EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91–513 effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91–513, set out as an Effective Date note under section 801 of this title.

EFFECTIVE DATE OF 1965 AMENDMENT

Amendment by Pub. L. 89–74 effective Feb. 1, 1966, subject to registration with Secretary of names, places of business, establishments, and other prescribed information prior to Feb. 1, 1966, see section 11 of Pub. L. 89–74, set out as a note under section 321 of this title.

SAVINGS PROVISION

Amendment by Pub. L. 91–513 not to affect or abate any prosecutions for any violation of law or any civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of such amendment, and all administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs [now the Drug Enforcement Administration] on Oct. 27, 1970, to be continued and brought to final determination in accord with laws and regulations in effect prior to Oct. 27, 1970, see section 702 of Pub. L. 91–513, set out as a note under section 321 of this title.

DEVICE MODIFICATIONS

Pub. L. 114–255, div. A, title III, §3059(b), Dec. 13, 2016, 130 Stat. 1130, provided that: ''The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue final guidance regarding when a premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) is required to be submitted for a modification or change to a legally marketed device. Such final guidance shall be issued not later than 1 year after the date on which the comment period closes for the draft guidance on such subject.''

DECLARATION OF POLICY OF DRUG LISTING ACT OF 1972

Pub. L. 92–387, §2, Aug. 16, 1972, 86 Stat. 559, provided that: ''The Federal Government which is responsible for regulating drugs has no ready means of determining what drugs are actually being manufactured or packed by establishments registered under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] except by periodic inspection of such registered establishments. Knowledge of which particular drugs are being manufactured or packed by each registered establishment would substantially assist in the enforcement of Federal laws requiring that such drugs be pure, safe, effective, and properly labeled. Information on the discontinuance of a particular drug could serve to alleviate the burden of reviewing and implementing enforcement actions against drugs which, although commercially discontinued, remain active for regulatory purposes. Information on the type and number of different drugs being manufactured or packed by drug establishments could permit more effective and timely regulation by the agencies of the Federal Government responsible for regulating drugs, including identification of which drugs in interstate commerce are subject to section 505 or 507 [21 U.S.C. 355, 357], or to other provisions of the Federal Food, Drug, and Cosmetic Act.''

CONGRESSIONAL DECLARATION OF NEED FOR REGISTRATION AND INSPECTION OF DRUG ESTABLISHMENTS

Pub. L. 87–781, title III, §301, Oct. 10, 1962, 76 Stat. 793, provided that: ''The Congress hereby finds and declares that in order to make regulation of interstate commerce in drugs effective, it is necessary to provide for registration and inspection of all establishments in which drugs are manufactured, prepared, propagated, compounded, or processed; that the products of all such establishments are likely to enter the channels of interstate commerce and directly affect such commerce; and that the regulation of interstate commerce in drugs without provision for registration and inspection of establishments that may be engaged only in intrastate commerce in such drugs would discriminate against and depress interstate commerce in such drugs, and adversely burden, obstruct, and affect such interstate commerce.''

REGISTRATION OF CERTAIN PERSONS OWNING OR OPERATING DRUG ESTABLISHMENTS PRIOR TO OCT. 10, 1962

Pub. L. 87–781, title III, §303, Oct. 10, 1962, 76 Stat. 795, provided that any person who, on the day immediately preceding Oct. 10, 1962, owned or operated an establishment which manufactured or processed drugs, registered before the first day of the seventh month following October, 1962, would be deemed to be registered in accordance with subsec. (b) of this section for the calendar year 1962 and if registered within this period and effected in 1963, be deemed in compliance for that calendar year.

§ 360a. Clinical trial guidance for antibiotic drugs

(a) In general

Not later than 1 year after September 27, 2007, the Secretary shall issue guidance for the conduct of clinical trials with respect to antibiotic drugs, including antimicrobials to treat acute bacterial sinusitis, acute bacterial otitis media, and acute bacterial exacerbation of chronic bronchitis. Such guidance shall indicate the appropriate models and valid surrogate markers.

(b) Review

Not later than 5 years after September 27, 2007, the Secretary shall review and update the guidance described under subsection (a) to reflect developments in scientific and medical information and technology.

(June 25, 1938, ch. 675, §511, as added Pub. L. 110–85, title IX, §911, Sept. 27, 2007, 121 Stat. 951.)

PRIOR PROVISIONS

A prior section 360a, act June 25, 1938, ch. 675, §511, as added July 15, 1965, Pub. L. 89–74, §3(b), 79 Stat. 227; amended Oct. 24, 1968, Pub. L. 90–639, §2(a), 82 Stat. 1361, regulated the manufacture, compounding, and processing of depressant and stimulant drugs and their sale, delivery, disposal, possession, and recordkeeping activities connected therewith, prior to repeal by Pub. L. 91–513, title II, §§701(a), 704, Oct. 27, 1970, 84 Stat. 1281, 1284, effective on the first day of the seventh calendar month that began after Oct. 26, 1970.

§ 360a–1. Clinical trials

(a) Review and revision of guidance documents

(1) In general

The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall review and, as appropriate, revise not fewer than 3 guidance documents per year, which shall include—

(A) reviewing the guidance documents of the Food and Drug Administration for the conduct of clinical trials with respect to antibacterial and antifungal drugs; and

(B) as appropriate, revising such guidance documents to reflect developments in scientific and medical information and technology and to ensure clarity regarding the procedures and requirements for approval of antibacterial and antifungal drugs under chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.).

(2) Issues for review

At a minimum, the review under paragraph (1) shall address the appropriate animal models of infection, in vitro techniques, valid microbiological surrogate markers, the use of noninferiority versus superiority trials, trial enrollment, data requirements, and appropriate delta values for noninferiority trials.

(3) Rule of construction

Except to the extent to which the Secretary makes revisions under paragraph (1)(B), nothing in this section shall be construed to repeal or otherwise effect the guidance documents of the Food and Drug Administration.

(b) Recommendations for investigations

(1) Request

The sponsor of a drug intended to be designated as a qualified infectious disease product may request that the Secretary provide written recommendations for nonclinical and clinical investigations which the Secretary believes may be necessary to be conducted with the drug before such drug may be approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in treating, detecting, preventing, or identifying a qualifying pathogen, as defined in section 505E of such Act [21 U.S.C. 355f].

(2) Recommendations

If the Secretary has reason to believe that a drug for which a request is made under this subsection is a qualified infectious disease product, the Secretary shall provide the person making the request written recommendations for the nonclinical and clinical investigations which the Secretary believes, on the basis of information available to the Secretary at the time of the request, would be necessary for approval under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) of such drug for the use described in paragraph (1).

(c) Qualified infectious disease product

For purposes of this section, the term ''qualified infectious disease product'' has the meaning given such term in section 505E(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355f(g)], as added by section 801 of this Act.

(Pub. L. 112–144, title VIII, § 804, July 9, 2012, 126 Stat. 1080.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (a)(1)(B), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to this chapter. Chapter V of the Act is classified generally to this subchapter. For complete classification of this Act to the Code, see section 301 of this title and Tables.

This Act, referred to in subsec. (c), is Pub. L. 112–144, July 9, 2012, 126 Stat. 993, known as the Food and Drug Administration Safety and Innovation Act. For complete classification of this Act to the Code, see Tables.

CODIFICATION

Section was enacted as part of the Food and Drug Administration Safety and Innovation Act, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

§ 360a–2. Susceptibility test interpretive criteria for microorganisms

(a) Purpose; identification of criteria

(1) Purpose

The purpose of this section is to clarify the Secretary's authority to—

(A) efficiently update susceptibility test interpretive criteria for antimicrobial drugs when necessary for public health, due to, among other things, the constant evolution of microorganisms that leads to the development of resistance to drugs that have been effective in decreasing morbidity and mortality for patients, which warrants unique management of antimicrobial drugs that is inappropriate for most other drugs in order to delay or prevent the development of further resistance to existing therapies;

(B) provide for public notice of the availability of recognized interpretive criteria and interpretive criteria standards; and

(C) clear under section 360(k) of this title, classify under section 360c(f)(2) of this title, or approve under section 360e of this title, antimicrobial susceptibility testing devices utilizing updated, recognized susceptibility test interpretive criteria to characterize the in vitro susceptibility of particular bacteria, fungi, or other microorganisms, as applicable, to antimicrobial drugs.

(2) Identification of criteria

The Secretary shall identify appropriate susceptibility test interpretive criteria with respect to antimicrobial drugs—

(A) if such criteria are available on the date of approval of the drug under section 355 of this title or licensure of the drug under section 262 of title 42 (as applicable), upon such approval or licensure; or

(B) if such criteria are unavailable on such date, on the date on which such criteria are available for such drug.

(3) Bases for initial identification

The Secretary shall identify appropriate susceptibility test interpretive criteria under paragraph (2), based on the Secretary's review of, to the extent available and relevant—

(A) preclinical and clinical data, including pharmacokinetic, pharmacodynamic, and epidemiological data;

(B) the relationship of susceptibility test interpretive criteria to morbidity and mortality associated with the disease or condition for which such drug is used; and

(C) such other evidence and information as the Secretary considers appropriate.

(b) Susceptibility test Interpretive Criteria Website

(1) In general

Not later than 1 year after December 13, 2016, the Secretary shall establish, and maintain thereafter, on the website of the Food and Drug Administration, a dedicated website that contains a list of any appropriate new or updated susceptibility test interpretive criteria standards and interpretive criteria in accordance with paragraph (2) (referred to in this