''(c) REPORT.—Not later than 1 year after the date of enactment of this Act [Oct. 24, 2018], or, if earlier, at the time the guidelines under subsection (a) are finalized, the Commissioner of Food and Drugs shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, and post on the public website of the Food and Drug Administration, a report on how the Food and Drug Administration will utilize the guidelines under subsection (a) to protect the public health and a description of the public health need with respect to each such indication-specific treatment guideline.

''(d) UPDATES.—The Commissioner of Food and Drugs shall periodically—

''(1) update the guidelines under subsection (a), informed by public input described in subsection (b); and

''(2) submit to the committees specified in subsection (c) and post on the public website of the Food and Drug Administration an updated report under such subsection.

''(e) STATEMENT TO ACCOMPANY GUIDELINES AND RECOMMENDATIONS.—The Commissioner of Food and Drugs shall ensure that opioid analgesic prescribing guidelines and other recommendations developed under this section are accompanied by a clear statement that such guidelines or recommendations, as applicable—

''(1) are intended to help inform clinical decision-making by prescribers and patients; and

''(2) are not intended to be used for the purposes of restricting, limiting, delaying, or denying coverage for, or access to, a prescription issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.''

PRESCRIBER EDUCATION

Pub. L. 114–198, title I, §106(b), July 22, 2016, 130 Stat. 703, provided that: ''Not later than 1 year after the date of the enactment of this Act [July 22, 2016], the Secretary [of Health and Human Services], acting through the Commissioner of Food and Drugs, as part of the Food and Drug Administration's evaluation of the Extended-Release/Long-Acting Opioid Analgesics Risk Evaluation and Mitigation Strategy, and in consultation with relevant stakeholders, shall develop recommendations regarding education programs for prescribers of opioids pursuant to section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1), including recommendations on—

''(1) which prescribers should participate in such programs; and

''(2) how often participation in such programs is necessary.''

GUIDANCE

Pub. L. 112–144, title XI, §1132(c), July 9, 2012, 126 Stat. 1122, provided that: ''Not later than 1 year after the date of enactment of this Act [July 9, 2012], the Secretary of Health and Human Services shall issue guidance that, for purposes of section 505–1(h)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(h)(2)(A)), describes the types of modifications to approved risk evaluation and mitigation strategies that shall be considered to be minor modifications of such strategies.''

§ 355–2. Actions for delays of generic drugs and biosimilar biological products

(a) Definitions

In this section—

(1) the term ''commercially reasonable, market-based terms'' means—

(A) a nondiscriminatory price for the sale of the covered product at or below, but not greater than, the most recent wholesale acquisition cost for the drug, as defined in section 1395w–3a(c)(6)(B) of title 42;

(B) a schedule for delivery that results in the transfer of the covered product to the eligible product developer consistent with the timing under subsection (b)(2)(A)(iv); and

(C) no additional conditions are imposed on the sale of the covered product;

(2) the term ''covered product''—

(A) means—

(i) any drug approved under subsection (c) or (j) of section 355 of this title or biological product licensed under subsection (a) or (k) of section 262 of title 42;

(ii) any combination of a drug or biological product described in clause (i); or

(iii) when reasonably necessary to support approval of an application under section 355 of this title, or section 262 of title 42, as applicable, or otherwise meet the requirements for approval under either such section, any product, including any device, that is marketed or intended for use with such a drug or biological product; and

(B) does not include any drug or biological product that appears on the drug shortage list in effect under section 356e of this title, unless—

(i) the drug or biological product has been on the drug shortage list in effect under such section 356e of this title continuously for more than 6 months; or

(ii) the Secretary determines that inclusion of the drug or biological product as a covered product is likely to contribute to alleviating or preventing a shortage.

(3) the term ''device'' has the meaning given the term in section 321 of this title;

(4) the term ''eligible product developer'' means a person that seeks to develop a product for approval pursuant to an application for approval under subsection (b)(2) or (j) of section 355 of this title or for licensing pursuant to an application under section 262(k) of title 42;

(5) the term ''license holder'' means the holder of an application approved under subsection (c) or (j) of section 355 of this title or the holder of a license under subsection (a) or (k) of section 262 of title 42 for a covered product;

(6) the term ''REMS'' means a risk evaluation and mitigation strategy under section 355–1 of this title;

(7) the term ''REMS with ETASU'' means a REMS that contains elements to assure safe use under section 355–1(f) of this title;

(8) the term ''Secretary'' means the Secretary of Health and Human Services;

(9) the term ''single, shared system of elements to assure safe use'' means a single, shared system of elements to assure safe use under section 355–1(f) of this title; and

(10) the term ''sufficient quantities'' means an amount of a covered product that the eligible product developer determines allows it to—

(A) conduct testing to support an application under—

(i) subsection (b)(2) or (j) of section 355 of this title; or

(ii) section 262(k) of title 42; and

(B) fulfill any regulatory requirements relating to approval of such an application.

(b) Civil action for failure to provide sufficient quantities of a covered product

(1) In general

An eligible product developer may bring a civil action against the license holder for a covered product seeking relief under this subsection in an appropriate district court of the United States alleging that the license holder has declined to provide sufficient quantities of the covered product to the eligible product developer on commercially reasonable, market-based terms.

(2) Elements

(A) In general

To prevail in a civil action brought under paragraph (1), an eligible product developer shall prove, by a preponderance of the evidence—

(i) that—

(I) the covered product is not subject to a REMS with ETASU; or

(II) if the covered product is subject to a REMS with ETASU—

(aa) the eligible product developer has obtained a covered product authorization from the Secretary in accordance with subparagraph (B); and

(bb) the eligible product developer has provided a copy of the covered product authorization to the license holder;

(ii) that, as of the date on which the civil action is filed, the eligible product developer has not obtained sufficient quantities of the covered product on commercially reasonable, market-based terms;

(iii) that the eligible product developer has submitted a written request to purchase sufficient quantities of the covered product to the license holder, and such request—

(I) was sent to a named corporate officer of the license holder;

(II) was made by certified or registered mail with return receipt requested;

(III) specified an individual as the point of contact for the license holder to direct communications related to the sale of the covered product to the eligible product developer and a means for electronic and written communications with that individual; and

(IV) specified an address to which the covered product was to be shipped upon reaching an agreement to transfer the covered product; and

(iv) that the license holder has not delivered to the eligible product developer sufficient quantities of the covered product on commercially reasonable, market-based terms—

(I) for a covered product that is not subject to a REMS with ETASU, by the date that is 31 days after the date on which the license holder received the request for the covered product; and

(II) for a covered product that is subject to a REMS with ETASU, by 31 days after the later of—

(aa) the date on which the license holder received the request for the covered product; or

(bb) the date on which the license holder received a copy of the covered product authorization issued by the Secretary in accordance with subparagraph (B).

(B) Authorization for covered product subject to a REMS with ETASU

(i) Request

An eligible product developer may submit to the Secretary a written request for the eligible product developer to be authorized to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU.

(ii) Authorization

Not later than 120 days after the date on which a request under clause (i) is received, the Secretary shall, by written notice, authorize the eligible product developer to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU for purposes of—

(I) development and testing that does not involve human clinical trials, if the eligible product developer has agreed to comply with any conditions the Secretary determines necessary; or

(II) development and testing that involves human clinical trials, if the eligible product developer has—

(aa)(AA) submitted protocols, informed consent documents, and informational materials for testing that include protections that provide safety protections comparable to those provided by the REMS for the covered product; or

(BB) otherwise satisfied the Secretary that such protections will be provided; and

(bb) met any other requirements the Secretary may establish.

(iii) Notice

A covered product authorization issued under this subparagraph shall state that the provision of the covered product by the license holder under the terms of the authorization will not be a violation of the REMS for the covered product.

(3) Affirmative defense

In a civil action brought under paragraph (1), it shall be an affirmative defense, on which the defendant has the burden of persuasion by a preponderance of the evidence—

(A) that, on the date on which the eligible product developer requested to purchase sufficient quantities of the covered product from the license holder—

(i) neither the license holder nor any of its agents, wholesalers, or distributors was engaged in the manufacturing or commercial marketing of the covered product; and

(ii) neither the license holder nor any of its agents, wholesalers, or distributors otherwise had access to inventory of the covered product to supply to the eligible product developer on commercially reasonable, market-based terms;

(B) that—

(i) the license holder sells the covered product through agents, distributors, or wholesalers;

(ii) the license holder has placed no restrictions, explicit or implicit, on its agents, distributors, or wholesalers to sell covered products to eligible product developers; and

(iii) the covered product can be purchased by the eligible product developer in sufficient quantities on commercially reasonable, market-based terms from the agents, distributors, or wholesalers of the license holder; or

(C) that the license holder made an offer to the individual specified pursuant to paragraph (2)(A)(iii)(III), by a means of communication (electronic, written, or both) specified pursuant to such paragraph, to sell sufficient quantities of the covered product to the eligible product developer at commercially reasonable market-based terms—

(i) for a covered product that is not subject to a REMS with ETASU, by the date that is 14 days after the date on which the license holder received the request for the covered product, and the eligible product developer did not accept such offer by the date that is 7 days after the date on which the eligible product developer received such offer from the license holder; or

(ii) for a covered product that is subject to a REMS with ETASU, by the date that is 20 days after the date on which the license holder received the request for the covered product, and the eligible product developer did not accept such offer by the date that is 10 days after the date on which the eligible product developer received such offer from the license holder.

(4) Remedies

(A) In general

If an eligible product developer prevails in a civil action brought under paragraph (1), the court shall—

(i) order the license holder to provide to the eligible product developer without delay sufficient quantities of the covered product on commercially reasonable, market-based terms;

(ii) award to the eligible product developer reasonable attorney's fees and costs of the civil action; and

(iii) award to the eligible product developer a monetary amount sufficient to deter the license holder from failing to provide eligible product developers with sufficient quantities of a covered product on commercially reasonable, market-based terms, if the court finds, by a preponderance of the evidence—

(I) that the license holder delayed providing sufficient quantities of the covered product to the eligible product developer without a legitimate business justification; or

(II) that the license holder failed to comply with an order issued under clause (i).

(B) Maximum monetary amount

A monetary amount awarded under subparagraph (A)(iii) shall not be greater than the revenue that the license holder earned on the covered product during the period—

(i) beginning on—

(I) for a covered product that is not subject to a REMS with ETASU, the date that is 31 days after the date on which the license holder received the request; or

(II) for a covered product that is subject to a REMS with ETASU, the date that is 31 days after the later of—

(aa) the date on which the license holder received the request; or

(bb) the date on which the license holder received a copy of the covered product authorization issued by the Secretary in accordance with paragraph (2)(B); and

(ii) ending on the date on which the eligible product developer received sufficient quantities of the covered product.

(C) Avoidance of delay

The court may issue an order under subparagraph (A)(i) before conducting further proceedings that may be necessary to determine whether the eligible product developer is entitled to an award under clause (ii) or (iii) of subparagraph (A), or the amount of any such award.

(c) Limitation of liability

A license holder for a covered product shall not be liable for any claim under Federal, State, or local law arising out of the failure of an eligible product developer to follow adequate safeguards to assure safe use of the covered product during development or testing activities described in this section, including transportation, handling, use, or disposal of the covered product by the eligible product developer.

(d) Omitted

(e) Rule of construction

(1) Definition

In this subsection, the term ''antitrust laws''—

(A) has the meaning given the term in subsection (a) of section 12 of title 15; and

(B) includes section 45 of title 15 to the extent that such section applies to unfair methods of competition.

(2) Antitrust laws

Nothing in this section shall be construed to limit the operation of any provision of the antitrust laws.

(f) Omitted

(g) Rule of construction

Nothing in this section, the amendments made by this section, or in section 355–1 of this title, shall be construed as—

(1) prohibiting a license holder from providing an eligible product developer access to a covered product in the absence of an authorization under this section; or

(2) in any way negating the applicability of a REMS with ETASU, as otherwise required under such section 355–1 of this title, with respect to such covered product.

(Pub. L. 116–94, div. N, title I, § 610, Dec. 20, 2019, 133 Stat. 3130.)

Editorial Notes

CODIFICATION

Section was enacted as part of the Further Consolidated Appropriations Act, 2020, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

Section is comprised of section 610 of Pub. L. 116–94. Subsecs. (d) and (f) of section 610 of Pub. L. 116–94 amended section 355–1 of this title.

§ 355a. Pediatric studies of drugs

(a) Definitions

As used in this section, the term ''pediatric studies'' or ''studies'' means at least one clinical investigation (that, at the Secretary's discretion, may include pharmacokinetic studies) in pediatric age groups (including neonates in appropriate cases) in which a drug is anticipated to be used, and, at the discretion of the Secretary, may include preclinical studies.

(b) Market exclusivity for new drugs

(1) In general

Except as provided in paragraph (2), if, prior to approval of an application that is submitted under section 355(b)(1) of this title, the Secretary determines that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), the applicant agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with subsection (d)(4)—

(A)(i)(I) the period referred to in subsection (c)(3)(E)(ii) of section 355 of this title, and in subsection (j)(5)(F)(ii) of such section, is deemed to be five years and six months rather than five years, and the references in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of such section to four years, to forty-eight months, and to seven and one-half years are deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

(II) the period referred to in clauses (iii) and (iv) of subsection (c)(3)(E) of such section, and in clauses (iii) and (iv) of subsection (j)(5)(F) of such section, is deemed to be three years and six months rather than three years; and

(ii) if the drug is designated under section 360bb of this title for a rare disease or condition, the period referred to in section 360cc(a) of this title is deemed to be seven years and six months rather than seven years; and

(B)(i) if the drug is the subject of—

(I) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 355 of this title and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

(II) a listed patent for which a certification has been submitted under subsections (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 355 of this title,

the period during which an application may not be approved under section 355(c)(3) of this title or section 355(j)(5)(B) of this title shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

(ii) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 355 of this title, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 355(c)(3) of this title or section 355(j)(5)(B) of this title shall be extended by a period of six months after the date the patent expires (including any patent extensions).

(2) Exception

The Secretary shall not extend the period referred to in paragraph (1)(A) or (1)(B) if the determination made under subsection (d)(4) is made later than 9 months prior to the expiration of such period.

(c) Market exclusivity for already-marketed drugs

(1) In general

Except as provided in paragraph (2), if the Secretary determines that information relating to the use of an approved drug in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under section 355(b)(1) of this title for pediatric studies (which shall include a timeframe for completing such studies), the holder agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with subsection (d)(4)—

(A)(i)(I) the period referred to in subsection (c)(3)(E)(ii) of section 355 of this title, and in subsection (j)(5)(F)(ii) of such section, is deemed to be five years and six months rather than five years, and the references in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of such section to four years, to forty-eight months, and to seven and one-half years are deemed to be four and one-half years, fifty-four months, and eight years, respectiv ely; or

(II) the period referred to in clauses (iii) and (iv) of subsection (c)(3)(E) of such sec-