

**§ 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.)

## 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Sections 191 to 193 of this title, referred to in text, were repealed by Pub.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 Repealed.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.

## 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.

## SUBCHAPTER II—DEFINITIONS

321. Definitions; generally.  
321a. "Butter" defined.  
321b. "Package" defined.  
321c. Nonfat dry milk; "milk" defined.  
321d. Market names for catfish and ginseng.

## SUBCHAPTER III—PROHIBITED ACTS AND PENALTIES

331. Prohibited acts.  
332. Injunction proceedings.  
333. Penalties.  
333a. Repealed.  
334. Seizure.  
335. Hearing before report of criminal violation.  
335a. Debarment, temporary denial of approval, and suspension.  
335b. Civil penalties.  
335c. Authority to withdraw approval of abbreviated drug applications.  
336. Report of minor violations.  
337. Proceedings in name of United States; provision as to subpoenas.  
337a. Extraterritorial jurisdiction.

## SUBCHAPTER IV—FOOD

341. Definitions and standards for food.  
342. Adulterated food.  
343. Misbranded food.  
343-1. National uniform nutrition labeling.  
343-2. Dietary supplement labeling exemptions.  
343-3. Disclosure.  
343a. Repealed.  
344. Emergency permit control.  
345. Regulations making exemptions.  
346. Tolerances for poisonous or deleterious substances in food; regulations.  
346a. Tolerances and exemptions for pesticide chemical residues.  
346b. Authorization of appropriations.  
347. Intrastate sales of colored oleomargarine.  
347a. Congressional declaration of policy regarding oleomargarine sales.  
347b. Contravention of State laws.  
348. Food additives.  
349. Bottled drinking water standards; publication in Federal Register.

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

- Sec. 350. Vitamins and minerals.  
 350a. Infant formulas.  
 350b. New dietary ingredients.  
 350c. Maintenance and inspection of records.  
 350d. Registration of food facilities.  
 350e. Sanitary transportation practices.  
 350f. Reportable food registry.  
 350g. Hazard analysis and risk-based preventive controls.  
 350h. Standards for produce safety.  
 350i. Protection against intentional adulteration.  
 350j. Targeting of inspection resources for domestic facilities, foreign facilities, and ports of entry; annual report.  
 350k. Laboratory accreditation for analyses of foods.  
 350l. Mandatory recall authority.  
 350l-1. Annual report to Congress.
- SUBCHAPTER V—DRUGS AND DEVICES
- PART A—DRUGS AND DEVICES
351. Adulterated drugs and devices.  
 352. Misbranded drugs and devices.  
 353. Exemptions and consideration for certain drugs, devices, and biological products.  
 353a. Pharmacy compounding.  
 353a-1. Enhanced communication.  
 353b. Outsourcing facilities.  
 353c. Prereview of television advertisements.  
 354. Veterinary feed directive drugs.  
 355. New drugs.  
 355-1. Risk evaluation and mitigation strategies.  
 355-2. Actions for delays of generic drugs and bi-similar biological products.  
 355a. Pediatric studies of drugs.  
 355b. Adverse-event reporting.  
 355c. Research into pediatric uses for drugs and biological products.  
 355c-1. Report.  
 355d. Internal committee for review of pediatric plans, assessments, deferrals, deferral extensions, and waivers.  
 355e. Pharmaceutical security.  
 355f. Extension of exclusivity period for new qualified infectious disease products.  
 355g. Utilizing real world evidence.  
 356. Expedited approval of drugs for serious or life-threatening diseases or conditions.  
 356-1. Accelerated approval of priority countermeasures.  
 356a. Manufacturing changes.  
 356b. Reports of postmarketing studies.  
 356c. Discontinuance or interruption in the production of life-saving drugs.  
 356c-1. Annual reporting on drug shortages.  
 356d. Coordination; task force and strategic plan.  
 356e. Drug shortage list.  
 356f. Hospital repackaging of drugs in shortage.  
 356g. Standards for regenerative medicine and regenerative advanced therapies.  
 356h. Competitive generic therapies.  
 356i. Prompt reports of marketing status.  
 357. Qualification of drug development tools.  
 358. Authority to designate official names.  
 359. Nonapplicability of subchapter to cosmetics.  
 360. Registration of producers of drugs or devices.  
 360a. Clinical trial guidance for antibiotic drugs.  
 360a-1. Clinical trials.  
 360a-2. Susceptibility test interpretive criteria for microorganisms.  
 360b. New animal drugs.  
 360c. Classification of devices intended for human use.  
 360c-1. Reporting.  
 360d. Performance standards.  
 360e. Premarket approval.  
 360e-1. Pediatric uses of devices.  
 360e-3. Breakthrough devices.
- Sec. 360f. Banned devices.  
 360g. Judicial review.  
 360g-1. Agency documentation and review of significant decisions regarding devices.  
 360h. Notification and other remedies.  
 360h-1. Program to improve the device recall system.  
 360i. Records and reports on devices.  
 360j. General provisions respecting control of devices intended for human use.  
 360k. State and local requirements respecting devices.  
 360l. Postmarket surveillance.  
 360m. Accredited persons.  
 360n. Priority review to encourage treatments for tropical diseases.  
 360n-1. Priority review for qualified infectious disease products.
- PART B—DRUGS FOR RARE DISEASES OR CONDITIONS
- 360aa. Recommendations for investigations of drugs for rare diseases or conditions.  
 360bb. Designation of drugs for rare diseases or conditions.  
 360cc. Protection for drugs for rare diseases or conditions.  
 360dd. Open protocols for investigations of drugs for rare diseases or conditions.  
 360ee. Grants and contracts for development of drugs for rare diseases and conditions.  
 360ff. Priority review to encourage treatments for rare pediatric diseases.  
 360ff-1. Targeted drugs for rare diseases.
- PART C—ELECTRONIC PRODUCT RADIATION CONTROL
- 360hh. Definitions.  
 360ii. Program of control.  
 360jj. Studies by Secretary.  
 360kk. Performance standards for electronic products.  
 360ll. Notification of defects in and repair or replacement of electronic products.  
 360mm. Imports.  
 360nn. Inspection, records, and reports.  
 360oo. Prohibited acts.  
 360pp. Enforcement.  
 360qq. Repealed.  
 360rr. Federal-State cooperation.  
 360ss. State standards.
- PART D—DISSEMINATION OF TREATMENT INFORMATION
- 360aaa to 360aaa-6. Omitted.
- PART E—GENERAL PROVISIONS RELATING TO DRUGS AND DEVICES
- 360bbb. Expanded access to unapproved therapies and diagnostics.  
 360bbb-0. Expanded access policy required for investigational drugs.  
 360bbb-0a. Investigational drugs for use by eligible patients.  
 360bbb-1. Dispute resolution.  
 360bbb-2. Classification of products.  
 360bbb-3. Authorization for medical products for use in emergencies.  
 360bbb-3a. Emergency use of medical products.  
 360bbb-3b. Products held for emergency use.  
 360bbb-3c. Expedited development and review of medical products for emergency uses.  
 360bbb-4. Countermeasure development, review, and technical assistance.  
 360bbb-4a. Priority review to encourage treatments for agents that present national security threats.  
 360bbb-4b. Medical countermeasure master files.  
 360bbb-5. Critical Path Public-Private Partnerships.  
 360bbb-6. Risk communication.  
 360bbb-7. Notification.  
 360bbb-8. Consultation with external experts on rare diseases, targeted therapies, and genetic targeting of treatments.