

the drug or drugs contained therein and directions for using the same.

(Mar. 3, 1915, ch. 74, § 9, 38 Stat. 821.)

**§ 212. Offenses; punishment; duty to enforce provisions**

Any person, firm, or corporation, whose permanent allegiance is due to the United States, violating any of the provisions of this chapter shall be deemed guilty of a misdemeanor and, upon conviction thereof, shall be punished by a fine of not less than \$50 and not more than \$100 or by imprisonment for not less than one month and not more than sixty days, or by both such fine and imprisonment, in the discretion of the court, and if the offense be continuing in its character, each week or part of a week during which it continues shall constitute a separate and distinct offense. And it shall be the duty of the consular and judicial officers of the United States in China to enforce the provisions of this chapter.

(Mar. 3, 1915, ch. 74, § 11, 38 Stat. 821.)

**§ 213. Fraudulent representations to evade or defeat restrictions**

No person, firm, or corporation whose permanent allegiance is due to the United States seeking to procure in the consular districts of the United States in China any substance the sale of which is regulated by the provisions of this chapter shall make any fraudulent representations so as to evade or defeat the restrictions herein imposed.

(Mar. 3, 1915, ch. 74, § 8, 38 Stat. 821.)

**§ 214. Previous laws unaffected**

Nothing in this chapter shall be construed as modifying or revoking any of the provisions of sections 191 to 193<sup>1</sup> of this title.

(Mar. 3, 1915, ch. 74, § 13, 38 Stat. 822.)

**Editorial Notes**

**REFERENCES IN TEXT**

Sections 191 to 193 of this title, referred to in text, were repealed by Pub. L. 91-513, title III, §1101(a)(1), Oct. 27, 1970, 84 Stat. 1291. See section 801 et seq. of this title.

**§ 215. "Consul" defined**

The word "consul" as used in this chapter shall mean the consular officer in charge of the district concerned.

(Mar. 3, 1915, ch. 74, § 12, 38 Stat. 822.)

**CHAPTER 8—NARCOTIC FARMS**

**§§ 221 to 237. Repealed. July 1, 1944, ch. 373, title XIII, § 1313, 58 Stat. 714**

Section 221, act Jan. 19, 1929, ch. 82, § 1, 45 Stat. 1085, defined "habit-forming narcotic drug", "narcotic", and "addict". See section 201 of Title 42, The Public Health and Welfare.

Section 222, act Jan. 19, 1929, ch. 82, § 2, 45 Stat. 1085, provided for narcotic farms.

Section 222a, act June 23, 1935, ch. 725, § 1, 49 Stat. 1840, provided name for narcotic farm at Lexington, Ky.

Section 222b, act Mar. 28, 1938, ch. 55, § 1, 52 Stat. 134, provided name for narcotic farm at Fort Worth, Texas.

Section 223, act Jan. 19, 1929, ch. 82, § 3, 45 Stat. 1085; 1939 Reorg. Plan No. I, § 205(b), eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1425, provided for an annual estimate of expenses of maintenance of narcotic farms.

Section 224, act Jan. 19, 1929, ch. 82, § 4, 45 Stat. 1086, provided for construction of buildings for two of the narcotic farms.

Section 225, acts Jan. 19, 1929, ch. 82, § 5, 45 Stat. 1086; June 14, 1930, ch. 488, § 4(a), 46 Stat. 586; 1939 Reorg. Plan No. I, §§ 201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, provided for control and management of narcotic farms.

Section 226, act Jan. 19, 1929, ch. 82, § 6, 45 Stat. 1086; 1939 Reorg. Plan No. I, §§ 201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, provided for care and treatment of addicts.

Section 227, act Jan. 19, 1929, ch. 82, § 7, 45 Stat. 1086, provided for transfer to and from farms of addicts who are prisoners.

Section 228, act Jan. 19, 1929, ch. 82, § 8, 45 Stat. 1087, provided that it was the duty of prosecuting officers to report convicted persons believed to be addicts.

Section 229, act Jan. 19, 1929, ch. 82, § 9, 45 Stat. 1087; 1939 Reorg. Plan No. I, §§ 201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, provided for employment of addicts.

Section 230, act Jan. 19, 1929, ch. 82, § 10, 45 Stat. 1087, provided for parole of inmates.

Section 231, act Jan. 19, 1929, ch. 82, § 11, 45 Stat. 1087; 1939 Reorg. Plan No. I, §§ 201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, provided for discharge of addicts.

Section 232, act Jan. 19, 1929, ch. 82, § 12, 45 Stat. 1088; 1939 Reorg. Plan No. I, §§ 201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, provided for admission of voluntary patients.

Section 233, act Jan. 19, 1929, ch. 82, § 13, 45 Stat. 1088; 1939 Reorg. Plan No. I, §§ 201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, provided for furnishing of gratuities and transportation to discharged convicts.

Section 234, act Jan. 19, 1929, ch. 82, § 14, 45 Stat. 1089; 1939 Reorg. Plan No. I, §§ 201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, provided penalties for introduction of narcotic drugs into a narcotic farm.

Section 235, act Jan. 19, 1929, ch. 82, § 15, 45 Stat. 1089, provided penalties for escape of inmates.

Section 236, act Jan. 19, 1929, ch. 82, § 16, 45 Stat. 1089, provided penalties for procuring of escape by inmates.

Section 237, act Jan. 19, 1929, ch. 82, § 17, 45 Stat. 1089, provided for deportation of alien inmates who are entitled to a discharge from narcotic farms.

**Editorial Notes**

**RENUMBERING OF REPEALING ACT**

Title XIII, §1313, formerly title VI, §611, of act July 1, 1944, which repealed these sections, was renumbered title VII, §711, by act Aug. 13, 1946, ch. 958, § 5, 60 Stat. 1049; §713, by act Feb. 28, 1948, ch. 83, §9(b), 62 Stat. 47; title VIII, §813, by act July 30, 1956, ch. 779, §3(b), 70 Stat. 721; title IX, §913, by Pub. L. 88-581, §4(b), Sept. 4, 1964, 78 Stat. 919; title X, §1013, by Pub. L. 89-239, §3(b), Oct. 6, 1965, 79 Stat. 931; title XI, §1113, by Pub. L. 91-572, §6(b), Dec. 24, 1970, 84 Stat. 1506; title XII, §1213, by Pub. L. 92-294, §3(b), May 16, 1972, 86 Stat. 137; title XIII, §1313, by Pub. L. 93-154, §2(b)(2), Nov. 16, 1973, 87 Stat. 604, and was repealed by Pub. L. 93-222, §7(b), Dec. 29, 1973, 87 Stat. 936.

**CHAPTER 9—FEDERAL FOOD, DRUG, AND COSMETIC ACT**

**SUBCHAPTER I—SHORT TITLE**

Sec.  
301. Short title.

<sup>1</sup> See References in Text note below.

Sec.		Sec.	
	SUBCHAPTER II—DEFINITIONS		
321.	Definitions; generally.	353c.	Prereview of television advertisements.
321a.	“Butter” defined.	353d.	Process to update labeling for certain generic drugs.
321b.	“Package” defined.	354.	Veterinary feed directive drugs.
321c.	Nonfat dry milk; “milk” defined.	355.	New drugs.
321d.	Market names for catfish and ginseng.	355-1.	Risk evaluation and mitigation strategies.
	SUBCHAPTER III—PROHIBITED ACTS AND PENALTIES	355-2.	Actions for delays of generic drugs and bio-similar biological products.
331.	Prohibited acts.	355a.	Pediatric studies of drugs.
332.	Injunction proceedings.	355b.	Adverse-event reporting.
333.	Penalties.	355c.	Research into pediatric uses for drugs and biological products.
333a.	Repealed.	355c-1.	Report.
334.	Seizure.	355d.	Internal committee for review of pediatric plans, assessments, deferrals, deferral extensions, and waivers.
335.	Hearing before report of criminal violation.	355e.	Pharmaceutical security.
335a.	Debarment, temporary denial of approval, and suspension.	355f.	Extension of exclusivity period for new qualified infectious disease products.
335b.	Civil penalties.	355g.	Utilizing real world evidence.
335c.	Authority to withdraw approval of abbreviated drug applications.	355h.	Regulation of certain nonprescription drugs that are marketed without an approved drug application.
336.	Report of minor violations.	356.	Expedited approval of drugs for serious or life-threatening diseases or conditions.
337.	Proceedings in name of United States; provision as to subpoenas.	356-1.	Accelerated approval of priority countermeasures.
337a.	Extraterritorial jurisdiction.	356-2.	Accelerated approval Council.
	SUBCHAPTER IV—FOOD	356a.	Manufacturing changes.
341.	Definitions and standards for food.	356b.	Reports of postmarketing studies.
342.	Adulterated food.	356c.	Discontinuance or interruption in the production of life-saving drugs.
343.	Misbranded food.	356c-1.	Annual reporting on drug shortages.
343-1.	National uniform nutrition labeling.	356d.	Coordination; task force and strategic plan.
343-2.	Dietary supplement labeling exemptions.	356e.	Drug shortage list.
343-3.	Disclosure.	356f.	Hospital repackaging of drugs in shortage.
343a.	Repealed.	356g.	Standards for regenerative medicine and regenerative advanced therapies.
344.	Emergency permit control.	356h.	Competitive generic therapies.
345.	Regulations making exemptions.	356i.	Prompt reports of marketing status.
346.	Tolerances for poisonous or deleterious substances in food; regulations.	356j.	Discontinuance or interruption in the production of medical devices.
346a.	Tolerances and exemptions for pesticide chemical residues.	356k.	Platform technologies.
346b.	Authorization of appropriations.	356l.	Advanced manufacturing technologies designation program.
347.	Intrastate sales of colored oleomargarine.	357.	Qualification of drug development tools.
347a.	Congressional declaration of policy regarding oleomargarine sales.	358.	Authority to designate official names.
347b.	Contravention of State laws.	359.	Nonapplicability of subchapter to cosmetics.
348.	Food additives.	360.	Registration of producers of drugs or devices.
349.	Bottled drinking water standards; publication in Federal Register.	360a.	Clinical trial guidance for antibiotic drugs.
350.	Vitamins and minerals.	360a-1.	Clinical trials.
350a.	Infant formulas.	360a-2.	Susceptibility test interpretive criteria for microorganisms.
350a-1.	Protecting infants and improving formula supply.	360b.	New animal drugs.
350b.	New dietary ingredients.	360b-1.	Priority zoonotic animal drugs.
350c.	Maintenance and inspection of records.	360c.	Classification of devices intended for human use.
350d.	Registration of food facilities.	360c-1.	Reporting.
350e.	Sanitary transportation practices.	360d.	Performance standards.
350f.	Reportable food registry.	360e.	Premarket approval.
350g.	Hazard analysis and risk-based preventive controls.	360e-1.	Pediatric uses of devices.
350h.	Standards for produce safety.	360e-3.	Breakthrough devices.
350i.	Protection against intentional adulteration.	360e-4.	Predetermined change control plans for devices.
350j.	Targeting of inspection resources for domestic facilities, foreign facilities, and ports of entry; annual report.	360f.	Banned devices.
350k.	Laboratory accreditation for analyses of foods.	360g.	Judicial review.
350l.	Mandatory recall authority.	360g-1.	Agency documentation and review of significant decisions regarding devices.
350l-1.	Annual report to Congress.	360g-2.	Third party data transparency.
350m.	Requirements for critical food.	360h.	Notification and other remedies.
	SUBCHAPTER V—DRUGS AND DEVICES	360h-1.	Program to improve the device recall system.
	PART A—DRUGS AND DEVICES	360i.	Records and reports on devices.
351.	Adulterated drugs and devices.	360j.	General provisions respecting control of devices intended for human use.
352.	Misbranded drugs and devices.	360k.	State and local requirements respecting devices.
353.	Exemptions and consideration for certain drugs, devices, and biological products.	360l.	Postmarket surveillance.
353a.	Pharmacy compounding.	360m.	Accredited persons.
353a-1.	Enhanced communication.	360n.	Priority review to encourage treatments for tropical diseases.
353b.	Outsourcing facilities.		