

FOOD AND DRUG LAW

Cases and Materials — SECOND EDITION

PETER BARTON HUTT
RICHARD A. MERRILL

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STATUTORY SUPPLEMENT
to
FOOD AND DRUG LAW

Cases and Materials

SECOND EDITION

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PREFACE

This Supplement contains in full or partial text the principal statutes pertinent to the study of federal food and drug law. The Food, Drug, and Cosmetic Act of 1938, as amended, is reproduced in full text. This version includes all amendments made by Congress through December 31, 1990, as well as the Radiation for Safety and Health Act, originally part of the Public Health Service Act, which has now been codified in the FD&C Act. Also reproduced in full are the 1906 Food and Drugs Act and the Fair Packaging and Labeling Act. Other related statutes whose enforcement is delegated to the Food and Drug Administration or that apply to food and drugs and related products but are administered by another agency, such as the Federal Trade Commission Act, are included in partial text only. The complete current versions of these laws, as well as other federal health and safety statutes, are reproduced in a useful compilation published biennially as a Committee Print of the Committee on Interstate and Foreign Commerce of the U.S. House of Representatives.

All provisions of statutes currently in force are included in their amended form as of December 31, 1990. It is not feasible to reproduce or illustrate each amendment of these laws, particularly the much-amended Federal Food, Drug, and Cosmetic Act, since their original enactment. The principal amendments to the 1906 Food and Drugs Act and the 1938 Food, Drug, and Cosmetic Act are set out in a compilation published periodically by the Superintendent of the Document Room, U.S. House of Representatives.

This Supplement does not reproduce many laws of general applicability to which the Food and Drug Administration is subject. It includes pertinent sections of the Administrative Procedure Act, including section 552, the Freedom of Information Act, but among the other important general laws we have omitted are the Federal Advisory Committee Act; the Paperwork Reduction Act; and the National Environmental Policy Act. For a comprehensive listing of regulatory statutes that are potentially applicable to producers of food, drugs, medical devices, cosmetics, biologics, and electronic products, *see* Appendix A of Hutt and Merrill, *FOOD AND DRUG LAW: CASES AND MATERIALS* (Second Edition), published by The Foundation Press, Inc. (1991).

The statutory provisions included in this Supplement are lengthy and in many places complex. They represent nearly a century of Congressional draftsmanship. While not even seasoned lawyers have mastered every detail of these intricate enactments, it is important for students and practitioners alike to understand the basic concepts

PREFACE

embodied in the law and to appreciate the broad array of statutory powers that FDA can rely upon in carrying out its responsibilities.

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FEDERAL FOOD, DRUG, AND COSMETIC ACT

(References in brackets [] are to title 21, United States Code)

CHAPTER I—SHORT TITLE

SECTION 1. This Act may be cited as the Federal Food, Drug, and Cosmetic Act.

CHAPTER II—DEFINITIONS *

SEC. 201. [321] For the purposes of this Act—

(a)(1) The term “State”, except as used in the last sentence of section 702(a), means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(2) The term “Territory” means any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone.

(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 U.S. Department of Health, Education, and Welfare.

(d) The term “Secretary” means the Secretary of Health, Education, and Welfare.

* The following additional definitions applicable to this Act are provided for in other Acts:

Butter. The Act of March 4, 1923 (21 U.S.C. 321a), defines butter as “the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 per centum by weight of milk fat, all tolerances having been allowed for.”

Package. The Act of July 24, 1919 (21 U.S.C. 321b), states “The word ‘package’ shall include and shall be construed to in-

clude wrapped meats inclosed in papers or other materials as prepared by the manufacturers thereof for sale.”

Nonfat Dry Milk, Milk. The Act of July 2, 1956 (21 U.S.C. 321c), defines nonfat dry milk as “the product resulting from the removal of fat and water from milk, and contains the lactose, milk proteins, and milk minerals in the same relative proportions as in the fresh milk from which made. It contains not over 5 per centum by weight of moisture. The fat content is not over 1½ per centum by weight unless otherwise indicated.”, and defines milk to mean sweet milk of cows.

(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.

(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C). A food for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) or sections 403(r)(1)(B) and 403(r)(5)(D), is made in accordance with the requirements of section 403(r) is not a drug under clause (B) solely because the label or labeling contains such a claim.

(2) The term "counterfeit drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

(h) The term "device" (except when used in paragraph (n) of this section and in sections 301(i), 403(f), 502(c), and 602(c)) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

(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, promot-

ing 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.

(j) The term "official compendium" means the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, official National Formulary, or any supplement to any of them.

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

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

(m) The term "labeling" means all labels and other written, printed, or graphic matter (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.

(o) The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

(p) The term "new drug" means—

(1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906,

as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(q) The term “pesticide chemical” means any substance which, alone, in chemical combination or in formulation with one or more other substances, is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C., secs. 135–135k) as now in force or as hereafter amended, and which is used in the production, storage, or transportation of raw agricultural commodities.

(r) The term “raw agricultural commodity” means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

(s) The term “food additive” means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

(1) a pesticide chemical in or on a raw agricultural commodity;
or

(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or

(3) a color additive; or

(4) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act, the Poultry Products Inspection Act (21 U.S.C. 451 and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 and the following); or

(5) a new animal drug.

(t)(1) The term “color additive” means a material which—

(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

(2) The term "color" includes black, white, and intermediate grays.

(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest.

(u) The term "safe," as used in paragraph (s) of this section and in sections 409, 512, and 706, has reference to the health of man or animal.

(v) *.

(w) The term "new animal drug" means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed—

(1) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a "new animal drug" if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(x) The term "animal feed", as used in paragraph (w) of this section, in section 512, and in provisions of this Act referring to such paragraph or section, means an article which is intended for use for food for animals other than man and which is intended for use as a substantial

* Repealed by sec. 701 of P.L. 91-513.

source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal.

(y) 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 of Health, Education, and Welfare 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.

(5) The presiding officer in such hearing shall prepare a written report of the hearing to which shall be attached all written material presented at the hearing. The participants in the hearing shall be given the opportunity to review and correct or supplement the presiding officer's report of the hearing.

(6) The Secretary may require the hearing to be transcribed. A party to the hearing shall have the right to have the hearing transcribed at his expense. Any transcription of a hearing shall be included in the presiding officer's report of the hearing.

(z) The term "saccharin" includes calcium saccharin, sodium saccharin, and ammonium saccharin.

(aa) The term "infant formula" means a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.

CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. [331] 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 412 or 703; or the failure to establish or maintain any record, or make any report, required under section 412, 505(i) or (k), 507(d) or (g), 512(j), (l) or (m), 515(f), or 519 or the refusal to permit access to or verification or copying of any such required record.

(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 333(c)(2) of this title 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; or the giving of a guaranty or undertaking referred to in section 333(c)(2) of this title which guaranty or undertaking is false.

(i)(1) 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 promulgated under the provisions of section 404, 506, 507, or 706.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drugs a counterfeit drug.

(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

(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 under authority of section 404, 409, 412, 505, 506, 507, 510, 512, 513, 514, 515, 516, 518, 519, 520, 704, 706, or 708 concerning any method or process which as a trade secret is entitled to protection. This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

(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 (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

(l) The using, on the labeling of any drug or device or in any advertising relating to such drug or device, of any representation or suggestion that approval of an application with respect to such drug or device is in effect under section 505, 515, or 520(g), as the case may be, or that such drug or device complies with the provisions of such section.

(m) The sale or offering for sale of colored oleomargarine or colored margarine, or the possession or serving of colored oleomargarine or colored margarine in violation of section 407(b) or 407(c).

(n) The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with section 704.

(o) In the case of a prescription drug distributed or offered for sale in interstate commerce, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable State law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved by the Secretary. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this Act.

(p) The failure to register in accordance with section 510, the failure to provide any information required by section 510(j) or 510(k); or the failure to provide a notice required by section 510(j)(2).

(q)(1) The failure or refusal to (A) comply with any requirement prescribed under section 518 or 520(g), or (B) furnish any notification or other material or information required by or under section 519 or 520(g).

(2) With respect to any device, the submission of any report that is required by or under this Act that is false or misleading in any material respect.

(r) The movement of a device in violation of an order under section 304(g) or the removal or alteration of any mark or label required by the order to identify the device as detained.

(s) The failure to provide the notice required by section 412(c) or 412(d), the failure to make the reports required by section 412(f)(1)(B), the failure to retain the records required by section 412(b)(4), or the failure to meet the requirements prescribed under section 412(f)(3).

(t) The importation of a drug in violation of section 801(d)(1), the sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 503(c), the sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade such a coupon, or the counterfeiting of such a coupon in violation of section 503(c)(2), the distribution of a drug sample in violation of section 503(d) or the failure to otherwise comply with the requirements of section 503(d), or the distribution of drugs in violation of section 503(e) or the failure to otherwise comply with the requirements of section 503(e).

INJUNCTION PROCEEDINGS

SEC. 302. [332] (a) The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown, and subject to the provisions of section 381 (relating to notice to opposite party) of Title 28, to restrain violations of section 301 of this title, except paragraphs (h), (i), and (j) of said section.

(b) In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this Act, trial shall be by the court, or, upon demand of the accused, by a jury. Such trial shall be conducted in accordance with the practice and procedure applicable in the case of proceedings subject to the provisions of section 22 of such Act of October 15, 1914, as amended. [This section, which appeared as U.S.C., title 28, sec. 387, has been repealed. It is now covered by Rule 42(b), Federal Rules of Criminal Procedure.]

PENALTIES

SEC. 303. [333] (a)(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.

(2) Notwithstanding the provisions of paragraph (1) of this section, if any person commits such a violation after a conviction of him under

this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than \$10,000 or both.

(b)(1) Notwithstanding subsection (a), any person who violates section 301(t) because of an importation of a drug in violation of section 801(d)(1), because of a sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 503(c), because of the sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade such a coupon, or the counterfeiting of such a coupon in violation of section 503(c)(2), or distribution of drugs in violation of section 503(e)(2)(A) shall be imprisoned for not more than 10 years or fined not more than \$250,000, or both.

(2) Any manufacturer or distributor who distributes drug samples by means other than the mail or common carrier whose representative, during the course of the representative's employment or association with that manufacturer or distributor, violated section 301(t) because of a violation of section 503(c)(1) or violated any State law prohibiting the sale, purchase, or trade of a drug sample subject to section 503(b) or the offer to sell, purchase, or trade such a drug sample shall, upon conviction of the representative for such violation, be subject to the following civil penalties:

(A) A civil penalty of not more than \$50,000 for each of the first two such violations resulting in a conviction of any representative of the manufacturer or distributor in any 10-year period.

(B) A civil penalty of not more than \$1,000,000 for each violation resulting in a conviction of any representative after the second conviction in any 10-year period.

For the purposes of this paragraph, multiple convictions of one or more persons arising out of the same event or transaction, or a related series of events or transactions, shall be considered as one violation.

(3) Any manufacturer or distributor who violates section 301(t) because of a failure to make a report required by section 503(d)(3)(E) shall be subject to a civil penalty of not more than \$100,000.

(4)(A) If a manufacturer or distributor or any representative of such manufacturer or distributor provides information leading to the arrest and conviction of any representative of that manufacturer or distributor for a violation of section 301(t) because of a sale, purchase, or trade or offer to purchase, sell, or trade a drug sample in violation of section 503(c)(1) or for a violation of State law prohibiting the sale, purchase, or trade or offer to sell, purchase, or trade a drug sample, the conviction of such representative shall not be considered as a violation for purposes of paragraph (2).

(B) If, in an action brought under paragraph (2) against a manufacturer or distributor relating to the conviction of a representative of such