

**Administrative Law – Final Examination**

**Spring 2009**

**Professor Davies**

N.B. Short-answer questions omitted herein; only the essay portions of the exam are included.

**EXAMINATION COVER SHEET**

Student Examination Number: \_\_\_\_\_

**Final Examination  
Tuesday, April 28, 2009  
Spring 2009**

⌚ **Time Allowed:** 3 hours, 45 minutes

**Authorized Materials:** This exam is open book. You may consult any hard copy written materials, but you may not receive assistance from other people.

**Special Instructions:** This exam consists of five parts:

- **Fact Pattern**
- **Essay Question No. 1**
- **Essay Question No. 2**
- **Short Answer Questions**
- **Bonus Questions**

**The exam is being graded on a 200 point scale. The three bonus questions at the end are worth up to a total of 6 additional points. The point value of each section in percentage terms is as follows:**

**Essay Question No. 1 – 50%**

**Essay Question No. 2 – 25%**

**Short Answer Questions – 25%**

**The Fact Pattern provided at the beginning of the exam is common to all questions. You may answer the question sections in any order you choose, but a grasp of the Fact Pattern is necessary for each section (excepting the bonus questions).**

With respect to the short answer questions, record the question numbers and your answers to each *in your word-processed answer* or, if you are using one, *your Bluebook*. **Do not write your answers on the examination itself.**

You will be graded both on your ability to spot the issues of law, fact, and policy presented and on the quality of your analysis of those issues. Organize your answer before you begin to write. Concise expression and clarity of analysis will be rewarded in grading.

The essay questions may fail to provide some information that you consider important. Should you find it necessary to make assumptions beyond those stated in the question, clearly explain your assumptions and their significance in your answer.

There are 18 pages to the exam, not including this cover sheet. Make sure you have all of them.

When time is called, you must stop working on your exam immediately and turn in your copy of the exam and your answers.

Good luck!

**GENERAL INSTRUCTIONS FOR ALL EXAMS:**

1. Exams do not leave the exam room! Write your exam number on your copy of the examination questions, and return it to the proctor at the end of the exam.
2. Students may NOT take any bluebooks or scratch paper from the examination room, whether blank or used. Return to proctor.
3. If you are using a bluebook print your exam number, the title of the course and the instructor's name on the front of each bluebook.
4. Number each bluebook (1 of 3, 2 of 3, 3 of 3, etc.) and place all bluebooks and examination questions inside the first numbered bluebook.
5. If the examination utilizes a computer answer sheet (Scantron):
  - You must use BLACK or BLUE INK only; no pencils
  - You may use CORRECTION TAPE only; no liquid paper
  - Print your examination number in the box found in the lower left-hand section of the form. Write the number in the first 4 spaces, and zero-fill any remaining spaces.

For example, if your examination number is 2983:

**IDENTIFICATION NUMBER**

2	9	8	3	0	0	0	0
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Fill in the bubbles corresponding to the numbers written.

## Fact Pattern

Finally realizing that he has never actually been funny, Carrot Top (a.k.a. Scott Thompson) has committed to diversifying his career portfolio. In addition to his run in “comedy,” he has decided to start a new company. Inspired by recent visits to Albany, Columbus, and Provo, all places where he sampled different varieties of deep-fried candy bars, Carrot Top has found his vision: His new company will free the deep-fried candy bar from its county fair, carnival, and amusement park trappings and mass-market them for sale in grocery stores across the United States. Carrot Top breaks ground for his company’s headquarters and manufacturing and distribution facilities in Nevada. He incorporates the new company, Props for Your Heart, Inc. (“PYHI”), in Delaware.



*Carrot Top*



*A Sample PYHI Product*

PYHI, as a manufacturer of food products, is subject to regulation by the United States Food and Drug Administration (“FDA”). Structurally, the FDA is located within the United States Department of Health and Human Services (“HHS”). FDA is headed by its Commissioner, currently Kathy Griffin. HHS is headed by its Secretary, currently Ivanka Trump.

FDA’s headquarters are in Silver Spring, Maryland. The agency also has centers and field offices in other locations across the country.



*Commissioner Griffin*



*Secretary Trump*

Among other responsibilities, the FDA, by delegated authority from HHS, administers the Federal Food, Drug, and Cosmetic Act (“FDCA” or the “Act”). The FDCA gives the FDA the following powers:

**Section 701. Regulations and Hearings.**

(a) The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary.

. . .

(c) Hearings authorized or required by this Act shall be conducted by the Secretary or such officer or employee as he may designate for the purpose.

. . .

(e) (1) Any action for the issuance, amendment, or repeal of any regulation under section 403(j), 404(a), 406, 501(b), or 502 (d) or (h) of this Act . . . shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested persons, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. . . .

(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) is

made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3), the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. . . .

**Section 702. Examinations and Investigations.**

(a) (1) The Secretary is authorized to conduct examinations and investigations for the purposes of this Act through officers and employees of the Department or through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Secretary as an officer of the Department. . . .

**Section 704. Inspection.**

(a) Right of agents to enter; scope of inspection; notice; promptness; exclusions.

(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary . . . are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and

in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. . . . Each such inspection shall be commenced and completed with reasonable promptness. . . .

**Section 705. Publicity.**

(a) The Secretary shall cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this Act, including the nature of the charge and the disposition thereof.

(b) The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health, or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.

The FDCA's core purpose is to protect public health by ensuring the safety of food, drugs, and cosmetics sold in interstate commerce in the United States. To this end, the Act forbids the introduction of any food, drug, device, or cosmetic that is "adulterated" or "misbranded." The FDCA provides:

**Section 301. Prohibited acts.**

The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

. . .

(f) The refusal to permit entry or inspection as authorized by section 704. . . .

**Section 402. Adulterated food.**

A food shall be deemed to be adulterated—

(a) Poisonous, insanitary, or deleterious ingredients.

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health . . . or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or . . . (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409.

Because Congress gives great weight to the FDCA' objectives, the statute carries heavy penalties for its violation. To wit:

**Section 303. Penalties.**

(a) Violation of [Section 301]; second violation; intent to defraud or mislead.

(1) Any person who violates a provision of section 301 shall be imprisoned for not more than one year or fined not more than \$1,000, or both.

. . .

(d) Exceptions involving misbranded food. No person shall be subject to the penalties of subsection (a)(1) of this section for a violation of section 301 involving misbranded food if the violation exists solely because the food is misbranded under section 403(a)(2) because of its advertising.

**Section 304. Seizure.**

(a) Grounds and jurisdiction.

(1) Any article of food, drug, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce . . . shall be liable to be proceeded against . . . on libel of information and

condemned in any district court of the United States . . . of which the article is found. . . .

(3) (A) Except as provided in subparagraph (B), no libel for condemnation may be instituted under paragraph (1) or (2) against any food which -

(i) is misbranded under section 403(a)(2) because of its advertising, and

(ii) is being held for sale to the ultimate consumer in an establishment other than an establishment owned or operated by a manufacturer, packer, or distributor of the food.

. . .

(h) Administrative detention of foods.

(1) Detention authority.

(A) In general. An officer or qualified employee of the Food and Drug Administration may order the detention, in accordance with this subsection, of any article of food that is found during an inspection, examination, or investigation under this Act conducted by such officer or qualified employee, if the officer or qualified employee has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals.

(B) Secretary's approval.--An article of food may be ordered detained under subparagraph (A) only if the Secretary or an official designated by the Secretary approves the order. . . .

(4) Appeal of detention order.

(A) In general. With respect to an article of food ordered detained under paragraph (1), any person who would be entitled to be a claimant for such article if the article were seized under subsection (a) may appeal the order to the Secretary. Within five days after such an appeal is filed, the Secretary, after providing opportunity for an informal hearing, shall confirm or terminate the order involved, and such confirmation by the Secretary shall be considered a final agency action for purposes of section 702 of title 5, United States Code. If during such five-day period the Secretary fails to provide such an opportunity, or to confirm or terminate such order, the order is deemed to be terminated. . . .

The FDCA defines many terms used in the Act. These definitions are included in Section 201 of the statute:

**Section 201. Definitions; generally.**

For the purposes of this Act-

. . .

(b) The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term "Department" means the Department of Health and Human Services.

(d) The term "Secretary" means the Secretary of Health and Human Services.

(e) The term "person" includes individual, partnership, corporation, and association.

(f) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

. . .

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article . . . .

(l) The term "immediate container" does not include package liners.

(m) The term "labeling" means all labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(n) If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result

from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

. . .

(x) The term "informal hearing" means a hearing which is not subject to section 554, 556, or 557 of title 5 of the United States Code and which provides for the following:

(1) The presiding officer in the hearing shall be designated by the Secretary from officers and employees of the Department who have not participated in any action of the Secretary which is the subject of the hearing and who are not directly responsible to an officer or employee of the Department who has participated in any such action.

(2) Each party to the hearing shall have the right at all times to be advised and accompanied by an attorney.

(3) Before the hearing, each party to the hearing shall be given reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the action taken or proposed by the Secretary which is the subject of the hearing and a general summary of the information which will be presented by the Secretary at the hearing in support of such action.

(4) At the hearing the parties to the hearing shall have the right to hear a full and complete statement of the action of the Secretary which is the subject of the hearing together with the information and reasons supporting such action, to conduct reasonable questioning, and to present any oral or written information relevant to such action.

. . .

(ee) The term "Commissioner" means the Commissioner of Food and Drugs. . . .

To help enforce the FDCA, the FDA has adopted lengthy regulations. Three of these regulations have been in place since 1976, when they were promulgated pursuant to notice and comment rulemaking and memorialized in Title 21 of the Code of Federal Regulations:

**§ 1.378 What criteria does FDA use to order a detention?**

An officer or qualified employee of FDA may order the detention of any article of food that is found during an inspection, examination, or investigation under the act if the officer or qualified employee has credible evidence or information indicating that the article of food presents a threat of serious adverse health consequences or death to humans or animals.

**§ 1.379 How long may FDA detain an article of food?**

(a) FDA may detain an article of food for a reasonable period that may not exceed 20 calendar days after the detention order is issued. However, an article may be detained for 10 additional calendar days if a greater period of time is required to institute a seizure or injunction action. The authorized FDA representative may approve the additional 10-calendar day detention period at the time the detention order is issued, or at any time within the 20-calendar day period by amending the detention order.

(b) The entire detention period may not exceed 30 calendar days. . . .

**§ 7.40 Recall policy.**

(a) Recall is an effective method of removing or correcting consumer products that are in violation of laws administered by the Food and Drug Administration.

Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective. This section and §§ 7.41 through 7.59 recognize the voluntary nature of recall by providing guidance so that responsible firms may effectively discharge their recall responsibilities. These sections also recognize that recall is an alternative to a Food and Drug Administration-initiated court action for removing or correcting violative, distributed products by setting forth specific recall procedures for the Food and Drug Administration to monitor recalls and assess the adequacy of a firm's efforts in recall.

(b) Recall may be undertaken voluntarily and at any time by manufacturers and distributors, or at the request of the Food and Drug Administration. A request by the Food and Drug Administration that a firm recall a product is reserved for urgent situations and is to be directed to the firm that has primary responsibility for the manufacture and marketing of the product that is to be recalled.

(c) Recall is generally more appropriate and affords better protection for consumers than seizure, when many lots of product have been widely distributed. Seizure, multiple seizure, or other court action is indicated when a firm refuses to undertake a recall requested by the Food and Drug Administration, or where the agency has reason to believe that a recall would not be effective, determines that a recall is ineffective, or discovers that a violation is continuing.

Just before Carrot Top formed PYHI, the United States elected a new president, Richard Simmons, who recently was sworn into office. As one of his first acts as president, Simmons proclaims a “war on obesity, in the proud American tradition of prior wars on crime, drugs, and terrorism.” President Simmons also appoints one of the lowest-level employees in his press secretary's office, Ryan Seacrest, to be the official Czar of the War on Obesity (“Czar” or “War Czar”). Seacrest's charge as War Czar is

primarily as policy advisor. He is to keep Simmons informed of what the various federal agencies are doing to promote Simmons' professed goal of "not just Jazzercising, not just Disco-ercising, not just super duper Mr. Hooper shake it now exercising, but NO MORE OBESITY IN AMERICA. PERIOD."



*President Simmons*



*Czar Seacrest*

Following his appointment as War Czar, Seacrest convenes a meeting with both Secretary Trump and Commissioner Griffin at a Five Guys Burgers and Fries joint just off the Columbia Pike in Silver Spring, Maryland. Pictures of the three politicos exiting Five Guys are splashed on the covers of grocery store tabloids across the United States—in no small part because of Seacrest's professed disdain for beef and love for all foods lean, including fish. Still, no details of what the meeting was about surface in the press, on governmental websites, or otherwise.

Then, one month to the day after the Five Guys meeting, Commissioner Griffin holds a press conference in which she announces how FDA will begin participating in President Simmons' War on Obesity. At the press conference, she states: "The time has come for Americans to rise up against the plague that is obesity in our nation. No longer can we sit still. No longer can we be couch potatoes. Obesity causes numerous ailments and serious medical conditions, including coronary heart disease, Type 2 diabetes, cancer, hypertension, stroke, liver and gallbladder disease, and sleep apnea and respiratory problems, just to name a few. Every day, 821 Americans die in this country

as a result of obesity. This has to stop. It will stop. And the FDA is going to do everything it can to make it stop. Thank you.”

The next day, the FDA publishes in the Federal Register a document entitled Emergency Promulgation of Final Rule. This document includes a 200-page summary of medical research detailing the obesity-related health problems Commissioner Griffin had described in her press conference the day before. It also professes to link such health problems not only to obesity but, because obesity can be caused by overconsumption of high-calorie and fatty foods, to those foods themselves. The FDA, the document says, has developed a metric to determine when foods are too fatty. That metric deems any food product that has a 1-to-20 fat-to-calorie ratio to be an “Excessively Fat-Heavy Food.” At the end of the document, the following text appears:

Wherefore, pursuant to the FDCA, the following regulation is hereby issued and made effective immediately:

**FINAL RULE - FOR PUBLICATION IN THE C.F.R.**

**21 C.F.R. § 9999.001**

Any food, processed food, food additive, or the like that possesses a 1-to-20 (or higher) ratio of fat grams-to-calories per serving is an Excessively Fat-Heavy Food.

**21 C.F.R. § 9999.002**

Excessively Fat-Heavy Foods are “adulterated” under the FDCA.

**21 C.F.R. § 9999.003**

Any enforcement action brought pursuant to FDCA Section 301 on the basis of a food or food product being an Excessively Fat-Heavy Food shall be an informal hearing under the FDCA; provided, however, that this section does not apply to detention actions (except as FDCA Section 304 otherwise dictates).

Determined to carry its weight in the War on Obesity, the FDA begins sending out recall notices the day after it releases the Federal Register notice above. The FDA sends these recall notices to manufacturers and distributors of foods that it has determined likely satisfy the criteria of being Excessively Fat-Heavy Foods under 21 C.F.R. § 9999.001.

One of the foods the FDA identifies is deep-fried candy bars. Accordingly, by email, the FDA delivers the following message to PYHI:

Dear Mr. Top:

It has come to my attention that your company manufactures and distributes deep-fried candy bars. We have recently determined that deep-fried candy bars contain 40 fat grams for every 800 calories—a 1-to-20 fat gram-to-calorie ratio. Under 21 C.F.R. § 9999.001, this deems your product an Excessively Fat-Heavy Food. Under 21 C.F.R. § 9999.002, Excessively Fat-Heavy Foods are “adulterated” under the FDCA.

Accordingly, this is formal notice that Props for Your Heart, Inc. (“PYHI”) must immediately recall all of its deep-fried candy bars currently for sale or in transit to be made for sale anywhere in the United States. PYHI is also hereby ordered to cease and desist from manufacturing or releasing into interstate commerce any deep-fried candy bars, as doing so is a per se violation of FDCA § 301.

Failure to abide by the above directives will result in immediate detention of your products by the FDA.

Please do not hesitate to contact our new office of Excessively Fat-Heavy Foods Enforcement at the above number should you have any questions. Have a nice day.

Sincerely,

*Kathy Griffin*

Commissioner

Carrot Top, perhaps understandably, is hopping mad. He replies to the FDA’s email as follows:

Griffin-

Go pound sand.

Toodles,  
Carrot Top

The next day, FDA agents descend on the PYHI compound in Nevada, media in tow, and detain every deep-fried candy bar onsite. Thirty-five days go by and PYHI still does not have access to any of its deep-fried candy bar stock, which continues in the FDA’s detainer. With each passing day, the company is losing profits and inching closer to bankruptcy.

**Essay Question No. 1**

PYHI retains you as counsel to assist in this matter. The company's general counsel has asked that you draft her a memorandum addressing the following topics:

- A) Can PYHI challenge the FDA's actions in court?
- B) If PYHI can challenge the FDA's actions in court, on what grounds can the agency's actions be challenged and which grounds do you recommend as most viable?
- C) If PYHI can challenge the FDA's actions in court, what relief can PYHI receive?

**Essay Question No. 2**

While you are considering PYHI's ability to go to court over the FDA's detention actions, the agency brings a separate enforcement action against PYHI pursuant to FDCA § 301(b) for "misbranding" its deep-fried candy bars. Apparently, each PYHI deep-fried candy bar includes the following logo prominently across the back of its wrapper:

## **Props for Your Heart, Inc.**

**GOOD FOR YOU // GOOD FOR YOUR SOUL // GOOD FOR YOUR HEART**

The FDA brings its enforcement action by having its enforcement staff lodge a Complaint and Notice of Violation with the agency. The agency then assigns the case to an Administrative Law Judge, who gives each side thirty days to file, in turn, "appropriate legal briefs and any written testimony or affidavits the party may wish to file"—with the FDA going first, PYHI following thirty days later, and the FDA having the right to submit a reply brief.

The crux of the FDA's case is that by asserting that its products are "good for you," "your soul," and "your heart," PYHI has violated the FDCA's bar on misbranding food products because PYHI's deep-fried candy bars are Excessively Fat-Heavy Foods, and thus, unhealthy and adulterated by definition.

Following briefing and submittal of affidavits and written testimony by both the FDA and PYHI, the ALJ issues her ruling. The ALJ finds that PYHI violated Section 301 of the FDCA by misbranding its candy:

This agency long has adhered to the requirement that, to be considered "adulterated" under the FDCA, "[i]t is the character, not the quantity of [a] substance that controls its ability to injure." *In re 1491 Cases of Spanish Shellfish*, 98 FDA Rptr. 4th 1 (2020). To measure whether the "character" of a food is injurious to human or public health, the FDA consistently has applied the "ordinarily injurious" test. Under this test, the agency weighs (1) the dangers of deleterious substances against (2) the beneficial effects of foods that contain poisonous—as well as harmless—elements. *In re 99 Bottles of Beer on the Wall*, 199 FDA Rptr. 4th 18 (2022).

Here, based on the evidence before me, I find it beyond question that PYHI's "product," the so-called "deep fried candy bar," flunks the "ordinarily injurious" test. Even assuming the allegations made by PYHI about its product's "tastiness" are true, the product provides very little nutritional value. A few carbohydrates, trace minerals, and more than ample daily cholesterol intake does not a square meal make. Moreover, when compared against the deleterious nature of the fat content of the candy bars at issue, the product is plainly ordinarily injurious. PYHI rightly points out that not everyone will become fat from eating their product. It also provides convincing

evidence that most consumers do not over-indulge in PYHI deep-fried candy bars. But that evidence cannot overwhelm the FDA's own prior finding in its rulemaking that products that qualify as Excessively Fat-Heavy Foods are injurious to the public health and thus adulterated per se. Even if a single PYHI candy bar is not adulterated based on the evidence presented before me, taken as a cumulative whole, the FDA's rulemaking evidence proves that the product itself is.

Finally, I note that the FDA traditionally has employed a product-specific, rather than a product-wide, test for determining whether a product is "misbranded" under the FDCA. That is, prior FDA decisions have carved a clear exception for misbranding prosecutions: If a *food item* has accurate nutritional content on its package, the agency has never found a product misbranded. Only when a false health claim is combined with misinformation on the nutrition side of the equation has a mislabeling violation been found. The reason for this is simple. The FDA assumes that consumers are able to decipher the difference between advertising and hyperbole when accurate nutrition information accompanies the hyperbole. Without in any way abdicating the FDA's prior "food item" misbranding test, however, I find just cause for a new exception here. Where the FDA itself has found a type of food adulterated per se by regulation, as it has in this case, any claim that the food provides health benefits is misleading—and thus, misbranding—by definition.

Accordingly, given the importance of the War on Obesity and the many ills that PYHI's products cause, I hereby find that PYHI has violated the FDCA's prohibition on misbranding for every deep-fried candy bar it has introduced into interstate commerce. PYHI is hereby ordered to pay the full \$1,000 per violation fine—that is, \$1,000 per deep-fried candy bar introduced into interstate commerce—forthwith.

SO ORDERED.

PYHI immediately seeks review of the ALJ's order with the FDA, but the FDA summarily affirms the ALJ's decision. PYHI then moves the FDA to reconsider its decision, but the agency responds as follows: "PYHI's motion for reconsideration is denied; no further motions will be considered. This order constitutes final agency action."

Again, PYHI turns to you for help. The company's general counsel wants to know:

- 1) Whether the ALJ's order can be challenged in court; and
- 2) If so, on what grounds.