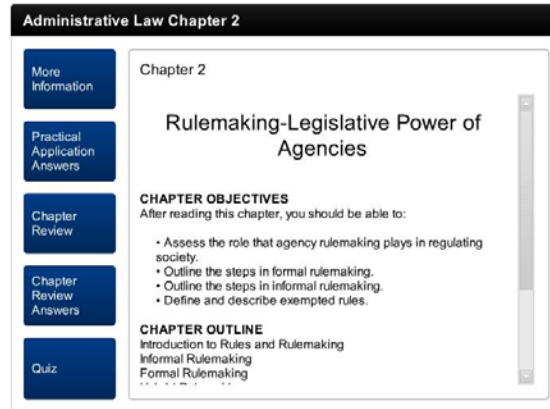


Administrative Law Chapter 2

Chapter 2



The screenshot shows a digital interface for 'Administrative Law Chapter 2'. On the left, there is a vertical menu with buttons for 'More Information', 'Practical Application Answers', 'Chapter Review', 'Chapter Review Answers', and 'Quiz'. The main content area on the right is titled 'Chapter 2' and 'Rulemaking-Legislative Power of Agencies'. It includes 'CHAPTER OBJECTIVES' (After reading this chapter, you should be able to: Assess the role that agency rulemaking plays in regulating society, Outline the steps in formal rulemaking, Outline the steps in informal rulemaking, Define and describe exempted rules.) and a 'CHAPTER OUTLINE' (Introduction to Rules and Rulemaking, Informal Rulemaking, Formal Rulemaking).

Step Text

Rulemaking-Legislative Power of Agencies

CHAPTER OBJECTIVES

After reading this chapter, you should be able to:

- Assess the role that agency rulemaking plays in regulating society.
- Outline the steps in formal rulemaking.
- Outline the steps in informal rulemaking.
- Define and describe exempted rules.

CHAPTER OUTLINE

Introduction to Rules and Rulemaking
Informal Rulemaking
Formal Rulemaking
Hybrid Rulemaking
Exempted Rulemaking
Negotiated Rulemaking
Rulemaking in Perspective

More Information

5 seconds

Administrative Law Chapter 2

More Information

1. Go to <http://www.regulations.gov> to see how to comment on pending federal regulations. Students can access the Web site and see how to make a comment to a regulation.

2. Stay on <http://www.regulations.gov> to view the comments of others. Students can access the Web site and see comments to regulations.

Practical Application Answers

Chapter Review

Chapter Review Answers

Quiz

Step Text

1. Go to <http://www.regulations.gov> to see how to comment on pending federal regulations.

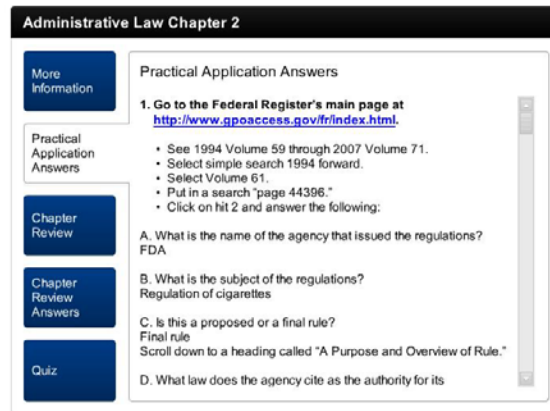
Students can access the Web site and see how to make a comment to a regulation.

2. Stay on <http://www.regulations.gov> to view the comments of others.

Students can access the Web site and see comments to regulations.

Practical Application Answers

5 seconds



The screenshot shows a web page titled "Administrative Law Chapter 2" with a sidebar on the left containing navigation links: "More Information", "Practical Application Answers", "Chapter Review", "Chapter Review Answers", and "Quiz". The main content area is titled "Practical Application Answers" and contains the following text:

1. Go to the Federal Register's main page at <http://www.gpoaccess.gov/fr/index.html>.

- See 1994 Volume 59 through 2007 Volume 71.
- Select simple search 1994 forward.
- Select Volume 61.
- Put in a search "page 44396."
- Click on hit 2 and answer the following:

A. What is the name of the agency that issued the regulations?
FDA

B. What is the subject of the regulations?
Regulation of cigarettes

C. Is this a proposed or a final rule?
Final rule
Scroll down to a heading called "A Purpose and Overview of Rule."

D. What law does the agency cite as the authority for its

Step Text

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Regulation of cigarettes

C. Is this a proposed or a final rule?
Final rule
Scroll down to a heading called "A Purpose and Overview of Rule."

D. What law does the agency cite as the authority for its jurisdiction over this subject?
Federal Food, Drug, and Cosmetic Act
Scroll down to a heading called "Background."

As of the date of these regulations, answer the following:

E. How many Americans smoked cigarettes?

50 million

F. How many used smokeless tobacco?

6 million

G. How many people die each year from tobacco-related illnesses?

400,000

2. Go to the Web site of the Food and Drug Administration (FDA) at

<http://www.fda.gov>.

Click on "About FDA."

A. State what the FDA regulates.

FDA is the federal agency responsible for ensuring that foods are safe, wholesome and sanitary; human and veterinary drugs, biological products, and medical devices are safe and effective; cosmetics are safe; and electronic products that emit radiation are safe. FDA also ensures that these products are honestly,

accurately and informatively represented to the public. Some of the agency's specific responsibilities include:

Biologics

- product and manufacturing establishment licensing
- safety of the nation's blood supply
- research to establish product standards and develop improved testing methods

Cosmetics

- safety
- labeling

Drugs

- product approvals
- OTC and prescription drug labeling
- drug manufacturing standards

Foods

- labeling
- safety of all food products (except meat and poultry)
- bottled water

Medical Devices

- premarket approval of new devices
- manufacturing and performance standards
- tracking reports of device malfunctioning and serious adverse reactions

Radiation-Emitting Electronic Products

- radiation safety performance standards for microwave ovens, television receivers, diagnostic
- x-ray equipment, cabinet x-ray systems (such as baggage x-rays at airports), laser products
- ultrasonic therapy equipment, mercury vapor lamps, and sunlamps
- accrediting and inspecting mammography facilities

Veterinary Products

- livestock feeds
- pet foods
- veterinary drugs and devices

B. State what the FDA does not regulate.

FDA Does Not Regulate

FDA's responsibilities are closely related to those of several other government agencies. Often frustrating and confusing for consumers is determining the appropriate regulatory agency to contact. The following contact information is for government agencies that have functions related to that of FDA. (Contact information is given for agency headquarters offices, which are located in the Washington, DC area. Local offices, listed in the phone book under U.S. Government, may be available to provide assistance as well.)

Advertising

The Federal Trade Commission is the federal agency which regulates all advertising, excluding prescription drugs and medical devices. FTC ensures that advertisements are truthful and not misleading for consumers. Consumers may write to FTC at 6th St. and Pennsylvania Ave., N.W., Washington, DC 20580; telephone (202) 326-2222.

Alcohol

The labeling and quality of alcoholic beverages are regulated by the Treasury Department's Bureau of Alcohol, Tobacco, and Firearms. ATF's address is 650 Massachusetts Ave., N.W., Washington, DC 20226; telephone (202) 927-7777.

Consumer Products

While FDA regulates a large portion of the products that consumers purchase, the agency has no jurisdiction over many household goods. The Consumer

Product Safety Commission (CPSC) is responsible for ensuring the safety of consumer goods such as household appliances (excluding those that emit radiation), paint, child-resistant packages, and baby toys. Consumers may send written inquiries to CPSC, Washington, DC 20207. CPSC operates a toll-free hotline at (800) 638-2772 or TTY (800) 638-8270 for consumers to report unsafe products or to obtain information regarding products and recalls.

Drugs of Abuse

Illegal drugs with no approved medical use—such as heroin and marijuana—are under the jurisdiction of the Drug Enforcement Administration. FDA assists DEA in deciding how stringent DEA controls should be on drugs that are medically accepted but that have a strong potential for abuse. DEA establishes limits on the amount of these prescription drugs that are permitted to be manufactured each year. Inquiries regarding DEA activities may be sent to the Drug Enforcement Administration, U.S. Department of Justice, Washington, DC 20537; telephone (202) 307-1000.

Health Insurance

FDA does not regulate health insurance, the cost of health care products or procedures, or reimbursement for health and medical expenses. Questions about Medicare should be directed to the Centers for Medicare and Medicaid Services.

Meat and Poultry

The U.S. Department of Agriculture's Food Safety and Inspection Service is responsible for the safety and labeling of traditional meats and poultry. (FDA regulates game meats, such as venison, ostrich and snake.) Consumers with questions regarding meat or poultry, including safe handling and storage practices, should write or call the Food Safety Inspection Service's Meat and Poultry Hotline, Room 2925S, Washington, DC 20250; telephone (800) 535-4555.

Pesticides

FDA, USDA, and the Environmental Protection Agency share the responsibility for regulating pesticides. EPA determines the safety and effectiveness of the chemicals and establishes tolerance levels for residues on feed crops, as well as for raw and processed foods. These tolerance levels (the amount of pesticide allowed to be present in a food product) are normally set 100 times below the level that might cause harm to people or the environment. FDA and USDA are responsible for monitoring the food supply to ensure that pesticide residues do not exceed the allowable levels in the products under their jurisdiction. Public inquiries regarding EPA should be mailed to U.S. Environmental Protection Agency, Office of Pesticide Programs

Public Docket (7506C), 3404, 401 M St., Washington, DC 20460; telephone (202) 260-2080.

Restaurants and Grocery Stores

Inspections and licensing of restaurants and grocery stores are typically handled by local county health departments.

Water

The regulation of water is divided between the Environmental Protection Agency and FDA. EPA has the responsibility for developing national standards for drinking water from municipal water supplies. FDA regulates the labeling and safety of bottled water.

3. Review Exhibit 2-1, which is an expert from the Federal Register concerning a proposed rule.

A. State the name of the agency which issued this rule.

Securities and Exchange Commission

B. What law does this rule implement?

Section 216 of the Fair and Accurate Credit Transaction Act of 2003

C. What is the last day to send a comment to the agency about this proposed rule?

October 20, 2004

D. What is the subject matter of the proposed rule?

Disposal of Consumer Report Information

4. Review Exhibit 2-3, which is an excerpt from the Code of Federal Regulations.

A. State the name of the agency which issued this rule.

Food and Drug Administration

B. What is the topic of this regulation?

Specific Food Labeling Requirements

C. How does the rule define the term "spice"?

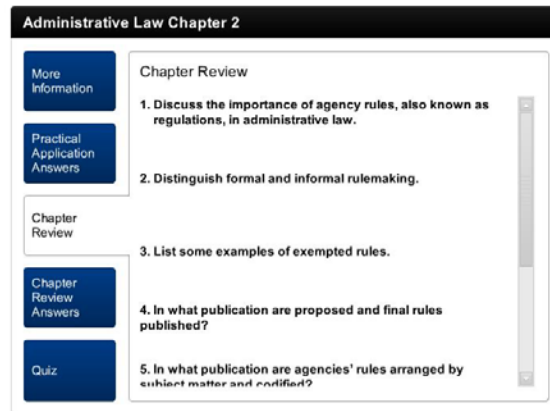
The term spice means any aromatic vegetable substance in the whole, broken, or ground form, except for those substances which have been traditionally regarded as foods, such as onions, garlic and celery; whose significant function in food is seasoning rather than nutritional; that is true to name; and from which no portion of any volatile oil or other flavoring principle has been removed.

D. Give three examples of a spice.

Allspice, Anise, Basil, Bay leaves, Caraway seed, Cardamom, Celery seed, Chervil, Cinnamon, Cloves, Coriander, Cumin seed, Dill seed, Fennel seed, Fenugreek, Ginger, Horseradish, Mace, Marjoram, Mustard flour, Nutmeg, Oregano, Paprika, Parsley, Pepper, black; Pepper, white; Pepper, red; Rosemary, Saffron, Sage, Savory, Star anise, Tarragon, Thyme, Turmeric.

Chapter Review

5 seconds



The screenshot shows a digital interface for 'Administrative Law Chapter 2'. On the left, there is a vertical sidebar with five blue buttons: 'More Information', 'Practical Application Answers', 'Chapter Review', 'Chapter Review Answers', and 'Quiz'. The main content area on the right is titled 'Chapter Review' and contains five numbered questions. A vertical scrollbar is visible on the right side of the main content area.

Administrative Law Chapter 2

Chapter Review

1. Discuss the importance of agency rules, also known as regulations, in administrative law.
2. Distinguish formal and informal rulemaking.
3. List some examples of exempted rules.
4. In what publication are proposed and final rules published?
5. In what publication are agencies' rules arranged by subject matter and codified?

Step Text

- 1. Discuss the importance of agency rules, also known as regulations, in administrative law.**
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Chapter Review Answers

5 seconds

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- 1. Discuss the importance of agency rules, also known as regulations, in administrative law.**
Rules represent the legislative power of agencies. Rules are the method that agencies use to implement the statutes according to the wishes of the legislative body.
- 2. Distinguish formal and informal rulemaking.**
Informal rulemaking is known as the "notice and comment" procedure. The agency publishes a notice of proposed rulemaking in the Federal Register and then waits for comments before publishing a final rule. Formal rulemaking is akin to a trial in court and involves a trial-type hearing with witnesses and is presided over by an administrative law judge (ALJ).
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Good cause exemption, military affairs, rules concerning public property, loans, grants, benefits, and contracts.
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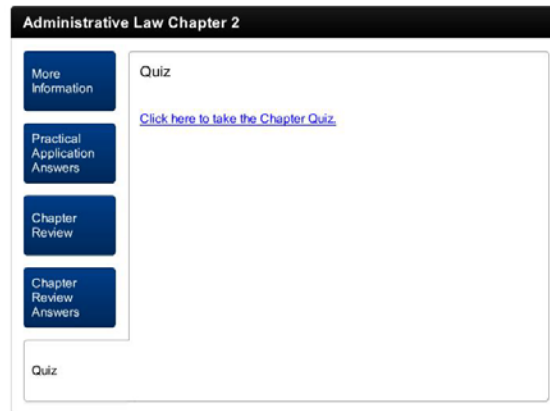
Federal Register

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Code of Federal Regulations

Quiz

5 seconds



The screenshot shows a user interface for 'Administrative Law Chapter 2'. On the left is a sidebar with four blue buttons: 'More Information', 'Practical Application Answers', 'Chapter Review', and 'Chapter Review Answers'. The main content area has a title 'Quiz' and a blue hyperlink that reads 'Click here to take the Chapter Quiz.' Below the main content area is a small box with the text 'Quiz'.

Step Text

[Click here to take the Chapter Quiz.](#)