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

Spring 2019
(January 2019 – May 2019)

Instructors:
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Office hours online by appointment

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812.604.7190 (office)
Office hours online by appointment

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 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 study.
Course Objectives:
As a student in this course, you will learn to navigate the regulations of food 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 US FDA food laws with other countries
- 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 label and market messages for a nutrition product (i.e., medical food, dietary supplement) with intended population and claims; be able to apply appropriate regulatory requirements.

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). 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. 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 a brief explanation for why the extension is needed.

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:

<table>
<thead>
<tr>
<th>Online Quizzes</th>
<th>20%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discussion Board</td>
<td>10%</td>
</tr>
<tr>
<td>Case Study</td>
<td>10%</td>
</tr>
<tr>
<td>Written assignments</td>
<td>25%</td>
</tr>
<tr>
<td>Product Labeling Project</td>
<td>35%</td>
</tr>
</tbody>
</table>

Grade Scale:

<table>
<thead>
<tr>
<th>Grade</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>A+</td>
<td>98.50-100</td>
</tr>
<tr>
<td>A</td>
<td>92.50-98.49</td>
</tr>
<tr>
<td>A-</td>
<td>90-92.49</td>
</tr>
<tr>
<td>B+</td>
<td>87.50-89.99</td>
</tr>
<tr>
<td>B</td>
<td>82.50-87.49</td>
</tr>
<tr>
<td>B-</td>
<td>80-82.49</td>
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</tbody>
</table>

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 the assignment on Canvas.

**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 their initial posting by 11:59pm ET on Thursday 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.

**Food Supplement Labeling Project**

The purpose of this project is to allow students to apply concepts presented throughout the course to an actual product. Each student will be required to do the following:

- Following directions found in the project guidance document to determine a medical food, nutrition bar, or dietary supplement for your project (refer to syllabus tab on Canvas).
- Identify a nutritional gap/consumer need your product will fill
- Design your product. This should include: product composition, specific ingredients/nutrients, safety information, recommended serving size, if beneficial ingredient what is the recommended daily intake to obtain
benefit (efficacious dose and form), how will your customer consume your product (mode of delivery), packaging, intended population

• Determine what country(s) 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? Any special regulations that apply due to target population, product category?

• Determine and outline the claims your food supplement will provide. When discussing your products benefit include scientific support to your consumer. 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 food supplement?

Parts of this project will be due throughout the semester. The final project will incorporate revisions of these parts and combine them 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.

Online Discussion Assignment Grading Criteria

<table>
<thead>
<tr>
<th>Quality of Posting/Reply</th>
<th>Details</th>
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</thead>
<tbody>
<tr>
<td>No Posting or postings are not relevant to discussion posed</td>
<td>Not Acceptable</td>
</tr>
<tr>
<td>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.</td>
<td>Met minimum standards</td>
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</tbody>
</table>
Postings show a strong grasp of material, original thought with solid facts to back-up opinions and statements. Directly contributes to the discussion 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. | Exceeded minimum standards

**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

<table>
<thead>
<tr>
<th>DATE</th>
<th>WEEK</th>
<th>TOPIC</th>
<th>Lecturer</th>
<th>Assignments Due</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>Course Introduction</td>
<td>Mitmesser/ Weir</td>
<td>Introductions, review syllabus, course overview, assignments</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Module 1: Regulations</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>FDA labeling laws for foods</td>
<td>Weir</td>
<td>1. Participate in the on-line Brainstorming session to consider your Food Supplement Labeling Project</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>DSHEA for dietary supplement labeling</td>
<td>Mitmesser</td>
<td>1. Food Supplement Labeling Project: Identify the nutritional gap, consumer need, and intended population you want to fill and target</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td>Labeling for Medical Foods</td>
<td>Weir</td>
<td>1. Medical Food warning letter assessment</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td>US Advertising and the Federal Trade Commission</td>
<td>Weir</td>
<td>1. Quiz on FTC false advertising 2. Food Supplement Labeling Project: Determine the ingredient(s)/nutrient(s) and dosage of your product</td>
</tr>
<tr>
<td>6</td>
<td></td>
<td>European Union – European Food Safety Authority</td>
<td>Weir</td>
<td>1. Look up, identify, and describe scientific opinion for 2 health claims published by EFSA 2. Food Supplement Labeling Project: Determine if your product needs to adhere to US or EU regulations</td>
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<tr>
<td>7</td>
<td></td>
<td>International influences</td>
<td>Weir</td>
<td>1. Globalization trend: Pro/Con discussion (divide class into 2) 2. Quiz on Module 1: Lessons 2,5,6,7)</td>
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<td><strong>Module 2: Claims &amp; Scientific Substantiation</strong></td>
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<tr>
<td>8</td>
<td></td>
<td>Overview of U.S. labeling claims</td>
<td>Mitmesser</td>
<td>1. Quiz on U.S. labeling claims 2. Food Supplement Labeling Project: Determine the mode of delivery and packaging of your product</td>
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<tr>
<td>9</td>
<td></td>
<td>Nutrient claims</td>
<td>Mitmesser</td>
<td>1. Personalized Nutrition Trend</td>
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<tr>
<td>10</td>
<td></td>
<td>Health claims</td>
<td>Mitmesser</td>
<td>1. Identify and present 1 health claim</td>
</tr>
<tr>
<td>11</td>
<td></td>
<td>Structure/Function claims</td>
<td>Mitmesser</td>
<td>1. Quiz for Module 2</td>
</tr>
</tbody>
</table>
2. Food Supplement Labeling Project: Determine and outline the claims your product will support. Provide the type of scientific substantiation for the claims

**Module 3: Case Studies**

| 12 | Case study: BrainStrong vs FTC | Mitmesser | 1. Choose 1 of 5 case studies and include statements that couple have been included in their advertisement. |
| 13 | Project Presentations | Mitmesser/Weir | 1. Food Supplement Labeling Projects Due 2. ½ of class will present their project via annotated ppt 3. Non-presenting students must comment and ask questions of 2 final projects |
| 14 | Project Presentations | Mitmesser/Weir | 1. ½ of class will present their project via annotated ppt 2. Non-presenting students must comment and ask questions of 2 final projects |

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

Upon completion of this week, students will be able to:
- Describe the importance of nutrition regulations
- 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 – Discussion Board:**
- Introduce yourself in the general class discussion forum. In your posting, include:
  - Your background
  - Why you are taking this course
  - What you hope to learn from this course

**Module 1: Regulations**

**Weeks 2 through 7.** In this module, we will provide an overview of the most essential regulations. Participants will be able to utilize resources to prepare a food label that meets US FDA requirements

**Week 2 FDA Labeling Laws for Foods (C 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

**Preparation:**
- Watch *FDA Laws* lecture

**Assignments for this week – Discussion Board**
- Begin to consider your Food Supplement Labeling Project and what are the labeling requirements via online brainstorming session

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**Week 3 DSHEA for Dietary Supplement Labeling (SH 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 fact panels.
- Navigate the Office of Dietary Supplements (ODS) website

**Preparation:**
- Watch *DSHEA* lecture

**Assignments for this week – Turn in assignment to Instructor:**
2. Food Supplement Labeling Project: Identify the nutritional gap, consumer need, and intended population you want to fill and target. Send to instructors for feedback.

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**Week 4 Medical Foods (C 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 – Turn in assignment to Instructor:**
- Review FDA warning letters to identify 3 key regulatory violations. State the regulatory difference between medical foods and dietary supplements.
Week 5 US Advertising and the Federal Trade Commission (C 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
Assignment for this week – Quiz and Turn in assignment to instructor:
- Quiz on FTC false advertising
- Food Supplement Labeling Project: Determine the ingredient(s)/nutrient(s) and dosage of your product. Send to instructors for feedback.

Week 6 European Union (C 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 – Turn in assignment to instructor:
- Look up, identify, and describe the scientific opinion of 2 health claims published by EFSA.
- Food Supplement Labeling Project: Determine if your product would need to adhere to Canada or EU regulations. Send to instructors for feedback.

Week 7 International Influences on food regulation (C 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 – Quiz and Discussion Board:
• Globalization trend: Pro/Con discussion (class will be assigned to Pro or Con group)
• Quiz on Module 1: Lessons 2, 5, 6, 7

Module 2: Claims & Scientific Substantiation

Weeks 8 through 11. In this module, we will describe the specific types of labeling claims in the U.S.

Participants will be able to identify and determine the appropriate use of nutrient claims, health claims, and structure/function claims.

Week 8 Overview of US Label Claims (SH Mitmesser)
Upon completion of this week, students will be able to:
• Navigate the FDA website and identify guidance for label claims and be able to identify claims related to special populations
• Evaluate safety information

Preparation:
• Watch Overview of U.S. lecture

Assignments for this week – Quiz and Turn in assignment to instructor:
• Quiz
• Food Supplement Labeling Project: Determine the mode of delivery and packaging of your food supplement. Send to instructors for feedback.

Week 9 Nutrient Claims (SH 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 – Turn in assignment to Instructor:
• Personalized Nutrition Trend: Identify a personalized nutrition product/service. Identify the claims associated with the product/service. Discuss whether the claims are appropriate for the product/service and why/why not (>1 page).

Week 10 Health Claims (SH 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 – Turn in assignment to Instructor:
• Identify the type of scientific evidence needed to support a health claim

**Week 11 Structure/Function Claims (SH Mitmesser)**

Upon completion of this week, students will be able to:
• Describe structure/function claims and apply to a product
• Explain the level of scientific evidence necessary to support a structure/function claim
• Compare and contrast the differences between health claim, nutrient claim, and structure/function claim

Preparation:
• Watch *Structure/Function Claims* lecture

Assignments for this week – Quiz and Turn in assignment to instructor:
• Quiz over Module 2
• Food Supplement Labeling Project: Determine and outline the claims your food supplement will support. Provide the type of scientific substantiation for the claim(s). Send to instructors for feedback

**Module 3: Case Studies**

**Week 12.** In this module we will use case studies as a way 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 12 Case study: BrainStrong (SH 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 calm
• 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](https://www.econsultancy.com/blog/68111-six-brands-that-have-made-false-health-claims-in-advertising)

Preparation:
• Watch *Case Study I* lecture

Assignment for this week – Turn in assignment to instructor:
3. Case study – each student will choose 1 of 5 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.
o Bayer vs FTC http://www.fdalawblog.net/Bayer%20decision%209-2015.pdf
o POM vs FTC https://www.ftc.gov/enforcement/cases-proceedings/pom-wonderful-llc-et-al

Week 13 Final Project (Mitmesser/Weir)
Assignments for this week – ALL Food Supplement Labeling presentations due
4. ½ of class will post annotated ppt on Discussion Board
5. Non-presenting students must comment and ask questions of 2 other student presentations

Week 14 Final Project (Mitmesser/Weir)
Assignments for this week:
6. ½ of class will post annotated ppt on Discussion Board
7. Non-presenting students must comment and ask questions of 2 other student presentations