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355f. 355g. 356. 356-1. 356a. 356b. 356c. 356c-1. 356e. 356f. 356g. 357. 358. 359. 360. 360.	tensions, and waivers. Pharmaceutical security. Extension of exclusivity period for new qualified infectious disease products. Utilizing real world evidence. Expedited approval of drugs for serious or life-threatening diseases or conditions. Accelerated approval of priority countermeasures. Manufacturing changes. Reports of postmarketing studies. Discontinuance or interruption in the production of life-saving drugs. Annual reporting on drug shortages. Coordination; task force and strategic plan. Drug shortage list. Hospital repackaging of drugs in shortage. Standards for regenerative medicine and regenerative advanced therapies. Qualification of drug development tools. Authority to designate official names. Nonapplicability of subchapter to cosmetics. Registration of producers of drugs or devices. Clinical trial guidance for antibiotic drugs.	360qq. 360rr. 360ss. PART I 360aaa t PART 360bbb. 360bbb-1 360bbb-3 360bbb-3 360bbb-4 360bbb-4 360bbb-5 360bbb-5	Repealed. Federal-State cooperation. State standards.  D—DISSEMINATION OF TREATMENT INFORMATION of 360aaa-6. Omitted  E—GENERAL PROVISIONS RELATING TO DRUGS AND DEVICES  Expanded access to unapproved therapies and diagnostics. Expanded access policy required for investigational drugs. Dispute resolution. Classification of products. Authorization for medical products for use in emergencies. a Emergency use of medical products. b-Products held for emergency use. Countermeasure development, review, and technical assistance. a-Priority review to encourage treatments for agents that present national security threats. Critical Path Public-Private Partnerships. Risk communication.
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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