services (RSVP) - (213) 740-9355(WELL), press “0” after hours – 24/7 on call
studenthealth.usc.edu/sexual-assault

Free and confidential therapy services, workshops, and training for situations related to gender-based harm.

Office for Equity, Equal Opportunity, and Title IX (EEO-TIX) - (213) 740-5086
eeotix.usc.edu

Information about how to get help or help someone affected by harassment or discrimination, rights of protected classes, reporting options, and additional resources for students, faculty, staff, visitors, and applicants.

Reporting Incidents of Bias or Harassment - (213) 740-5086 or (213) 821-8298

usc-advocate.symplicity.com/care_report

Avenue to report incidents of bias, hate crimes, and microaggressions to the Office for Equity, Equal Opportunity, and Title for appropriate investigation, supportive measures, and response.

The Office of Student Accessibility Services (OSAS) - (213) 740-0776

osas.usc.edu

OSAS ensures equal access for students with disabilities through providing academic accommodations and auxiliary aids in accordance with federal laws and university policy.

USC Campus Support and Intervention - (213) 821-4710

campussupport.usc.edu

Assists students and families in resolving complex personal, financial, and academic issues adversely affecting their success as a student.

Diversity, Equity and Inclusion - (213) 740-2101

diversity.usc.edu

Information on events, programs and training, the Provost's Diversity and Inclusion Council, Diversity Liaisons for each academic school, chronology, participation, and various resources for students.

USC Emergency - UPC: (213) 740-4321, HSC: (323) 442-1000 – 24/7 on call

dps.usc.edu, emergency.usc.edu

Emergency assistance and avenue to report a crime. Latest updates regarding safety, including ways in which instruction will be continued if an officially declared emergency makes travel to campus infeasible.

USC Department of Public Safety - UPC: (213) 740-6000, HSC: (323) 442-120 – 24/7 on call

dps.usc.edu

Non-emergency assistance or information.

Office of the Ombuds - (213) 821-9556 (UPC) / (323-442-0382 (HSC)

ombuds.usc.edu

A safe and confidential place to share your USC-related issues with a University Ombuds who will work with you to explore options or paths to manage your concern.

Occupational Therapy Faculty Practice - (323) 442-3340 or otfp@med.usc.edu

chan.usc.edu/otfp

Confidential Lifestyle Redesign services for USC students to support health promoting habits and routines that enhance quality of life and academic performance.