FEDERAL FOOD AND DRUGS ACT OF 1906 (THE "WILEY ACT")

PUBLIC LAW NUMBER 59-384
34 STAT. 768 (1906)
21 U.S.C. Sec 1-15 (1934)
(REPEALED IN 1938 BY 21 U.S.C. Sec 329 (a))

TABLE OF CONTENTS

FEDERAL FOOD AND DRUGS ACT OF 1906[1]

AN ACT For preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SEC. 1. MANUFACTURE OF ADULTERATED FOODS OR DRUGS.[2]
That it shall be unlawful for any person to manufacture within any Territory or the District of Columbia any article of food or drug which is adulterated or misbranded, within the meaning of this Act; and any person who shall violate any of the provisions of this section shall be guilty of a misdemeanor, and for each offense shall, upon conviction thereof, be fined not to exceed five hundred dollars or shall be sentenced to one year's imprisonment, both such fine and imprisonment, in the discretion of the court, and for each subsequent offense and conviction thereof shall be fined not less than one thousand dollars or sentenced to one year's imprisonment, or both such fine and imprisonment, in the discretion of the court.

SEC. 2. INTERSTATE COMMERCE OF ADULTERATED GOODS.
That the introduction into any State or Territory or the District of Columbia from any other State or Territory or the District of Columbia, or from any foreign country, or shipment to any foreign country of any article of food or drugs which is adulterated or misbranded, within the meaning of this Act, is hereby prohibited; and any person who shall ship or deliver for shipment from any State or Territory or the District of Columbia to any other State or Territory or the District of Columbia, or to a foreign country, or who shall receive in any State or Territory or the District of Columbia from any other State or Territory or the District of Columbia, or foreign country, and having so received, shall deliver, in original unbroken packages, for pay or otherwise, or offer to deliver to any other person, any such article so adulterated or misbranded within the meaning of this Act, or any person who shall sell or offer for sale in the District of Columbia or the Territories of the United States any such adulterated or misbranded foods or drugs or export or offer to export the same to any foreign country, shall be guilty of a misdemeanor, and for such offense be fined not exceeding two hundred dollars for the first offense and upon conviction for each subsequent offense not exceeding three hundred dollars or be imprisoned not exceeding one year, or both, in the discretion of the court: *Provided*, That no article shall be deemed misbranded or adulterated within the provisions of this Act when intended for export to any foreign country and prepared or packed according to the specifications or directions of the foreign purchaser when no substance is used in the preparation or packing thereof in conflict with the laws of the foreign country to which said article is intended to be shipped; but if said article shall be in fact sold or offered for sale for domestic use or consumption, then this proviso shall not exempt said article from the operation of any of the other provisions of this Act.

[1]Section headings added.
[2] Sections 1 to 5 repealed (June 25, 1938, ch. 675, 1 902(a), 52 Stat. 1059).

SEC. 3. RULES AND REGULATIONS.
That the Secretary of the Treasury, the Secretary of Agriculture, and the Secretary of Commerce and Labor shall make uniform rules and regulations for carrying out the provisions of this Act, including the collection and examination of specimens of foods and drugs manufactured or offered for sale in the District of Columbia or in any Territory of the United States, or which shall be offered for sale in unbroken packages in any State other than that in which they shall have been respectively manufactured or produced, or which shall be received from any foreign country, or intended for shipment to any foreign country, or which may be submitted for examination by the chief health, food, or drug officer of any State, Territory, or the District of Columbia, or at any domestic or foreign port through which such product is offered for interstate commerce, or for export or import between the United States and any foreign port or country.

SEC. 4. CHEMICAL EXAMINATIONS.
That the examinations of specimens of foods and drugs shall be made in the Bureau of Chemistry of the Department of Agriculture, or under the direction and supervision of such Bureau, for the purpose of determining from such examinations whether such articles are adulterated or misbranded within the meaning of this Act; and if it shall appear from any such examination that any of such specimens is adulterated or misbranded within the meaning of this Act, the Secretary of Agriculture shall cause notice thereof to be given to the party from whom such sample was obtained. Any party notified shall be given an opportunity to be heard under such rules and regulations as may be prescribed as aforesaid, and if it appears that any of the provisions of this Act have been violated by such party, then the Secretary of Agriculture shall at once certify the facts to the proper United States district attorney, with a copy of the results of the analysis or the examination of such article duly authenticated by the analyst or officer making such examination, under the oath of such officer. After judgment of the court, notice shall be given by publication in such manner as may be prescribed by the rules and regulations aforesaid.

SEC. 5. LEGAL PROCEEDINGS.
That it shall be the duty of each district attorney to whom the Secretary of Agriculture shall report any violation of this Act, or to whom any health or food or drug officer or agent of any State, Territory, or the District of Columbia shall present satisfactory evidence of any such violation, to cause appropriate proceedings to be commenced and prosecuted in the proper courts of the United States, without delay, for the enforcement of the penalties as in such case herein provided.

SEC. 6. DEFINITIONS.
That the term "drug," as used in this Act, shall include all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals. The term "food," as used herein, shall include all articles used for food, drink, confectionery, or condiment by man or other animals, whether simple, mixed, or compound.

SEC. 7. ADULTERATIONS.
That for the purposes of this Act an article Shall be deemed to be adulterated:

IN CASE OF DRUGS:

- **FIRST.** If, when a drug is sold under or by a name recognized in the United States Pharmacopoeia or National Formulary, it differs from the standard of strength, quality, or purity, as determined by the test laid down in the United States Pharmacopoeia or National Formulary official at the time of investigation: *Provided,* That no drug defined in the United States Pharmacopoeia or National Formulary shall be deemed to be adulterated under this provision if the standard of strength, quality, or purity be plainly stated upon the bottle, box, or other container thereof although the standard may differ from that determined by the test laid down in the United States Pharmacopoeia or National Formulary.
- **SECOND.** If its strength or purity fall below the professed standard or quality under which it is sold.

IN THE CASE OF CONFECTIONERY:
If it contain terra alba, barytes talc, chrome yellow, or other mineral substance or poisonous color or flavor, or other ingredient deleterious or detrimental to health, or any vinous, malt or spirituous liquor or compound or narcotic drug.

IN THE CASE OF FOOD:

- **FIRST.** If any substance has been mixed and packed with it so as to reduce or lower or injuriously affect its quality or strength.
- **SECOND.** If any substance has been substituted wholly or in part for the article.
- **THIRD.** If any valuable constituent of the article has been wholly or in part abstracted.
- **FOURTH.** If it be mixed, colored, powdered, coated, or stained in a manner whereby damage or inferiority is concealed.
- **FIFTH.** If it contain any added poisonous or other added deleterious ingredient which may render such article injurious to health: *Provided,* That when in the preparation of food products for shipment they are preserved by any external application applied in such manner that the preservative is necessarily removed mechanically, or by maceration in water, or otherwise, and directions for the removal of said preservative shall be printed on the covering or the package, the provisions of this Act shall be construed as applying only when said products are ready for consumption.
- **SIXTH.** If it consists in whole or in part of a filthy, decomposed, or putrid animal or vegetable substance, or any portion of an animal unfit for food, whether manufactured or not, or if it is the product of a diseased animal, or one that has died otherwise than by slaughter.

SEC. 8. MISBRANDING.
That the term "misbranded," as used herein, shall apply to all drugs, or articles of food, or

articles which enter into the composition of food, the package or label of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular, and to any food or drug product which is falsely branded as to the State, Territory, or country in which it is manufactured or produced.

That for the purposes of this Act an article shall also be deemed to be misbranded:

IN CASE OF DRUGS:

- **FIRST.** If it be an imitation of or offered for sale under the name of another article.
- **SECOND.** If the contents of the package as originally put up shall have been removed, in whole or in part, and other contents shall have been placed in such package, or if the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any such substances contained therein.

IN THE CASE OF FOOD:

- **FIRST.** If it be an imitation of or offered for sale under the distinctive name of another article.
- **SECOND.** If it be labeled or branded as to deceive or mislead the purchaser, or purport to be a foreign product when not so, or if the contents of the package as originally put up shall have been removed in whole or in part and other contents shall have been placed in such package, or if it fail to bear a statement on the label of the quantity or proportion of any morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any of such substances contained therein.
- **THIRD.** If in package form, and the contents are stated in terms of weight or measure, they are not plainly and correctly stated on the outside of the package.
- **FOURTH.** If the package containing it or its label shall bear any statement, design, or device regarding the ingredients or the substances contained therein, which statement, design, or device shall be false or misleading in any particular: *Provided,* That an article of food which does not contain any added poisonous or deleterious ingredients shall not be deemed to be adulterated or misbranded in the following cases:
    - **FIRST.** In the case of mixtures or compounds which may be now or from time to time hereafter known as articles of food, under their own distinctive names, and not an imitation of or offered for sale under the distinctive name of another article, if the name be accompanied on the same label or brand with a statement of the place where said article has been manufactured or produced.
    - **SECOND**. In the case of articles labeled, branded, or tagged so as to plainly indicate that they are compounds, imitations, or blends, and the

word "compound," "imitation," or "blend," as the case may be, is plainly stated on the package in which it is offered for sale: *Provided*, That the term blend as used herein shall be construed to mean a mixture of like substances, not excluding harmless coloring or flavoring ingredients used for the purpose of coloring and flavoring only: *And provided further*, That nothing in this Act shall be construed as requiring or compelling proprietors or manufacturers of foods which contain no unwholesome added ingredient to disclose their trade formulas, except in so far as the provisions of this Act may require to secure freedom from adulteration or misbranding.

SEC. 9. GUARANTY FROM MANUFACTURER.

That no dealer shall be prosecuted under the provisions of this Act when he can establish a guaranty signed by the wholesaler, jobber, manufacturer, or other party residing in the United States, from whom he purchases such articles, to the effect that the same is not adulterated or misbranded within the meaning of this Act, designating it. Said guaranty, to afford protection, shall contain the name and address of the party or parties making the sale of such articles tosuch dealer, and in such case said party or parties shall be amenable to the prosecutions, fines, and other penalties which would attach, in due course, to the dealer under the provisions of this Act.

SEC. 10. SEIZURE OF ORIGINAL PACKAGES.

That any article of food, drug, or liquor that is adulterated or misbranded within the meaning of this Act, and is being transported from one State, Territory, District, or insular possession to another for sale, or, having been transported, remains unloaded unsold or in original unbroken packages, or if it be sold or offered for sale in the District of Columbia or the Territories, or insular possessions of the United States, or if it be imported from a foreign country for sale, or if it is intended for export to a foreign country, shall be liable to be proceeded against in any district court of the United States within the district where the same is found, and seized for confiscation by a process of libel for condemnation. And if such article is condemned as being adulterated or misbranded, or of a poisonous or deleterious character, within the meaning of this Act, the same shall be disposed of by destruction or sale, as the said court may direct, and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States, but such goods shall not be sold in any jurisdiction contrary to the provisions of this Act or the laws of that jurisdiction: *Provided, however*, That upon the payment of the costs of such libel proceedings and the execution and delivery of a good and sufficient bond to the effect that such articles shall not be sold or otherwise disposed of contrary to the provisions of this Act, or the laws of any State, Territory, District, or insular possession, the court may by order direct that such articles be delivered to the owner thereof. The proceedings of such libel cases shall conform, as near as may be, to the proceedings in admiralty, except that either party may demand a trial by jury of any issue of fact joined in any such case, and all such proceedings shall be at the suit of and in the name of the United States.

SEC. 11. EXAMINATION OF IMPORTED FOOD AND DRUGS.

The Secretary of the Treasury shall deliver to the Secretary of Agriculture, upon his request from time to time, samples of foods and drugs which are being imported into the United States or offered for import, giving notice thereof to the owner or consignee, who may appear before the Secretary of Agriculture, and have the right introduce testimony, and if it appear from the examination of such samples that any article of food or drug offered to be imported into the United States is adulterated or misbranded within the meaning of this Act, or is otherwise dangerous to the health of the people of the United States, or is of a kind forbidden entry into, or forbidden to be sold or restricted in sale in the country in which it is made, or from which it is exported, or is otherwise falsely labeled in any respect, the said article shall be refused admission, and the Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any goods refused delivery which shall not be exported by the consignee within three months, from the date of notice of such refusal under such regulations as the Secretary of the Treasury may prescribe: *Provided,* That the Secretary of the Treasury may deliver to the consignee such goods pending examination and decision in the matter on execution of a penal bond for the amount of the full invoice value of such goods, together with the duty thereon, and on refusal to return such goods for any cause to the custody of the Secretary of the Treasury, when demanded, for the purpose of excluding them from the country, or for any other purpose, said consignee shall forfeit the full amount of the bond: *And provided further,* that all charges for storage, cargo, and labor on goods which are refused admission or delivery shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future importation made by such owner or consignee.

SEC. 12. DEFINITIONS AND LIABILITIES.

That the term 'Territory" as used in this Act shall include the insular possessions of the United States. The word "person" as used in this Act shall be construed to import both the plural and the singular, as the case demands, and shall include corporations, companies, societies and associations. When construing and enforcing the provisions of this Act, the act, omission, or failure of any officer, agent, or other person acting for or employed by any corporation, company, society, or association, within the scope of his employment or office, shall in every case be also deemed to be the act, omission, or failure of such corporation, company, society, or association as well as that of the person.

SEC. 13. EFFECTIVE DATE.

That this Act shall be in force and effect from and after the first day of January, nineteen hundred and seven.

APPROVED, JUNE 30, 1906.

AMENDATORY AND SUPPLEMENTAL ENACTMENTS TO

THE FEDERAL FOOD AND DRUG ACT OF 1906

****

AN ACT TO amend section eight of the Food and Drugs Act approved June thirtieth, nineteen hundred and six.[1]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

That that part of section eight of the Food and Drugs Act of June thirtieth, nineteen hundred and six, defining what shall be misbranding in the case of drugs, be, and the same is hereby, amended by adding thereto a third paragraph to read as follows:

- "If its package or label shall bear or contain any statement design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein, which is false and fraudulent."

So that the said part of said section eight shall read as follows:

SEC. 8. That the term 'misbranded,' as used herein, shall apply to all drug or articles of food or articles which enter into the composition of food, the package or label of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular, and to any food or drug product which is falsely branded as to the State, Territory, or country in which it is manufactured or produced.

That for the purposes of this Act an article shall also be deemed to be misbranded.

IN CASE OF DRUGS:

- **First.** If it be an imitation of or offered for sale under the name of another article.
- **Second.** If the contents of the package as originally put up shall have been removed, in whole or in part, and other contents shall have been placed in such package, or if the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any such substances contained therein.

- **Third.** If its package or label shall bear or contain any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein, which is false and fraudulent.

APPROVED, AUGUST 23, 1912.

****

AN ACT To amend section eight of an Act entitled "An Act for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes," approved June thirtieth, nineteen hundred and six.[2]

[1] 37 Stat. 416 (1912)(commonly known as the Sherley Amendment).
[2]37 Stat. 732 (1913) (Gould Amendment)

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SEC. 1. That section eight of an Act entitled "An Act for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes," approved June thirtieth nineteen hundred and six, be, and the same is hereby, amended by striking out the words:

"Third. If in package form, and the contents are stated in terms of weight or measure, they are not plainly and correctly stated on the outside of the package," and inserting in lieu thereof the following:

"Third. If in package form, the quantity of the contents be not plainly and conspicuously marked on the outside of the package in terms of weight, measure or numerical count: *Provided, however,* That reasonable variations shall be permitted, and tolerances and also exemptions as to small packages shall be established by rules and regulations made in accordance with the provisions of Section three of this Act."

SEC. 2. That this Act shall take effect and be in force from and after its passage: *Provided, however,* That no penalty of fine, imprisonment, or confiscation shall be enforced for any violation of its provisions as to domestic products prepared or foreign productions imported prior to eighteen months after its passage.

APPROVED, MARCH 3, 1913.

****

That the word "package" where it occurs the second and last time in the Act entitled "An Act to amend section 8 of an Act entitled, 'An Act for preventing the manufacture, sale,

or transportation of adulterated or misbranded or poisonous, deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes'," approved March 3, 1913, shall include and shall be construed to include wrapped meats inclosed in papers or other materials as prepared by the manufacturers thereof for sale.[1]

****

AN ACT TO define butter and to provide a standard therefor.[2]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

That for the purposes of the Food and Drug Act of June 30, 1906, "butter" shall be understood to mean 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.

APPROVED, MARCH 4, 1923.

[1] 41 Stat. 271 (1919) (Kenyon Amendment)
[2] 42 Stat. 1500 (1923)

****

Hereafter the examinations of specimens of foods, drugs, insecticides, paris greens, lead arsenates, and fungicides provided for by section 4 of the Food and Drugs Act of June 30, 1906, and by section 4 of the Insecticide Act of 1910, shall as be made in the Food, Drug, and Insecticide Administration or in such other branches of the Department of Agriculture as the Secretary of Agriculture may direct.[1]

****

AN ACT TO amend section 8 of the Act entitled "An Act for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes," approved June 30,1906, as amended.[2]

Be it enacted by the Senate and House of Representatives of the United Stares of America in Congress assembled,

That section 8 of the Act of June 30, 1906, entitled "An Act for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes," as amended, is amended by adding at the end thereof the following:

"Fifth. If it be canned food and falls below the standard of quality, condition, and/or fill of container, promulgated by the Secretary of Agriculture for such canned food and its package or label does not bear a plain and conspicuous statement prescribed by the Secretary of Agriculture indicating that such canned food falls below such standard. For the purposes of this paragraph the words canned food mean all food which is in hermetically sealed containers and is sterilized by heat, except meat and meat food products which are subject to the provisions of the Meat Inspection Act of March 4, 1907, as amended, and except canned milk; the word class means and is limited to a generic product for which a standard is to be established and does not mean a grade, variety, or species of a generic product. The Secretary of Agriculture is authorized to determine, establish, and promulgate, from time to time, a reasonable standard of quality, condition, and/or fill of container for each class of canned food as will, in his judgment, promote honesty and fair dealing in the interest of the consumer; and he is authorized to alter or modify such standard from time to time as, in his judgment, honesty and fair dealing in the interest of the consumer may require. The Secretary of Agriculture is further authorized to prescribe and promulgate from time to time the form of statement which must appear in a plain and conspicuous manner on each package or label of canned food which falls below the standard promulgated by him, and which will indicate that such canned food falls below such standard, and he is authorized to alter or modify such form of statement, from time to time, as in his judgment may be necessary. In promulgating such standards and forms of statements and any alteration or modification thereof, the Secretary of Agriculture shall specify the date or dates when such standards shall become effective, or after which such statements shall be used, and shall give public notice not less than ninety days in advance of the date or dates on which such standards shall become effective or such statements shall be used. Nothing in this paragraph shall be construed to authorize the manufacture, sale, shipment, or transportation of adulterated or misbranded foods."

APPROVED, JULY 8, 1930.

[1] 44 Stat. 976-1003 (1927).
[2] 46 Stat. 1019 (1930) (McNary-Mapes Amendments).

****

AN ACT TO amend the Act entitled "An Act for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes," approved June 30, 1906, as amended.[1]

Be it enacted by the Senate and House of Representatives of the United Stares of America in Congress assembled,

That the Act entitled "An Act for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes," approved June 30,

1906, as amended, is amended by adding after section 10 thereof the following new section:

SEC. 10A. The Secretary of Agriculture, upon application of any packer of any sea food sold in interstate commerce, may at his discretion designate supervisory inspectors to examine and inspect all premises, equipment, methods, materials, containers, and labels used by such applicants in the production of such food. If the food is found to conform to the requirements of this Act, the applicant shall be authorized, in accordance with regulations prescribed by the Secretary of Agriculture, to mark the food so as to indicate such conformity. Services to any applicant under this section shall be rendered only upon payment of fees to be fixed by regulations of the Secretary of Agriculture in such amount as to cover the cost of the supervisory inspection and examination, together with the reasonable costs of administration incurred by the Secretary of Agriculture in carrying out this section. Receipts from such fees shall be covered into the Treasury and shall be available to the Secretary of Agriculture for expenditures incurred in carrying out this section. Any person who forges, counterfeits, simulates, or falsely represents, or without proper authority uses any mark, stamp, tag, label, or other identification devices authorized by the provisions of this section or regulations thereunder, shall be guilty of a misdemeanor, and shall on conviction thereof be subject to imprisonment for not more than one year or a fine of not less than $1,000 nor more than $5,000, or both such imprisonment and fine.

APPROVED, JUNE 22, 1934.

[1] 48 Stat. 1204 (1934)