Food, Drug, and Cosmetic Act of 1938

Date: June 25, 1938
Author: Royal S. Copeland; U.S. Congress
Genre: legislation

Summary Overview

"An Act to Prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics and for other purposes"—better known by its short title of the Federal Food, Drug, and Cosmetic Act—was a piece of legislation, signed into law by President Franklin Roosevelt on June 25, 1938. This law implemented much needed updates to the regulatory structure governing the substances with which Americans attempted to feed, heal, and beautify themselves and also provided mechanisms for the enforcement of these regulations. While it has been amended over the years, in its original 1938 iteration, it consisted of nine chapters, with portions of five of them excerpted here.

Chapter I establishes the short title, by which the act is usually referred. Chapter II lays out the definitions of terms used within the legislation. Chapter III provides details of "prohibited acts" and sets out the penalties for them. Chapters IV, V, and VI address the particulars of food, medication and medical devices, and cosmetics, respectively. Chapters VII, VIII, and IX address administrative details, outlines dates for implementation of various portions of the act, and officially repeals the 1906 Pure Food and Drugs Act.

The Food, Drug, and Cosmetic Act of 1938 represented a significant increase in the regulatory power of the federal government and was important not only for its effect on American business but also as part of the larger picture of the era of the New Deal and the history of American liberalism.

Defining Moment

The Pure Food and Drugs Act of 1906 was a landmark piece of Progressive Era legislation, passed in the wake of muckraking journalism and reportage on the dangers to the consumer posed by the manufacturing and marketing methods of both the food and medical industries. Books like *The Jungle*, by Upton Sinclair, motivated both the public and politicians to take action. The 1906 act was a huge step forward for public health in the United States, but there were gaps in what the law gave the federal government authority to regulate. These gaps, along with court decisions that limited the government's ability to prosecute some cases under the law, allowed for a rise in the number and kinds of products that were potentially damaging to the health of those who used them. This was particularly true in the case of medical products.

By the 1930s, there was sufficient institutional and public pressure to move forward legislation that would enlarge the powers of the Food and Drug Administration (FDA) in a number of ways, including gaining the authority to inspect factories. Public attention also turned to cosmetics, thanks to publicity surrounding products like eyelash dyes that caused blindness and dangerous patent medicines that promised far more than they delivered. In 1937, a new sulfa drug caused over 100 deaths, with children among the victims. The time was right for legislation to make its way through Congress.

The Seventy-Fifth Congress passed a number of significant laws that enlarged the role that the federal government played in commerce and the economy. These included not only the Food, Drug, and Cosmetic Act, but also the Fair Labor Standards Act, the Air Commerce Act, the Marihuana Tax Act, and the Wheeler-Lea Act, which authorized the Federal Trade Commission to regulate false advertising claims. The Food, Drug, and Cosmetic Act was very much of a piece with these other measures aimed at protecting consumers, workers, air passengers, and others.

Author Biography

The primary sponsor of the 1938 Food, Drug, and Cosmetic Act was Democratic New York Senator Royal S. Copeland (1868–1938). Copeland was born in Michigan, where he was a school teacher and, later, a medical doctor specializing in homeopathic medicine. From 1895 to 1908, he was a professor of ophthalmology and oology at the University of Michigan Medical School. He served in local political offices during his time in Michigan but in 1908, he took an academic position in New York and in 1918, he became president of the New York City Board of Health. His political career on the national stage took off in 1922 when he was elected to the U.S. Senate. He was reelected in 1928 and 1934.

While in the Senate, in addition to authoring and sponsoring the Food, Drug, and Cosmetic Act, Copeland sponsored anticorruption legislation and chaired the Copeland Committee, which investigated air safety concerns following a number of high-profile airline crashes. Copeland died while in office, on June 17, 1938—just eight days before President Roosevelt signed the Food, Drug, and Cosmetic Act into law.

Historical Document

Food, Drug, and Cosmetic Act of 1938

Chapter II-Definitions

SEC. 201. For the purposes of this Act....

(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.

(g) The term "drug" means (1) articles recognized in the official United States Pharmacopoeia, official Homœopatic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2), or (3); but does not include devices or their components, parts, or accessories.

(h) The term "device"...means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

Chapter III-Prohibited Acts and Penalties

SEC. 301. 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.

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 404 or 505.

(e) The refusal to permit access to or copying of any record as required by section 703.

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

(g) The manufacture within any Territory of any food, drug, device, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 303 (c) (2), which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, or cosmetic....

(i) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations....

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired...concerning any method or process which as a trade secret is entitled to protection.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded.

Chapter IV-Food

Definitions and Standards for Food

SEC. 401. Whenever in the Judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of

container: Provided, That no definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocadoes, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Secretary shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the prescribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. Any definition and standard of identity prescribed by the Secretary for avocadoes, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

Adulterated Food

SEC. 402.

A food shall be deemed to be adulterated—

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 406; 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 (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(b) (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 406: Provided, That this paragraph shall not apply to fruit bearing or containing a coal-tar color if application for listing of such color has been made under this Act and such application has not been acted on by the Secretary, if such color was commonly used prior to the enactment of this Act for the purpose of coloring citrus fruit.

(d) If it is confectionery, and it bears or contains any alcohol or nonnutritive article or substance except harmless coloring, harmless flavoring, harmless resinous glaze not in excess of four-tens of 1 per centum, natural gum, and pectin: Provided, That this paragraph shall not apply to any confectionery by reason of its containing less than one-half of 1 per centum by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless nonnutritive masticatory substances.

Misbranded Food

SEC. 403.

A food shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If it is offered for sale under the name of another food.

(c) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(d) If its container is so made, formed, or filled as to be misleading.

(e) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(f) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(h) If it purports to be or is represented as—

(1) a food for which a standard of quality has been prescribed by regulations as provided by section 401, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or

(2) a food for which a standard or standards of fill of container have been prescribed by regulations...unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard....

(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

(k) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labelling stating that fact: *Provided*, that to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream.

Emergency Permit Control

SEC. 404.

(a) Whenever the Secretary finds after investigation that the distribution in interstate commerce of any class of food may, by reason of contamination with micro-organisms during the manufacture, processing, or packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he then, and in such case only, shall promulgate regulations providing for the issuance, to manufacturers, processors, or packers of such class of food in such locality, of permits to which shall be attached such conditions governing the manufacture, processing, or packing of such class of food, for such temporary period of time, as may be necessary to protect the public health; and after the effective date of such regulations, and during such temporary period, no

person shall introduce or deliver for introduction into interstate commerce any such food manufactured, processed, or packed by any such manufacturer, processor, or packer unless such manufacturer, processor, or packer holds a permit issued by the Secretary as provided by such regulations.

(b) The Secretary is authorized to suspend immediately upon notice any permit issued under authority of this section if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended shall be privileged at any time to apply for the reinstatement of such permit, and the Secretary shall, immediately after prompt hearing and an inspection of the establishment, reinstate such permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit, as originally issued or as amended.

Chapter V-Drugs and Devices

Adulterated Drugs and Devices

SEC. 501.

A drug or device shall be deemed to be adulterated—

(a) (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (3) if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if it is a drug and it bears or contains, for purposes of coloring only, a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 504.

(b) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except that whenever tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the Secretary, insufficient for the making of such determination, the Secretary shall bring such fact to the attention of the appropriate body charged with the revision of such compendium, and if such body fails within a reasonable time to prescribe tests or methods of assay which, in the judgment of the Secretary, are sufficient for purposes of this paragraph, then the Secretary shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be

made. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homœopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homœopathic drug, in which case it shall be subject to the provisions of the Homœopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopœia....

Misbranded Drugs and Devices

SEC. 502.

A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha eucaine, barbituric acid, betaeucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulphonmethane; or any chemical derivative of such substance, which derivative has been by the Secretary, after investigation, found to be, and by regulations designated as, habit forming; unless its label bears the name, quantity, and percentage of such substance or derivative and in juxtaposition therewith the statement "Warning-May be habit forming".

(e) If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2), in case it is fabricated from two or more

ingredients, the common or usual name of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including, whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein: Provided, That to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary....

New Drugs

SEC. 505.

(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an application filed pursuant to subsection (b) is effective with respect to such drug.

(b) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such drug.

(c) An application provided for in subsection (b) shall become effective on the sixtieth day after the filing thereof unless prior to such day the Secretary by notice to the applicant in writing postpones the effective date of the application to such time (not more than one hundred and eighty days after the filing thereof) as the Secretary deems necessary to enable him to study and investigate the application.

(d) If the Secretary finds, after due notice to the applicant and giving him an opportunity for a hearing, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection d, do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and

packing of such drug are inadequate to preserve its identity, strength, quality, and purity; or (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions, he shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

(e) The effectiveness of an application with respect to any drug shall, after due notice and opportunity for hearing to the applicant, by order of the Secretary be suspended if the Secretary finds (1) that clinical experience, tests by new methods, or tests by methods not deemed reasonably applicable when such application became effective show that such drug is unsafe for use under the conditions of use upon the basis of which the application became effective, or (2) that the application contains any untrue statement of a material fact. The order shall state the findings upon which it is based....

Chapter VI-Cosmetics

Adulterated Cosmetics

SEC. 601.

A cosmetic shall be deemed to be adulterated—

(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual: Provided, That this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness", and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this paragraph and paragraph (e) the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

(b) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(c) 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.

(d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(e) If it is not a hair dye and it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 604.

Misbranded Cosmetics

SEC. 602.

A cosmetic shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing (1) the name and pace of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If its container is so made, formed, or filled as to be misleading.

Glossary

adulteration: the addition of unnecessary or harmful substances in a product, often for the purposes of deceiving consumers

constituent: in this context, a significant ingredient in a food or medical product

homeopathic: a system of medical treatment that asserts the body can cure itself with the use of natural substances that stimulate the healing process

interstate commerce: business that takes place across state lines in the United States; such business is subject to the jurisdiction of the federal government since it involves more than one state

putrid: decayed or rotten

Document Analysis

Chapter II of the Food, Drug, and Cosmetic Act sets out a number of definitions that will be used in the law—often in specialized ways that are relevant to the way in which the legislation will be administered, enforced, and ruled on by courts. Those of us who are not lawyers or lawmakers might wonder why there needs to be a definition of "food" for example, but note how the definition provided in this law includes chewing gum and "articles used for components of any such article." Precise language like this usually anticipates arguments manufacturers might make to avoid regulation under the law and makes the law broad enough to be effectively enforced. Paragraph (g) specifies the recognized "formularies" or lists of accepted drugs. It does include homeopathic (or "homœopathic" in the spelling used in the act) medications and treatments—unsurprising since the author of the act, Senator Royal S. Copeland was a homeopathic physician. Finally, Chapter II expands the range of government overbite beyond what was included in the earlier 1906 law by specifying medical devices and cosmetics as being subject to government oversight. Note that soap was not included as a cosmetic, another example of how the "definitions" section of legislation is important for establishing the parameters of a law.

Chapter III outlines "prohibited acts" under the law and penalties that may be prescribed. These prohibited acts fall into two major categories. The first is the transport, sale, or manufacturing of "adulterated" or "misbranded" materials or doing anything that might cause food, medication, medical devices, or cosmetics to be adulterated or misbranded. The second category involves actions that attempt to prevent proper investigation and oversight, including forging paperwork or preventing authorized inspections by government officials. The prescribed penalties from Chapter III (not excerpted here) included seizures of illegal merchandise, as well as fines and imprisonment for those who were found guilty of violating the law.

Chapter IV addresses food and the opening section sets out the scope of the law, providing authorization for the creation of regulations that "promote honesty and fair dealing in the interest of consumers." The first section goes on to provide additional definitions for food regulation. Section 402 addresses "adulterated food," described as food that has had harmful substances added to it or food that has rotted or been packed under unsanitary conditions. In this way, the definition of "adulterated" was expanded from the narrower description in earlier laws and regulations. Section 403 provides for definitions and details for the regulation of "misbranded" food. Misbranding encompasses a variety of actions including deceptive labeling, such as labels that mislead consumers into thinking one food is another food. It also sets out what is required to be included on product labelling. Crucially, Section 404 of Chapter IV provides for government regulators with the authority to revoke permits when unsafe foods are found to be making their way to market and to determine when companies can have their permits restored.

Chapter V addresses the adulteration of drugs and medical devices, with Section 501 providing similar definitions as in Section 401, with authority provided for regulators to prescribe "appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity" of drugs. Like Chapter II, Section 501 provides special dispensation for homeopathic medications to be evaluated on their own terms. Section 502 outlines branding requirements including special requirements for habit-forming substances or other potentially harmful components. Section 505 sets out the requirements to bring a new drug to the market and outlines the procedure for applying for approval.

Chapter VI, covering cosmetics, follows the same pattern as Chapters IV and V, with the opening section on adulteration prescribing packaging language for cosmetics that may cause skin irritation.

Essential Themes

The 1938 Food, Drug, and Cosmetic Act in its entirety, beyond what is excerpted here, establishes a degree of government oversight of consumer affairs

that was unprecedented at the time. This oversight included the outlining of prohibited substances and requirements for labelling of foods, medications, and cosmetic products. It also allowed for extensive hands-on inspection and enforcement of the law. As discussed above, this law was very much in keeping with the legislative agenda of the Democratic majority in Congress and of President Roosevelt. The call for regulation to be based on the promotion of "honesty and fair dealing in the interest of consumers" is a clear example of the shift away from a focus on the protection of business interests to the detriment of the broader public. The Food, Drug, and Cosmetic Act was not the only instance of the federal government taking these steps in the 1930s, but it would be one of the most lasting.

—Aaron John Gulyas, MA

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