tions to, and publish the list of qualifying pathogens under subparagraph (A) and shall by regulation revise the list as necessary, in accordance with subsection (e).

(g) Qualified infectious disease product

The term ''qualified infectious disease product'' means a drug (including a biological product), including an antibacterial or antifungal drug, for human use that—

(1) acts on bacteria or fungi or on substances produced by such bacteria or fungi; and

(2) is intended to treat a serious or life-threatening infection, including such an infection caused by—

(A) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens; or

(B) qualifying pathogens listed by the Secretary under subsection (f).

(June 25, 1938, ch. 675, § 505E, as added Pub. L. 112–144, title VIII, § 801(a), July 9, 2012, 126 Stat. 1077; amended Pub. L. 117–328, div. FF, title III, § 3212(a), Dec. 29, 2022, 136 Stat. 5826.)

Editorial Notes

AMENDMENTS

2022—Subsec. (c)(4). Pub. L. 117–328, § 3212(a)(1), added par. (4).

Subsec. (d)(1). Pub. L. 117–328, § 3212(a)(2), inserted ''or section 262(a) of title 42'' after ''section 355(b) of this title''.

Subsec. (g). Pub. L. 117–328, § 3212(a)(3), amended subsec. (g) generally. Prior to amendment, text read as follows: ''The term 'qualified infectious disease product' means an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by—

''(1) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens; or

''(2) qualifying pathogens listed by the Secretary under subsection (f).''

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Pub. L. 112–144, title VIII, § 801(b), July 9, 2012, 126 Stat. 1079, provided that: ''Section 505E of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355f], as added by subsection (a), applies only with respect to a drug that is first approved under section 505(c) of such Act (21 U.S.C. 355(c)) on or after the date of the enactment of this Act [July 9, 2012].''

§ 355g. Utilizing real world evidence

(a) In general

The Secretary shall establish a program to evaluate the potential use of real world evidence—

(1) to help to support the approval of a new indication for a drug approved under section 355(c) of this title; and

(2) to help to support or satisfy postapproval study requirements.

(b) Real world evidence defined

In this section, the term ''real world evidence'' means data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than traditional clinical trials.

(c) Program framework

(1) In general

Not later than 2 years after December 13, 2016, the Secretary shall establish a draft framework for implementation of the program under this section.

(2) Contents of framework

The framework shall include information describing—

(A) the sources of real world evidence, including ongoing safety surveillance, observational studies, registries, claims, and patient-centered outcomes research activities;

(B) the gaps in data collection activities;

(C) the standards and methodologies for collection and analysis of real world evidence; and

(D) the priority areas, remaining challenges, and potential pilot opportunities that the program established under this section will address.

(3) Consultation

(A) In general

In developing the program framework under this subsection, the Secretary shall consult with regulated industry, academia, medical professional organizations, representatives of patient advocacy organizations, consumer organizations, disease research foundations, and other interested parties.

(B) Process

The consultation under subparagraph (A) may be carried out through approaches such as—

(i) a public-private partnership with the entities described in such subparagraph in which the Secretary may participate;

(ii) a contract, grant, or other arrangement, as the Secretary determines appropriate, with such a partnership or an independent research organization; or

(iii) public workshops with the entities described in such subparagraph.

(d) Program implementation

The Secretary shall, not later than 3 years after December 13, 2016, and in accordance with the framework established under subsection (c), implement the program to evaluate the potential use of real world evidence.

(e) Guidance for industry

The Secretary shall—

(1) utilize the program established under subsection (a), its activities, and any subsequent pilots or written reports, to inform a guidance for industry on—

(A) the circumstances under which sponsors of drugs and the Secretary may rely on real world evidence for the purposes described in paragraphs (1) and (2) of subsection (a); and

(B) the appropriate standards and methodologies for collection and analysis of real world evidence submitted for such purposes;

(2) not later than 5 years after December 13, 2016, issue draft guidance for industry as described in paragraph (1); and

(3) not later than 18 months after the close of the public comment period for the draft guidance described in paragraph (2), issue revised draft guidance or final guidance.

(f) Rule of construction

(1) In general

Subject to paragraph (2), nothing in this section prohibits the Secretary from using real world evidence for purposes not specified in this section, provided the Secretary determines that sufficient basis exists for any such nonspecified use.

(2) Standards of evidence and Secretary's authority

This section shall not be construed to alter—

(A) the standards of evidence under—

(i) subsection (c) or (d) of section 355 of this title, including the substantial evidence standard in such subsection (d); or

(ii) section 262(a) of title 42; or

(B) the Secretary's authority to require postapproval studies or clinical trials, or the standards of evidence under which studies or trials are evaluated.

(June 25, 1938, ch. 675, § 505F, as added Pub. L. 114–255, div. A, title III, § 3022, Dec. 13, 2016, 130 Stat. 1096; amended Pub. L. 115–52, title IX, § 901(c), (d), Aug. 18, 2017, 131 Stat. 1076.)

Editorial Notes

AMENDMENTS

2017—Subsec. (b). Pub. L. 115–52, § 901(c), substituted ''traditional'' for ''randomized''.

Subsec. (d). Pub. L. 115–52, § 901(d), substituted ''3 years'' for ''2 years''.

§ 355h. Regulation of certain nonprescription drugs that are marketed without an approved drug application

(a) Nonprescription drugs marketed without an approved application

Nonprescription drugs marketed without an approved drug application under section 355 of this title, as of March 27, 2020, shall be treated in accordance with this subsection.

(1) Drugs subject to a final monograph; category I drugs subject to a tentative final monograph

A drug is deemed to be generally recognized as safe and effective under section 321(p)(1) of this title, not a new drug under section 321(p) of this title, and not subject to section 353(b)(1) of this title, if—

(A) the drug is—

(i) in conformity with the requirements for nonprescription use of a final monograph issued under part 330 of title 21, Code of Federal Regulations (except as provided in paragraph (2)), the general requirements for nonprescription drugs, and conditions or requirements under subsections (b), (c), and (k); and

(ii) except as permitted by an order issued under subsection (b) or, in the case of a minor change in the drug, in conformity with an order issued under subsection (c), in a dosage form that, immediately prior to March 27, 2020, has been used to a material extent and for a material time under section 321(p)(2) of this title; or

(B) the drug is—

(i) classified in category I for safety and effectiveness under a tentative final monograph that is the most recently applicable proposal or determination issued under part 330 of title 21, Code of Federal Regulations;

(ii) in conformity with the proposed requirements for nonprescription use of such tentative final monograph, any applicable subsequent determination by the Secretary, the general requirements for nonprescription drugs, and conditions or requirements under subsections (b), (c), and (k); and

(iii) except as permitted by an order issued under subsection (b) or, in the case of a minor change in the drug, in conformity with an order issued under subsection (c), in a dosage form that, immediately prior to March 27, 2020, has been used to a material extent and for a material time under section 321(p)(2) of this title.

(2) Treatment of sunscreen drugs

With respect to sunscreen drugs subject to this section, the applicable requirements in terms of conformity with a final monograph, for purposes of paragraph (1)(A)(i), shall be the requirements specified in part 352 of title 21, Code of Federal Regulations, as published on May 21, 1999, beginning on page 27687 of volume 64 of the Federal Register, except that the applicable requirements governing effectiveness and labeling shall be those specified in section 201.327 of title 21, Code of Federal Regulations.

(3) Category III drugs subject to a tentative final monograph; category I drugs subject to proposed monograph or advance notice of proposed rulemaking

A drug that is not described in paragraph (1), (2), or (4) is not required to be the subject of an application approved under section 355 of this title, and is not subject to section 353(b)(1) of this title, if—

(A) the drug is—

(i) classified in category III for safety or effectiveness in the preamble of a proposed rule establishing a tentative final monograph that is the most recently applicable proposal or determination for such drug issued under part 330 of title 21, Code of Federal Regulations;

(ii) in conformity with—

(I) the conditions of use, including indication and dosage strength, if any, described for such category III drug in such preamble or in an applicable subsequent proposed rule;

(II) the proposed requirements for drugs classified in such tentative final monograph in category I in the most recently proposed rule establishing requirements related to such tentative final monograph and in any final rule es-