

- 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.  
 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.  
 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.  
 357. Repealed.  
 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.  
 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.  
 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.
- Sec. 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.
- 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-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-4. Countermeasure development, review, and technical assistance.  
 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.  
 360bbb-8a. Optimizing global clinical trials.  
 360bbb-8b. Use of clinical investigation data from outside the United States.  
 360bbb-8c. Patient participation in medical product discussion.
- PART F—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES
- 360ccc. Conditional approval of new animal drugs for minor use and minor species.  
 360ccc-1. Index of legally marketed unapproved new animal drugs for minor species.  
 360ccc-2. Designated new animal drugs for minor use or minor species.
- PART G—MEDICAL GASES
- 360ddd. Definitions.  
 360ddd-1. Regulation of medical gases.  
 360ddd-2. Inapplicability of drug fees to designated medical gases.

- Sec.  
PART H—PHARMACEUTICAL DISTRIBUTION SUPPLY CHAIN
- 360eee. Definitions.  
360eee-1. Requirements.  
360eee-2. National standards for prescription drug wholesale distributors.  
360eee-3. National standards for third-party logistics providers.  
360eee-4. Uniform national policy.
- PART I—NONPRESCRIPTION SUNSCREEN AND OTHER ACTIVE INGREDIENTS
- 360fff. Definitions.  
360fff-1. Submission of requests.  
360fff-2. Eligibility determinations; data submission; filing.  
360fff-3. GRASE determination.  
360fff-4. Guidance; other provisions.  
360fff-5. Sunscreen monograph.  
360fff-6. Non-sunscreen time and extent applications.  
360fff-7. Report.
- SUBCHAPTER VI—COSMETICS
361. Adulterated cosmetics.  
362. Misbranded cosmetics.  
363. Regulations making exemptions.  
364. Repealed.
- SUBCHAPTER VII—GENERAL AUTHORITY
- PART A—GENERAL ADMINISTRATIVE PROVISIONS
371. Regulations and hearings.  
372. Examinations and investigations.  
372a. Transferred.  
373. Records.  
374. Inspection.  
374a. Inspections relating to food allergens.  
375. Publicity.  
376. Examination of sea food on request of packer; marking food with results; fees; penalties.  
377. Revision of United States Pharmacopoeia; development of analysis and mechanical and physical tests.  
378. Advertising of foods.  
379. Confidential information.  
379a. Presumption of existence of jurisdiction.  
379b. Consolidated administrative and laboratory facility.  
379c. Transferred.  
379d. Automation of Food and Drug Administration.  
379d-1. Conflicts of interest.  
379d-2. Policy on the review and clearance of scientific articles published by FDA employees.  
379d-3. Streamlined hiring authority.  
379d-4. Reporting requirements.  
379d-5. Guidance document regarding product promotion using the Internet.
- PART B—COLORS
- 379e. Listing and certification of color additives for foods, drugs, devices, and cosmetics.
- PART C—FEES
- SUBPART 1—FREEDOM OF INFORMATION FEES
- 379f. Recovery and retention of fees for freedom of information requests.
- SUBPART 2—FEES RELATING TO DRUGS
- 379g. Definitions.  
379h. Authority to assess and use drug fees.  
379h-1. Fees relating to advisory review of prescription-drug television advertising.  
379h-2. Reauthorization; reporting requirements.
- SUBPART 3—FEES RELATING TO DEVICES
- 379i. Definitions.
- Sec.  
379j. Authority to assess and use device fees.  
379j-1. Reauthorization; reporting requirements.
- SUBPART 4—FEES RELATING TO ANIMAL DRUGS
- 379j-11. Definitions.  
379j-12. Authority to assess and use animal drug fees.  
379j-13. Reauthorization; reporting requirements.
- SUBPART 5—FEES RELATING TO GENERIC NEW ANIMAL DRUGS
- 379j-21. Authority to assess and use generic new animal drug fees.  
379j-22. Reauthorization; reporting requirements.
- SUBPART 6—FEES RELATED TO FOOD
- 379j-31. Authority to collect and use fees.
- SUBPART 7—FEES RELATING TO GENERIC DRUGS
- 379j-41. Definitions.  
379j-42. Authority to assess and use human generic drug fees.  
379j-43. Reauthorization; reporting requirements.
- SUBPART 8—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS
- 379j-51. Definitions.  
379j-52. Authority to assess and use biosimilar biological product fees.  
379j-53. Reauthorization; reporting requirements.
- SUBPART 9—FEES RELATING TO OUTSOURCING FACILITIES
- 379j-61. Definitions.  
379j-62. Authority to assess and use outsourcing facility fees.
- PART D—INFORMATION AND EDUCATION
- 379k. Information system.  
379k-1. Electronic format for submissions.  
379l. Education.
- PART E—ENVIRONMENTAL IMPACT REVIEW
- 379o. Environmental impact.
- PART F—NATIONAL UNIFORMITY FOR NONPRESCRIPTION DRUGS AND PREEMPTION FOR LABELING OR PACKAGING OF COSMETICS
- 379r. National uniformity for nonprescription drugs.  
379s. Preemption for labeling or packaging of cosmetics.
- PART G—SAFETY REPORTS
- 379v. Safety report disclaimers.
- PART H—SERIOUS ADVERSE EVENT REPORTS
- 379aa. Serious adverse event reporting for nonprescription drugs.  
379aa-1. Serious adverse event reporting for dietary supplements.
- PART I—REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION
- 379dd. Establishment and functions of the Foundation.  
379dd-1. Location of Foundation.  
379dd-2. Activities of the Food and Drug Administration.
- SUBCHAPTER VIII—IMPORTS AND EXPORTS
381. Imports and exports.  
382. Exports of certain unapproved products.  
383. Office of International Relations.  
384. Importation of prescription drugs.  
384a. Foreign supplier verification program.  
384b. Voluntary qualified importer program.  
384c. Inspection of foreign food facilities.

- Sec.  
384d. Accreditation of third-party auditors.  
384e. Recognition of foreign government inspections.

## SUBCHAPTER IX—TOBACCO PRODUCTS

387. Definitions.  
387a. FDA authority over tobacco products.  
387a-1. Final rule.  
387b. Adulterated tobacco products.  
387c. Misbranded tobacco products.  
387d. Submission of health information to the Secretary.  
387e. Annual registration.  
387f. General provisions respecting control of tobacco products.  
387f-1. Enforcement action plan for advertising and promotion restrictions.  
387g. Tobacco product standards.  
387h. Notification and other remedies.  
387i. Records and reports on tobacco products.  
387j. Application for review of certain tobacco products.  
387k. Modified risk tobacco products.  
387l. Judicial review.  
387m. Equal treatment of retail outlets.  
387n. Jurisdiction of and coordination with the Federal Trade Commission.  
387o. Regulation requirement.  
387p. Preservation of State and local authority.  
387q. Tobacco Products Scientific Advisory Committee.  
387r. Drug products used to treat tobacco dependence.  
387s. User fees.  
387t. Labeling, recordkeeping, records inspection.  
387u. Studies of progress and effectiveness.

## SUBCHAPTER X—MISCELLANEOUS

391. Separability clause.  
392. Exemption of meats and meat food products.  
393. Food and Drug Administration.  
393a. Office of Pediatric Therapeutics.  
394. Scientific review groups.  
395. Loan repayment program.  
396. Practice of medicine.  
397. Contracts for expert review.  
398. Notices to States regarding imported food.  
399. Grants to enhance food safety.  
399a. Office of the Chief Scientist.  
399b. Office of Women's Health.  
399c. Improving the training of State, local, territorial, and tribal food safety officials.  
399d. Employee protections.  
399e. Nanotechnology.  
399f. Ensuring adequate information regarding pharmaceuticals for all populations, particularly underrepresented subpopulations, including racial subgroups.

## SUBCHAPTER I—SHORT TITLE

## § 301. Short title

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

(June 25, 1938, ch. 675, § 1, 52 Stat. 1040.)

## EFFECTIVE DATE; POSTPONEMENT IN CERTAIN CASES

Act June 23, 1939, ch. 242, §§ 1, 2, 53 Stat. 853, 854, provided that:

“[SEC. 1] (a) The effective date of the following provisions of the Federal Food, Drug, and Cosmetic Act is hereby postponed until January 1, 1940: Sections 402(c) [342(c) of this title]; 403(e)(1) [343(e)(1) of this title]; 403(g), (h), (i), (j), and (k) [343(g) to (k) of this title]; 501(a), (4) [351(a)(4) of this title]; 502(b), (d), (e), (f), (g), and (h) [352(b), (d) to (h) of this title]; 601(e) [361(e) of this title]; and 602(b) [362(b) of this title].

“(b) The Secretary of Agriculture shall promulgate regulations further postponing to July 1, 1940[,] the effective date of the provisions of sections 403(e)(1) [343(e)(1) of this title]; 403(g), (h), (i), (j), and (k) [343(g) to (k)]; 502(b), (d), (e), (f), (g), and (h) [352(b), (d) to (h) of this title]; and 602(b) [362(b) of this title] of such Act with respect to lithographed labeling which was manufactured prior to February 1, 1939, and to containers bearing labeling which, prior to February 1, 1939, was lithographed, etched, stamped, pressed, printed, fused or blown on or in such containers, where compliance with such provisions would be unduly burdensome by reason of causing the loss of valuable stocks of such labeling or containers, and where such postponement would not prevent the public interest being adequately served: Provided, That in no case shall such regulations apply to labeling which would not have complied with the requirements of the Food and Drugs Act of June 30, 1906, as amended.

“SEC. 2. (a) The provisions of section 8 [section 10 of this title], paragraph fifth, under the heading ‘In the case of food’, of the Food and Drugs Act of June 30, 1906, as amended, and regulations promulgated thereunder, and all other provisions of such Act to the extent that they may relate to the enforcement of such section 8 [section 10 of this title] and of such regulations, shall remain in force until January 1, 1940.

“(b) The provisions of such Act of June 30, 1906, as amended, [sections 1 to 5, 7 to 15, and 372a of this title] to the extent that they impose, or authorize the imposition of, any requirement imposed by section 403(k) of the Federal Food, Drug, and Cosmetic Act [section 343(k) of this title], shall remain in force until January 1, 1940.

“(c) Notwithstanding the provisions of section 1 of this Act, such section shall not apply—

“(1) to the provisions of section 502(d) and (e) of the Federal Food, Drug, and Cosmetic Act [352(d), (e) of this title], insofar as such provisions relate to any substance named in section 8 [section 10 of this title], paragraph second, under the heading ‘In the case of drugs’, of the Food and Drugs Act of June 30, 1906, as amended, or a derivative of any such substance; or

“(2) to the provisions of section 502(b), (d), (e), (f), (g), and (h) of the Federal Food, Drug, and Cosmetic Act [352(b), (d) to (h) of this title], insofar as such provisions relate to drugs to which section 505 [355 of this title] of such Act applies.”

## EFFECTIVE DATE

Act June 25, 1938, ch. 675, § 1002(a), formerly § 902(a), 52 Stat. 1059; renumbered § 1002(a), Pub. L. 111-31, div. A, title I, § 101(b)(2), June 22, 2009, 123 Stat. 1784, provided that: “This Act [enacting this chapter and repealing sections 1 to 5 and 7 to 15 of this title], shall take effect twelve months after the date of its enactment [June 25, 1938]. The Federal Food and Drugs Act of June 30, 1906, as amended (U.S.C., 1934 ed., title 21, secs. 1-15), shall remain in force until such effective date, and, except as otherwise provided in this subsection, is hereby repealed effective upon such date: *Provided*, That the provisions of section 701 [section 371 of this title] shall become effective on the enactment of this Act, and thereafter the Secretary is authorized hereby to (1) conduct hearings and to promulgate regulations which shall become effective on or after the effective date of this Act as the Secretary shall direct, and (2) designate prior to the effective date of this Act food having common or usual names and exempt such food from the requirements of clause (2) of section 403(i) [section 343(i) of this title] for a reasonable time to permit the formulation, promulgation, and effective application of definitions and standards of identity therefor as provided by section 401 [section 341 of this title]: *Provided further*, That sections 502(j), 505, and 601(a) [sections 352(j), 355, 361(a), respectively of this title], and all other provisions of this Act to the extent that they may relate to the enforcement of such sections, shall take effect on the date of the enactment of this Act, except that in the case of a cosmetic to which the proviso of section