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.)

Editorial Notes

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.)

Editorial Notes

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.

Statutory Notes and Related Subsidiaries

DECENTRALIZED CLINICAL STUDIES

Pub. L. 117–328, div. FF, title III, §3606, Dec. 29, 2022, 136 Stat. 5865, provided that:

''(a) GUIDANCE.—The Secretary [of Health and Human Services] shall—

''(1) not later than 1 year after the date of enactment of this Act [Dec. 29, 2022], issue or revise draft guidance that includes recommendations to clarify and advance the use of decentralized clinical studies to support the development of drugs and devices, including recommendations for how to advance the use of flexible and novel clinical trial designs and to help improve trial participant engagement, recruitment, enrollment, and retention of a meaningfully diverse clinical population, including with respect to race, ethnicity, age, sex, and geographic location, when appropriate; and

''(2) not later than 1 year after closing the comment period on such draft guidance, finalize such guidance.

''(b) CONTENT OF GUIDANCE.—The guidance under subsection (a) shall address the following:

''(1) Recommendations related to digital health technology or other assessment options, such as telehealth, local laboratories, local health care providers, or other options for remote data collection, could support decentralized clinical studies, including guidance on considerations for selecting technological platforms and mediums, data collection and use, data integrity and security, and communication to study participants through digital technology.

''(2) Recommendations for subject recruitment, retention, and engagement, including considerations for sponsors to minimize or reduce burdens for clinical study participants through the use of digital health technology, telehealth, local health care providers and laboratories, health care provider home visits, direct-to-participant engagement, electronic informed consent, or other means, as appropriate.

''(3) Recommendations with respect to the evaluation of data collected within a decentralized clinical study setting.

''(4) Recommendations for methods of remote data collection, including clinical trial participant experience data, through the use of digital health technologies, telemedicine, local laboratories, local health care providers, or other options for data collection.

''(5) Considerations for sponsors to minimize or reduce burdens for clinical trial participants associated with participating in a clinical trial, such as the use of digital technologies, telemedicine, local laboratories, local health care providers, or other data collection or assessment options, health care provider home visits, direct-to-participant shipping of investigational drugs and devices, and electronic informed consent, as appropriate.

''(6) Recommendations regarding conducting decentralized clinical trials to facilitate and encourage meaningful diversity among clinical trial participants, including with respect to race, ethnicity, age, sex, and geographic location, as appropriate.

''(7) Recommendations for strategies and methods for recruiting, retaining, and engaging with clinical trial participants, including communication regarding the role of clinical trial participants and community partners to facilitate clinical trial recruitment and engagement, including with respect to diverse and underrepresented populations, as appropriate.

''(8) Considerations for review and oversight by sponsors and institutional review boards, including remote trial oversight.

''(9) Recommendations for decentralized clinical trial protocol designs and processes for evaluating such proposed clinical trial designs.

''(10) Recommendations related to digital health technology and other remote assessment tools that may support decentralized clinical trials, including guidance on appropriate technological platforms and tools, data collection and use, data integrity, and communication to clinical trial participants through such technology.

''(11) A description of the manner in which the Secretary will assess or evaluate data collected within a decentralized clinical trial to support the development of the drug or device, if the manner is different from that used for a nondecentralized trial.

''(12) Considerations for sponsors to validate digital technologies and establish appropriate clinical endpoints for use in decentralized trials.

''(13) Considerations for privacy and security of personally identifiable information of trial participants.

''(14) Considerations for conducting clinical trials using centralized approaches in conjunction with decentralized approaches.

''(c) DEFINITION.—In this section, the term 'decentralized clinical study' means a clinical study in which some or all of the study-related activities occur at a location separate from the investigator's location.''

MODERNIZING CLINICAL TRIALS

Pub. L. 117–328, div. FF, title III, §3607, Dec. 29, 2022, 136 Stat. 5866, provided that:

''(a) CLARIFYING THE USE OF DIGITAL HEALTH TECHNOLOGIES IN CLINICAL TRIALS.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act [Dec. 29, 2022], the Secretary [of Health and Human Services] shall issue or revise draft guidance regarding the appropriate use of digital health technologies in clinical trials to help improve recruitment for, retention in, participation in, and data collection during, clinical trials, and provide for novel clinical trial designs utilizing such technology for purposes of supporting the development of, and review of applications for, drugs and devices. Not later than 18 months after the public comment period on such draft guidance ends, the Secretary shall issue a revised draft guidance or final guidance.

''(2) CONTENT.—The guidance described in paragraph (1) shall include—

''(A) recommendations for data collection methodologies by which sponsors may incorporate the use of digital health technologies in clinical trials to collect data remotely from trial participants;

''(B) considerations for privacy and security protections for data collected during a clinical trial, including—

''(i) recommendations for the protection of trial participant data that are collected or used in research using digital health technologies;

''(ii) compliance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 ([Pub. L. 104–191;] 42 U.S.C. 1320d–2 note), subpart B of part 50 of title 21, Code of Federal Regulations, subpart C of part 56 of title 21, Code of Federal Regulations, the Federal policy for the protection of human subjects under subpart A of part 46 of title 45, Code of Federal Regulations (commonly known as the 'Common Rule'), and part 2 of title 42, Code of Federal Regulations (or any successor regulations); and

''(iii) recommendations for the protection of clinical trial participant data against cybersecurity threats, as applicable;

''(C) considerations on data collection methods to help increase recruitment of clinical trial participants and the level of participation of such participants, reduce burden on clinical trial participants, and optimize data quality;

''(D) recommendations for the use of electronic methods to obtain informed consent from clinical trial participants, taking into consideration applicable Federal law, including subpart B of part 50 of title 21, Code of Federal Regulations (or successor regulations), and, as appropriate, State law;

''(E) best practices for communication between sponsors and the Secretary on the development of data collection methods;

''(F) the appropriate format to submit such data to the Secretary;

''(G) a description of the manner in which the Secretary may assess or evaluate data collected through digital health technologies to support the development of the drug or device;

''(H) recommendations regarding the data and information needed to demonstrate that a digital health technology is fit-for-purpose for a clinical trial, and a description of how the Secretary will evaluate such data and information; and

''(I) recommendations for increasing access to, and the use of, digital health technologies in clinical trials to facilitate the inclusion of diverse and underrepresented populations, as appropriate, including considerations for access to, and the use of, digital health technologies in clinical trials by people with disabilities and pediatric populations.

''(b) SEAMLESS AND CONCURRENT CLINICAL TRIALS.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary shall issue or revise draft guidance on the use of seamless, concurrent, and other innovative clinical trial designs to support the expedited development and review of applications for drugs, as appropriate. Not later than 18 months after the public comment period on such draft guidance ends, the Secretary shall issue a revised draft guidance or final guidance.

''(2) CONTENT.—The guidance described in paragraph (1) shall include—

''(A) recommendations on the use of expansion cohorts and other seamless clinical trial designs to assess different aspects of product candidates in one continuous trial, including how such clinical trial designs can be used as part of meeting the substantial evidence standard under section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d));

''(B) recommendations on the use of clinical trial designs that involve the concurrent conduct of different or multiple clinical trial phases, and the concurrent conduct of preclinical testing, to expedite the development of new drugs and facilitate the timely collection of data;

''(C) recommendations for how to streamline trial logistics and facilitate the efficient collection and analysis of clinical trial data, including any planned interim analyses and how such analyses could be used to streamline the product development and review processes;

''(D) considerations to assist sponsors in ensuring the rights, safety, and welfare of clinical trial participants, maintaining compliance with good clinical practice regulations, minimizing risks to clinical trial data integrity, and ensuring the reliability of clinical trial results;

''(E) recommendations for communication between sponsors and the Food and Drug Administration on the development of seamless, concurrent, or other adaptive clinical trial designs, including review of, and feedback on, clinical trial protocols; and

''(F) a description of the manner in which the Secretary will assess or evaluate data collected through seamless, concurrent, or other adaptive clinical trial designs to support the development of drugs.

''(c) INTERNATIONAL HARMONIZATION.—The Secretary shall, as appropriate, work with foreign regulators pursuant to memoranda of understanding or other arrangements governing the exchange of information to facilitate international harmonization of the regulation and use of decentralized clinical trials, digital technology in clinical trials, and seamless, concurrent, and other adaptive or innovative clinical trial designs.''

§ 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 main-