

NUTC 281
Nutrition Product Regulations: Labeling and Claims
Tufts University, Friedman School of Nutrition Science and Policy
Online Graduate Certificate Program

Spring 2021
(January 2021 – May 2021)

Instructors:

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Tufts Graduate Credit: 3

Prerequisite: None

Course Description:

Understanding the regulatory environment is critical to the successful development, manufacturing, labeling, marketing, and delivery of nutrition-related products to the consumer. Knowing how to manage risk while navigating the regulatory path to market is essential. Students in this course will become familiar with: the regulations applicable to foods, medical foods, dietary supplements, personalized nutrition products and ingredients; how to represent scientific evidence accurately and appropriately when substantiating label claims and advertisements; and develop a working knowledge of potential legal ramifications by examining a relevant case studies.

Course Objectives:

As a student in this course, you will learn to navigate the regulations of food and dietary supplement products to ensure market access and keeping your product on the market.

By the end of the course, students will be able to:

- Summarize FDA labeling laws and compare requirements for different types of products.
- Compare and contrast international and European food laws to the US FDA food laws.
- Identify and determine the appropriate use of nutrient claims, health claims, and structure/function claims
- Determine the type of scientific evidence necessary to support each claim
- Identify potential risks associated with the labeling of nutrition-related products/services
- Create a novel product with an FDA compliant label, appropriate product claims and marketing messages.

Academic Conduct:

Each student is responsible for upholding the highest standards of academic integrity, as specified in the Friedman School's Policies and Procedures manual (<http://nutrition.tufts.edu/student/documents>) and Tufts University policies ([http://uss.tufts.edu/studentaffairs/judicialaffairs/Academic Integrity.pdf](http://uss.tufts.edu/studentaffairs/judicialaffairs/Academic%20Integrity.pdf)). It is the responsibility of each student to understand and comply with these standards, as violations will be sanctioned by penalties ranging from failure on an assignment and the course to dismissal from the school.

Class Policies and Expectations

Student will have only one opportunity to complete each assignment, and all assignments are due on the date/time specified, unless agreed upon by Professor. Extensions can be granted on a case by case basis if instructors are informed prior to conflict. Students will have only one opportunity to compete each exam. Each exam must be completed and successfully submitted within the specified time period. Students who are unable to complete an assignment on time for any reason should notify the instructors by email (preferred) or phone call prior to the deadline, with an explanation as to why an extension is needed. The exception: Parts of the Product Development Project will be turned in throughout the semester and modified based on instructor feedback.

There are NO opportunities for extra credit work.

Students are expected to complete all assignments on their own, i.e. without assistance from other students, faculty, etc. unless otherwise noted. All outside documents used in the preparation of students' work must be properly referenced.

Instructors and other university personnel may request that students submit written assignments to plagiarism prevention resources, websites, or other authoritative databanks, such as (but not limited to) “turnitin.com” or a similar site. These services compare students-produced documents with web content, newspapers, journals, magazines, books, student essays, and other data to determine the originality of student work.

Students are expected to familiarize themselves with and adhere to the official policies regarding academic integrity for Tufts University that are presented in this handbook:

<http://www.nutrition.tufts.edu/student/documents/policies-procedures>

Communication Policy:

All communication will be sent to your Tufts email address. Please check it at least once a day. Students should try to seek out information for themselves before contacting the instructor. The answers to your questions may have already been posted by your peers or the instructors in the discussion board, which can be found on the Canvas course website. Please use the discussion board to post questions to your fellow students and the instructors about any course-related issues. If you cannot find your answer contact the instructors via email as soon as possible. Please do not wait until the last minute. Since students may not all be in the same time zone, you must give us time to respond to your question. Faculty will respond within 48 hours.

Assessment and Grading:

Online Quizzes	20%
Discussion Board	10%
Case Study	10%
Written assignments	25%
Product Labeling Project	35%

Grade Scale:

Grade	Score
A+	98.50-100
A	92.50-98.49
A-	90-92.49
B+	87.50-89.99
B	82.50-87.49
B-	80-82.49

No credit for course if grade is below a B-, per Friedman School Policy.

Assignments and Submission Instructions:

Assignments for this course (viewing online lectures, participating in online discussion forum, quizzes, case study, final project) are located in each week's module. Assignments should be submitted through Canvas, Discussion Board or where indicated by Instructors.

Lectures

Students will acquire new information from the on-line lecture and assigned readings and will provide an analysis of these facts during discussion board postings, quizzes and final project to successfully realize completion of this course. The lectures and assigned readings should be considered as the vehicle to provide proper guidance throughout the course. Supplemental readings may also be posted to enhance your understanding and analysis.

Online Discussion Forum

Students **must participate** in all discussion forums. For each discussion, students will be expected to 1) reflect on the assigned lecture and read background materials prior to their participation, 2) compose and submit initial posting by 11:59pm ET on Friday of that week, and 3) compose and submit at least 2 reply postings by 11:59pm ET on the following Sunday. Each student will be expected to post thoughtful, substantive comments that address the specific questions posed by the instructor, incorporate facts from the text/lectures, and are directly relevant to the assigned topic. Students will be graded on the quality of their initial and reply postings, demonstrated understanding of the assigned materials, and timeliness of each posting. Students are expected to participate actively, and in a timely fashion. Please refer to the Grading Criteria for Online Discussions rubric for details on these expectations, and how they relate to your grade for this assignment. Students may submit their postings only during the week in which a discussion forum is active.

All discussion forums (graded and ungraded) and detailed instructions can be found under the **Modules** link on the Canvas course site.

Online Discussion Forum Grading Criteria:

Quality of Posting/Reply	Details
No Posting or postings are not relevant to discussion posed	Not Acceptable
Posting reflect reading and are relevant to questions posed. Only 1 posting noted and/or postings did not make an analysis of new information presented in the lecture or readings.	Met minimum standards
Postings show a strong grasp of material, original thought with solid facts to back-up opinions and statements. Directly contributes to the discussion	Exceeded minimum standards

and communicates well with other students. Shows an ability to apply nutrition related topics to real life situations. At least 2-3 quality postings meeting word count requirements.	
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Product Development Project

The students will work on this project throughout the semester; parts of the project will be turned in and receive Professor feedback and guidance with the intent that all parts will be combined into a final presentation at the end of the semester. The purpose of this project is to give students the opportunity to apply concepts presented throughout the course to an actual novel nutrition solution and product. Each student will be required to do the following:

- Following directions found in the project guidance document to create a novel product with an FDA compliant label, appropriate product claims and marketing messages (refer to syllabus tab on Canvas).
- Identify a nutritional gap and consumer need that your nutrition product will fill.
- Your novel nutrition product should include: 1) product composition, 2) specific ingredients 3) level of nutrients/ingredinetns, 3) safety information (i.e. allergens) , 4) recommended serving size,5) beneficial ingredient(s) and recommended daily intake to obtain benefit (efficacious dose and form) and the science to support benefit(s), 6) how will your customer consume your product (mode of delivery), 7) packaging, 8) intended population.
- Determine what country(s) in which you plan to launch your product. What specific regulations do you need to follow? What are the labeling requirements for your package, website, brochure, etc? Are there special regulations that apply due to target population, product category?
- Determine and outline the claims your product will provide. When discussing the benefits of your product, include scientific support. What are the claim statements you plan to include on your label (marketing materials, i.e., brochures, website, print ads)?
- Identify potential risks with regard to challenges from FTC, competitors, legal watchdogs, etc. Have other companies gotten in trouble for a similar product?

Parts of this project will be due throughout the semester. The final project will incorporate revisions of these parts and be combined into one final project that will be presented at the end of the semester.

The following guidelines will be used in evaluating course performance:

1. Assignments will be evaluated on the basis of completeness, originality, scientific soundness and relevance to the assigned topic
2. Written work will be evaluated on the quality of thought, completeness, and adherence to guidelines, appropriate scientific references (as defined in course lectures) and ability to incorporate and communicate ideas and information effectively.
3. Adherence to instructions and guidelines of the assignments.
4. Participation in all class activities and discussion. Missed work will affect your grade unless prior arrangements were requested and approved in writing by the instructors for make-up work.
5. On-line discussions will be evaluated according to the discussion rubric.

Accommodation of Disabilities:

Tufts University is committed to providing equal access and support to all students through the provision of reasonable accommodations so that each student may access their curricula and achieve their personal and academic potential. If you have a disability that requires reasonable accommodations please contact the Friedman School Assistant Dean of Student Affairs at 617-636-6719 to make arrangements for determination of appropriate accommodations. Please be aware that accommodations cannot be enacted retroactively, making timeliness a critical aspect for their provision.

Technical Support

Online course support is provided by Friedman support staff and/or IT Support. Please do not contact faculty or TA's for technical support.

- **Telephone:** (617) 627-3376
- **Email:** canvas@tufts.edu
- **Hours:** 24 hours a day, seven days a week.

When reporting a problem, please include:

- The name and number of your online course (e.g. "NUTC 281 Online")
- Your operating system and browser
- A detailed description of the problem

This information will expedite the troubleshooting process. If you are sending a support request via email, please use your Tufts email address.

Many problems with Canvas are a result of using an unsupported

browser. Please make sure you are using an up-to-date version of Firefox, Safari, Chrome, or Internet Explorer.

Course Schedule *at-a-glance*: *This schedule is subject to modification at the instructors' discretion*

DATE	WEEK	TOPIC	Lecturer	Assignment Due This week	Product Development Project Milestone Due This week
	1	Course Introduction	Mitmesser/Weir	Introduce yourself in the general class discussion forum. Post on Discussion Board.	List 3 new nutrition product launches into the market. Post on Canvas.
Module 1: Claims and Scientific Substantiation					
	2	US Food Law overview	Weir	Navigate the FDA website and Answer label questions. Post on Discussion Board.	None
	3	US Food Supplement Labeling: DSHEA	Mitmesser	Practice making one nutrition facts label and one supplement facts label with all FDA required information. Post on Canvas.	None
	4	Nutrient Content Claims	Mitmesser	Quiz	Submit 2-3 ideas for a product (must be a food, dietary supplement, or medical food) you would like to develop throughout the semester. Post on Canvas.
	5	Health claims and Qualified Health Claims	Mitmesser	Give an example of a Health Claim and Qualified Health Claim; identify the type of scientific evidence needed to support each. Post on Canvas.	None
	6	Structure/ Function Claims	Mitmesser	Quiz	Create a label for your product. Post on Canvas.
	7	Personalized Nutrition	Weir	Quiz	None
Module 2: Regulations					
	8	US Regulations	Weir	Small Group Assignment. A different product will be assigned	None

		for Medical Foods		to each small group. The group must determine if the product should be classified as a: <ul style="list-style-type: none"> ✓ Medical food ✓ Dietary supplement ✓ Food Post on Canvas.	
	9	US FTC and Advertising	Weir	Identify 2 food or dietary supplement advertisements that could potentially lead to an FTC false advertising case. Post on Canvas.	None
	10	European Union – Food Laws	Weir	None	Determine and outline the scientific support needed for your product. Identify the type of each claim. Post on Canvas.
	11	International Influences on Food Regulations	Weir	Quiz	None
	12	FTC Case Study	Mitmesser	Case Study. Each student will choose 1 case (choose only 1 of the 4 options) and critically assess the case. Post on Canvas.	None
Module 3: Final Project Presentations					
	13-14	Final Project Presentations	Mitmesser/Weir	None	Final project presentation. Post on Discussion Board. Students provide feedback on each presentation.

Week 1 Introduction to Nutrition Regulations: Products, Claims, and Labeling

Upon completion of this week, students will be able to:

- Discover new nutrition products that are on the market
- Become familiar with FDA website [Labeling & Nutrition \(Food Labeling Guide website\)](#), Office of Dietary Supplements ([ODS website](#)).

Preparation:

- Watch *Introduction* lecture

Assignments for this week:

1. Introduce yourself in the general class discussion forum. In your posting, include (Post on Discussion Board):
 - a. Your background
 - b. Why you are taking this course
 - c. What you hope to learn from this course
2. List 3 new nutrition product launches on the market today. Answer the following questions (Post on Canvas):
 - a. Do you like the product? Why or why not.
 - b. What consumer benefit is the product providing?
 - c. How is it different than other products?

Module 1: Claims and Substantiation

Weeks 2 through 7. In this module, we will describe the specific types of labeling claims in the U.S. Students will identify the critical requirements US FDA has established for labeling Foods and Dietary Supplements.

Week 2 US Food Law Overview (Weir)

Upon completion of this week, students will be able to:

- Identify the organizational structure of FDA and its primary regulations relevant to food labeling
- Navigate internet-based resources to identify relevant US food laws and regulations.
- Discuss updated scientific information and the proposed changes to Nutrition Facts Label
- Identify the critical principles of US FDA requirements relevant to labeling foods
- Compare labels for foods, dietary supplements, and medical foods.

Preparation:

- Watch *FDA Laws* lecture

Assignments for this week:

1. Demonstrate basic knowledge of the US FDA label for a nutrition-related product (Post on Discussion Board). Answer the following questions:
 - a. List three major elements of a product label?
 - b. When must you add a Nutrition Facts Panel to your product label?

- c. What are the alternative label formats for small or intermediate-sized packages?
- d. List two major changes to the Nutrition Facts label.
- e. A label will be required for your final project. What must you consider when designing your package and label?

Week 3 US Food Supplement Labeling: DSHEA (Mitmesser)

Upon completion of this week, students will be able to:

- Describe and/or summarize DSHEA
- Identify the critical requirements US FDA has established for labeling dietary supplements (including advertising materials such as brochures, websites).
- Compare food labels to determine food composition, nutrients, serving sizes and nutrition facts vs supplement facts.
- Navigate the Office of Dietary Supplements (ODS) website

Preparation:

- Watch *DSHEA* lecture and *Warnings* lecture

Assignments for this week:

1. Practice making one nutrition facts label and one supplement facts label with all FDA required information (Post on Canvas).

Week 4 Nutrient Content Claims (Mitmesser)

Upon completion of this week, students will be able to:

- Describe nutrient content claims
- Discuss the different nutrient claims and apply to a given product
- Explain the level of scientific evidence necessary to support a nutrient claim

Preparation:

- Watch *Nutrient Claims* lecture

Assignments for this week:

1. Quiz – you will have 10 minutes to take the quiz; 1 attempt.
2. Submit 2-3 ideas for a product (must be a food, dietary supplement, or medical food) you would like to develop throughout the semester (Post on Canvas). Answer the following for each idea:
 - a. The target population the product is intended for (i.e., elderly, someone that is vitamin D deficient, someone with a dairy allergy)
 - b. Why does this population need this product?
 - c. How is your product unique compared to other products on the market?

Week 5 Health Claims and Qualified Health Claims (Mitmesser)

Upon completion of this week, students will be able to:

- Describe the different types of health claims and apply to a product
- Explain the level of scientific evidence necessary to support a health claim

Preparation:

- Watch *Health Claims* lecture

Assignments for this week:

1. Given an example of a Health Claim and a Qualified Health Claim. Identify the type of scientific evidence needed to support each (you do not need to identify the actual evidence) (Post on Canvas).

Week 6 Structure/Function Claims (Mitmesser)

Upon completion of this week, students will be able to:

- Describe structure/function claims
- Compare and contrast the differences between health claims, nutrient content claims, and structure/function claims
- Explain the level of scientific evidence necessary to support a structure/function claim

Preparation:

- Watch *Structure/Function Claims* lecture

Assignments for this week:

1. Quiz – you will have 10 minutes to take the quiz; 1 attempt.
2. Create a label for your product (Post on Canvas). This should include the following:
 - a. All ingredients in the product
 - b. Dose of each active ingredient
 - c. What makes your product unique and differentiated?
 - d. Nutrition or supplement facts panel

Week 7 Personalized Nutrition (Weir)

Upon completion of this week, students will be able to:

- Describe wellness claims as defined by the US FDA
- Discuss the FDA's approach to wellness benefits
- Navigate FTC website resources relevant to wellness

Preparation:

- Watch *Personalized* lecture

Assignments for this week:

1. Quiz – you will have 10 minutes to take the quiz; 1 attempt.

Module 2: Regulations

Weeks 8 through 12. Students will learn the global regulatory requirements for Foods, Medical Foods, Dietary Supplements, with a particular focus on the US. We will use case studies as a tool to understand how the FDA applies and interprets the law. You will gain an understanding of how companies interpret FDA regulations and the challenges they face.

Week 8 US Regulations for Medical Foods (Weir)

Upon completion of this week, students will be able to:

- Navigate internet-based resources to identify food laws and regulations.
- Compare and contrast dietary supplements and medical foods
- Discuss the approach to placing medical foods in market including what scientific evidence is needed.

Preparation:

- Watch *Medical Foods* lecture

Assignments for this week:

1. Small group assignment (Post on Canvas). A different product will be assigned to each small group. The group must determine if the product should be classified as:
 - ✓ Medical Food
 - ✓ Dietary Supplement
 - ✓ Food
2. Provide supporting evidence for your choice
3. All students in a group will submit the same response.

Week 9 US FTC and Advertising (Weir)

Upon completion of this week, students will be able to:

- Describe the responsibilities of the Federal Trade Commission (FTC), and the Food and Drug Administration (FDA) as applied to food advertising and marketing foods and dietary supplements.
- Be able to identify FTC's advertising principles
- Discuss advertising information and evaluate FTC compliance (i.e., scientific support, testimony).

Preparation:

- Watch *FTC* lecture

Assignments for this week:

1. Identify 2 food or dietary supplement advertisements that could potentially lead to an FTC false advertising case. Describe what changes could be made to become compliant (Post on Canvas)

Week 10 European Union Food Laws (Weir)

Upon completion of this week, students will be able to:

- Navigate internet-based resources to identify relevant European food laws and regulations.
- Describe the role of the European Food Safety Authority (EFSA) and the impact on health claims on products in the EU.
- Discuss EFSA's approach to assessing scientific evidence supporting a claim

Preparation:

- Watch *EU* lecture

Assignments for this week:

1. Determine and outline the scientific support needed for your product. Identify each claim as a structure/function claim, nutrient content claim, or

health claim. provide supporting scientific evidence for each claim (Post on Canvas).

Week 11 International Influences on Food Regulations (Weir)

Upon completion of this week, students will be able to:

- Summarize the factors that influence international food regulations: Codex, WHO, WTO.
- Be able to identify food safety, market trends, private standard influences on global food trade.
- Summarize the Codex Standard making process and the implications for industry (A case study)

Preparation:

- Watch *International* lecture

Assignments for this week:

1. Quiz – you will have 10 minutes to take the quiz; 1 attempt.

Week 12 Case study: Company vs FTC (Mitmesser)

Upon completion of this week, students will be able to:

- Apply skills you have acquired through Module 1 and Module 2
- Understand the opportunities and risks associated with inappropriate scientific support for a claim
- Evaluate and interpret the final ruling of a case study
- Discuss how and what the company involved in the case study could have done differently
- <https://www.econsultancy.com/blog/68111-six-brands-that-have-made-false-health-claims-in-advertising>

Preparation:

- Watch *Case Study* lecture

Assignment for this week – Turn in assignment to instructor:

1. Case study – each student will choose 1 of 4 cases provided below and critically assess the case. Present additional statements (≥ 2) that the company could have included to help their case and make the claims stronger (Post on Canvas).
 - a. Mini wheats vs FTC <https://www.ftc.gov/news-events/press-releases/2009/04/kellogg-settles-ftc-charges-ads-frosted-mini-wheats-were-false>
 - b. Bayer vs FTC <http://www.fdalawblog.net/Bayer%20decision%209-2015.pdf>
 - c. POM vs FTC <https://www.ftc.gov/enforcement/cases-proceedings/pom-wonderful-llc-et-al>
 - d. Green coffee vs FTC <https://www.ftc.gov/news-events/press-releases/2017/05/ftc-sends-additional-refund-checks-totaling->

[almost-2-million?utm_campaign=PennCorner-2017-06&utm_content=refunds&utm_medium=email&utm_source=govdelivery](https://www.penncorner.com/2017/06/28/2-million-refunds-returned-to-pennsylvania-consumers/)

Module 3: Final Project Presentations

Weeks 13-14 Final Product Development Project Presentations (Mittmesser/Weir)

Assignment:

1. Present your final presentation for your novel product that you've been development throughout the semester
2. Post your annotated ppt presentation (7-10 slides) (Post on Discussion Board)
3. All presentations must be posted by April 25 by 11:59pm
4. Each student must provide feedback on each presentation
5. You have through the end of week 14 (May 2 by 11:59pm) to view and comment on the presentations