the date the stay of regulation of approval has been removed, whichever is later, of the number of the patent to be extended and the date the stay was imposed and the date commercial marketing was permitted. On receipt of such notice, the Director shall promptly issue to the owner of record of the patent a certificate of extension, under seal, stating the fact and length of the extension and identifying the composition of matter or process for using such composition to which such extension is applicable. Such certificate shall be recorded in the official file of each patent extended and such certificate shall be considered as part of the original patent, and an appropriate notice shall be published in the Official Gazette of the Patent and Trademark Office.

(Added Pub. L. 97–414, § 11(a), Jan. 4, 1983, 96 Stat. 2065; amended Pub. L. 106–113, div. B, § 1000(a)(9) [title IV, § 4732(a)(6), (10)(A)], Nov. 29, 1999, 113 Stat. 1536, 1501A–582; Pub. L. 107–273, div. C, title III, § 13206(b)(1)(B), Nov. 2, 2002, 116 Stat. 1906.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in text, is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of Title 21, Food and Drugs. Section 409 of the Federal Food, Drug, and Cosmetic Act is classified to section 348 of Title 21. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

Date of enactment of this section, referred to in text, means date of enactment of Pub. L. 97–414, which was approved Jan. 4, 1983.

AMENDMENTS

2002—Pub. L. 107–273 made technical correction to directory language of Pub. L. 106–113, § 1000(a)(9) [title IV, § 4732(a)(10)(A)]. See 1999 Amendment note below.

1999—Pub. L. 106–113, § 1000(a)(9) [title IV, § 4732(a)(10)(A)], as amended by Pub. L. 107–273, substituted ''Director shall promptly'' for ''Commissioner shall promptly''.

Pub. L. 106–113, § 1000(a)(9) [title IV, § 4732(a)(6)], substituted ''notify the Director'' for ''notify the Commissioner of Patents and Trademarks''.

EFFECTIVE DATE OF 1999 AMENDMENT

Amendment by Pub. L. 106–113 effective 4 months after Nov. 29, 1999, see section 1000(a)(9) [title IV, § 4731] of Pub. L. 106–113, set out as a note under section 1 of this title.

§ 155A. Patent term restoration

(a) Notwithstanding section 154 of this title, the term of each of the following patents shall be extended in accordance with this section:

(1) Any patent which encompasses within its scope a composition of matter which is a new drug product, if during the regulatory review of the product by the Federal Food and Drug Administration—

(A) the Federal Food and Drug Administration notified the patentee, by letter dated February 20, 1976, that such product's new drug application was not approvable under section 505(b)(1) of the Federal Food, Drug and Cosmetic Act;

(B) in 1977 the patentee submitted to the Federal Food and Drug Administration the results of a health effects test to evaluate the carcinogenic potential of such product;

(C) the Federal Food and Drug Administration approved, by letter dated December 18, 1979, the new drug application for such product; and

(D) the Federal Food and Drug Administration approved, by letter dated May 26, 1981, a supplementary application covering the facility for the production of such product.

(2) Any patent which encompasses within its scope a process for using the composition of matter described in paragraph (1).

(b) The term of any patent described in subsection (a) shall be extended for a period equal to the period beginning February 20, 1976, and ending May 26, 1981, and such patent shall have the effect as if originally issued with such extended term.

(c) The patentee of any patent described in subsection (a) of this section shall, within ninety days after the date of enactment of this section, notify the Director of the number of any patent so extended. On receipt of such notice, the Director shall confirm such extension by placing a notice thereof in the official file of such patent and publishing an appropriate notice of such extension in the Official Gazette of the Patent and Trademark Office.

(Added Pub. L. 98–127, § 4(a), Oct. 13, 1983, 97 Stat. 832; amended Pub. L. 106–113, div. B, § 1000(a)(9) [title IV, § 4732(a)(7), (10)(A)], Nov. 29, 1999, 113 Stat. 1536, 1501A–582; Pub. L. 107–273, div. C, title III, § 13206(b)(1)(B), Nov. 2, 2002, 116 Stat. 1906.)

REFERENCES IN TEXT

Section 505(b)(1) of the Federal Food, Drug and Cosmetic Act, referred to in subsec. (a)(1)(A), is classified to section 355(b)(1) of Title 21, Food and Drugs.

The date of enactment of this section, referred to in subsec. (c), is the date of enactment of Pub. L. 98–127, which was approved Oct. 13, 1983.

AMENDMENTS

2002—Subsec. (c). Pub. L. 107–273 made technical correction to directory language of Pub. L. 106–113, § 1000(a)(9) [title IV, § 4732(a)(10)(A)]. See 1999 Amendment note below.

1999—Subsec. (c). Pub. L. 106–113, § 1000(a)(9) [title IV, § 4732(a)(10)(A)], as amended by Pub. L. 107–273, substituted ''Director shall confirm'' for ''Commissioner shall confirm''.

Pub. L. 106–113, § 1000(a)(9) [title IV, § 4732(a)(7)], substituted ''notify the Director'' for ''notify the Commissioner of Patents and Trademarks''.

EFFECTIVE DATE OF 1999 AMENDMENT

Amendment by Pub. L. 106–113 effective 4 months after Nov. 29, 1999, see section 1000(a)(9) [title IV, § 4731] of Pub. L. 106–113, set out as a note under section 1 of this title.

§ 156. Extension of patent term

(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b), if—

(1) the term of the patent has not expired before an application is submitted under subsection (d)(1) for its extension;

(2) the term of the patent has never been extended under subsection (e)(1) of this section;

(3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of paragraphs (1) through (4) of subsection (d);

(4) the product has been subject to a regulatory review period before its commercial marketing or use;

(5)(A) except as provided in subparagraph (B) or (C), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred;

(B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent; or

(C) for purposes of subparagraph (A), in the case of a patent which—

(i) claims a new animal drug or a veterinary biological product which (I) is not covered by the claims in any other patent which has been extended, and (II) has received permission for the commercial marketing or use in non-food-producing animals and in food-producing animals, and

(ii) was not extended on the basis of the regulatory review period for use in non-food-producing animals,

the permission for the commercial marketing or use of the drug or product after the regulatory review period for use in food-producing animals is the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal.

The product referred to in paragraphs (4) and (5) is hereinafter in this section referred to as the ''approved product''.

(b) Except as provided in subsection (d)(5)(F), the rights derived from any patent the term of which is extended under this section shall during the period during which the term of the patent is extended—

(1) in the case of a patent which claims a product, be limited to any use approved for the product—

(A) before the expiration of the term of the patent—

(i) under the provision of law under which the applicable regulatory review occurred, or

(ii) under the provision of law under which any regulatory review described in paragraph (1), (4), or (5) of subsection (g) occurred, and

(B) on or after the expiration of the regulatory review period upon which the extension of the patent was based;

(2) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent and approved for the product—

(A) before the expiration of the term of the patent—

(i) under any provision of law under which an applicable regulatory review occurred, and

(ii) under the provision of law under which any regulatory review described in paragraph (1), (4), or (5) of subsection (g) occurred, and

(B) on or after the expiration of the regulatory review period upon which the extension of the patent was based; and

(3) in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make—

(A) the approved product, or

(B) the product if it has been subject to a regulatory review period described in paragraph (1), (4), or (5) of subsection (g).

As used in this subsection, the term ''product'' includes an approved product.

(c) The term of a patent eligible for extension under subsection (a) shall be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued, except that—

(1) each period of the regulatory review period shall be reduced by any period determined under subsection (d)(2)(B) during which the applicant for the patent extension did not act with due diligence during such period of the regulatory review period;

(2) after any reduction required by paragraph (1), the period of extension shall include only one-half of the time remaining in the periods described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g);

(3) if the period remaining in the term of a patent after the date of the approval of the approved product under the provision of law under which such regulatory review occurred when added to the regulatory review period as revised under paragraphs (1) and (2) exceeds fourteen years, the period of extension shall be reduced so that the total of both such periods does not exceed fourteen years; and

(4) in no event shall more than one patent be extended under subsection (e)(1) for the same regulatory review period for any product.

(d)(1) To obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Director. Except as provided in paragraph (5), such an application may only be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use. The application shall contain—

(A) the identity of the approved product and the Federal statute under which regulatory review occurred;

(B) the identity of the patent for which an extension is being sought and the identity of

each claim of such patent which claims the approved product or a method of using or manufacturing the approved product;

(C) information to enable the Director to determine under subsections (a) and (b) the eligibility of a patent for extension and the rights that will be derived from the extension and information to enable the Director and the Secretary of Health and Human Services or the Secretary of Agriculture to determine the period of the extension under subsection (g);

(D) a brief description of the activities undertaken by the applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities; and

(E) such patent or other information as the Director may require.

(2)(A) Within 60 days of the submittal of an application for extension of the term of a patent under paragraph (1), the Director shall notify—

(i) the Secretary of Agriculture if the patent claims a drug product or a method of using or manufacturing a drug product and the drug product is subject to the Virus-Serum-Toxin Act, and

(ii) the Secretary of Health and Human Services if the patent claims any other drug product, a medical device, or a food additive or color additive or a method of using or manufacturing such a product, device, or additive and if the product, device, and additive are subject to the Federal Food, Drug, and Cosmetic Act,

of the extension application and shall submit to the Secretary who is so notified a copy of the application. Not later than 30 days after the receipt of an application from the Director, the Secretary receiving the application shall review the dates contained in the application pursuant to paragraph (1)(C) and determine the applicable regulatory review period, shall notify the Director of the determination, and shall publish in the Federal Register a notice of such determination.

(B)(i) If a petition is submitted to the Secretary making the determination under subparagraph (A), not later than 180 days after the publication of the determination under subparagraph (A), upon which it may reasonably be determined that the applicant did not act with due diligence during the applicable regulatory review period, the Secretary making the determination shall, in accordance with regulations promulgated by such Secretary, determine if the applicant acted with due diligence during the applicable regulatory review period. The Secretary making the determination shall make such determination not later than 90 days after the receipt of such a petition. For a drug product, device, or additive subject to the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act, the Secretary may not delegate the authority to make the determination prescribed by this clause to an office below the Office of the Director[1] of Food and Drugs. For a product subject to the Virus-Serum-Toxin Act, the Secretary of Agriculture may not delegate the authority to make the determination prescribed by this clause to an office below the Office of the Assistant Secretary for Marketing and Inspection Services.

(ii) The Secretary making a determination under clause (i) shall notify the Director of the determination and shall publish in the Federal Register a notice of such determination together with the factual and legal basis for such determination. Any interested person may request, within the 60-day period beginning on the publication of a determination, the Secretary making the determination to hold an informal hearing on the determination. If such a request is made within such period, such Secretary shall hold such hearing not later than 30 days after the date of the request, or at the request of the person making the request, not later than 60 days after such date. The Secretary who is holding the hearing shall provide notice of the hearing to the owner of the patent involved and to any interested person and provide the owner and any interested person an opportunity to participate in the hearing. Within 30 days after the completion of the hearing, such Secretary shall affirm or revise the determination which was the subject of the hearing and shall notify the Director of any revision of the determination and shall publish any such revision in the Federal Register.

(3) For the purposes of paragraph (2)(B), the term ''due diligence'' means that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.

(4) An application for the extension of the term of a patent is subject to the disclosure requirements prescribed by the Director.

(5)(A) If the owner of record of the patent or its agent reasonably expects that the applicable regulatory review period described in paragraph (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii) of subsection (g) that began for a product that is the subject of such patent may extend beyond the expiration of the patent term in effect, the owner or its agent may submit an application to the Director for an interim extension during the period beginning 6 months, and ending 15 days, before such term is due to expire. The application shall contain—

(i) the identity of the product subject to regulatory review and the Federal statute under which such review is occurring;

(ii) the identity of the patent for which interim extension is being sought and the identity of each claim of such patent which claims the product under regulatory review or a method of using or manufacturing the product;

(iii) information to enable the Director to determine under subsection (a)(1), (2), and (3) the eligibility of a patent for extension;

(iv) a brief description of the activities undertaken by the applicant during the applicable regulatory review period to date with respect to the product under review and the significant dates applicable to such activities; and

(v) such patent or other information as the Director may require.

[1] So in original. Probably should be ''Commissioner''.

(B) If the Director determines that, except for permission to market or use the product commercially, the patent would be eligible for an extension of the patent term under this section, the Director shall publish in the Federal Register a notice of such determination, including the identity of the product under regulatory review, and shall issue to the applicant a certificate of interim extension for a period of not more than 1 year.

(C) The owner of record of a patent, or its agent, for which an interim extension has been granted under subparagraph (B), may apply for not more than 4 subsequent interim extensions under this paragraph, except that, in the case of a patent subject to subsection (g)(6)(C), the owner of record of the patent, or its agent, may apply for only 1 subsequent interim extension under this paragraph. Each such subsequent application shall be made during the period beginning 60 days before, and ending 30 days before, the expiration of the preceding interim extension.

(D) Each certificate of interim extension under this paragraph shall be recorded in the official file of the patent and shall be considered part of the original patent.

(E) Any interim extension granted under this paragraph shall terminate at the end of the 60-day period beginning on the date on which the product involved receives permission for commercial marketing or use, except that, if within that 60-day period the applicant notifies the Director of such permission and submits any additional information under paragraph (1) of this subsection not previously contained in the application for interim extension, the patent shall be further extended, in accordance with the provisions of this section—

(i) for not to exceed 5 years from the date of expiration of the original patent term; or

(ii) if the patent is subject to subsection (g)(6)(C), from the date on which the product involved receives approval for commercial marketing or use.

(F) The rights derived from any patent the term of which is extended under this paragraph shall, during the period of interim extension—

(i) in the case of a patent which claims a product, be limited to any use then under regulatory review;

(ii) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent then under regulatory review; and

(iii) in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make the product then under regulatory review.

(e)(1) A determination that a patent is eligible for extension may be made by the Director solely on the basis of the representations contained in the application for the extension. If the Director determines that a patent is eligible for extension under subsection (a) and that the requirements of paragraphs (1) through (4) of subsection (d) have been complied with, the Director shall issue to the applicant for the extension of the term of the patent a certificate of extension, under seal, for the period prescribed by subsection (c). Such certificate shall be recorded in the official file of the patent and shall be considered as part of the original patent.

(2) If the term of a patent for which an application has been submitted under subsection (d)(1) would expire before a certificate of extension is issued or denied under paragraph (1) respecting the application, the Director shall extend, until such determination is made, the term of the patent for periods of up to one year if he determines that the patent is eligible for extension.

(f) For purposes of this section:

(1) The term ''product'' means:

(A) A drug product.

(B) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

(2) The term ''drug product'' means the active ingredient of—

(A) a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act), or

(B) a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Virus-Serum-Toxin Act) which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques,

including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

(3) The term ''major health or environmental effects test'' means a test which is reasonably related to the evaluation of the health or environmental effects of a product, which requires at least six months to conduct, and the data from which is submitted to receive permission for commercial marketing or use. Periods of analysis or evaluation of test results are not to be included in determining if the conduct of a test required at least six months.

(4)(A) Any reference to section 351 is a reference to section 351 of the Public Health Service Act.

(B) Any reference to section 503, 505, 512, or 515 is a reference to section 503, 505, 512, or 515 of the Federal Food, Drug, and Cosmetic Act.

(C) Any reference to the Virus-Serum-Toxin Act is a reference to the Act of March 4, 1913 (21 U.S.C. 151–158).

(5) The term ''informal hearing'' has the meaning prescribed for such term by section 201(y)[2] of the Federal Food, Drug, and Cosmetic Act.

(6) The term ''patent'' means a patent issued by the United States Patent and Trademark Office.

(7) The term ''date of enactment'' as used in this section means September 24, 1984, for a human drug product, a medical device, food additive, or color additive.

(8) The term ''date of enactment'' as used in this section means the date of enactment of

[2] See References in Text note below.

the Generic Animal Drug and Patent Term Restoration Act for an animal drug or a veterinary biological product.

(g) For purposes of this section, the term ''regulatory review period'' has the following meanings:

(1)(A) In the case of a product which is a new drug, antibiotic drug, or human biological product, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a new drug, antibiotic drug, or human biological product is the sum of—

(i) the period beginning on the date an exemption under subsection (i) of section 505 or subsection (d) of section 507[2] became effective for the approved product and ending on the date an application was initially submitted for such drug product under section 351, 505, or 507,[2] and

(ii) the period beginning on the date the application was initially submitted for the approved product under section 351, subsection (b) of section 505, or section 507[2] and ending on the date such application was approved under such section.

(2)(A) In the case of a product which is a food additive or color additive, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a food or color additive is the sum of—

(i) the period beginning on the date a major health or environmental effects test on the additive was initiated and ending on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and

(ii) the period beginning on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and ending on the date such regulation became effective or, if objections were filed to such regulation, ending on the date such objections were resolved and commercial marketing was permitted or, if commercial marketing was permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings were finally resolved and commercial marketing was permitted.

(3)(A) In the case of a product which is a medical device, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a medical device is the sum of—

(i) the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and

(ii) the period beginning on the date an application was initially submitted with respect to the device under section 515 and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).

(4)(A) In the case of a product which is a new animal drug, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a new animal drug product is the sum of—

(i) the period beginning on the earlier of the date a major health or environmental effects test on the drug was initiated or the date an exemption under subsection (j) of section 512 became effective for the approved new animal drug product and ending on the date an application was initially submitted for such animal drug product under section 512, and

(ii) the period beginning on the date the application was initially submitted for the approved animal drug product under subsection (b) of section 512 and ending on the date such application was approved under such section.

(5)(A) In the case of a product which is a veterinary biological product, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory period for a veterinary biological product is the sum of—

(i) the period beginning on the date the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act became effective and ending on the date an application for a license was submitted under the Virus-Serum-Toxin Act, and

(ii) the period beginning on the date an application for a license was initially submitted for approval under the Virus-Serum-Toxin Act and ending on the date such license was issued.

(6) A period determined under any of the preceding paragraphs is subject to the following limitations:

(A) If the patent involved was issued after the date of the enactment of this section, the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

(B) If the patent involved was issued before the date of the enactment of this section and—

(i) no request for an exemption described in paragraph (1)(B) or (4)(B) was submitted and no request for the authority described in paragraph (5)(B) was submitted,

(ii) no major health or environmental effects test described in paragraph (2)(B) or (4)(B) was initiated and no petition for a regulation or application for registration described in such paragraph was submitted, or

(iii) no clinical investigation described in paragraph (3) was begun or product de-

velopment protocol described in such paragraph was submitted,

before such date for the approved product the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

(C) If the patent involved was issued before the date of the enactment of this section and if an action described in subparagraph (B) was taken before the date of the enactment of this section with respect to the approved product and the commercial marketing or use of the product has not been approved before such date, the period of extension determined on the basis of the regulatory review period determined under such paragraph may not exceed two years or in the case of an approved product which is a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act or the Virus-Serum-Toxin Act), three years.

(h) The Director may establish such fees as the Director determines appropriate to cover the costs to the Office of receiving and acting upon applications under this section.

(Added Pub. L. 98–417, title II, § 201(a), Sept. 24, 1984, 98 Stat. 1598; amended Pub. L. 100–670, title II, § 201(a)–(h), Nov. 16, 1988, 102 Stat. 3984–3987; Pub. L. 103–179, §§ 5, 6, Dec. 3, 1993, 107 Stat. 2040, 2042; Pub. L. 103–465, title V, § 532(c)(1), Dec. 8, 1994, 108 Stat. 4987; Pub. L. 105–115, title I, § 125(b)(2)(P), Nov. 21, 1997, 111 Stat. 2326; Pub. L. 106–113, div. B, § 1000(a)(9) [title IV, §§ 4404, 4732(a)(10)(A)], Nov. 29, 1999, 113 Stat. 1536, 1501A–560, 1501A–582; Pub. L. 107–273, div. C, title III, § 13206(a)(9), (b)(1)(B), Nov. 2, 2002, 116 Stat. 1904, 1906.)

REFERENCES IN TEXT

The Virus-Serum-Toxin Act, referred to in subsecs. (d)(2)(A)(i), (B)(i), (f)(2)(B), (4)(C), and (g)(5)(B), (6)(C), is the eighth paragraph under the heading ''Bureau of Animal Industry'' of act Mar. 4, 1913, ch. 145, 37 Stat. 828, as amended, which is classified generally to chapter 5 (§ 151 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Short Title note set out under section 151 of Title 21 and Tables.

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (d)(2)(A)(ii), (B)(ii), (f), and (g)(2)(B), (3)(B)(ii), (6)(C), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of Title 21. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

The Public Health Service Act, referred to in subsecs. (d)(2)(B)(i) and (f)(2)(A), is act July 1, 1944, ch. 373, 58 Stat. 682, as amended, which is classified generally to chapter 6A (§ 201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

Sections 503, 505, 512, and 515 of the Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (f)(4)(B) and (g)(1)(B), (3)(B), are classified, respectively, to sections 353, 355, 360b, and 360e of Title 21, Food and Drugs. Section 507 of the Act, referred to in subsec. (g)(1)(B), was classified to section 357 of Title 21, prior to repeal by Pub. L. 105–115, title I, § 125(b)(1), Nov. 21, 1997, 111 Stat. 2325.

Section 201 of the Federal Food, Drug, and Cosmetic Act, referred to in subsec. (f)(5), which is classified to section 321 of Title 21, was subsequently amended, and section 201(y) no longer defines the term ''informal hearing''. However, such term is defined elsewhere in that section.

Section 351 of the Public Health Service Act, referred to in subsecs. (f)(4)(A) and (g)(1)(B)(i), (ii), is classified to section 262 of Title 42, The Public Health and Welfare.

The date of enactment of the Generic Animal Drug and Patent Term Restoration Act, referred to in subsec. (f)(8), is the date of enactment of Pub. L. 100–670, which was approved Nov. 16, 1988.

The date of the enactment of this section, referred to in subsec. (g)(6), is the date of the enactment of Pub. L. 98–417, which was approved Sept. 24, 1984.

AMENDMENTS

2002—Subsec. (b)(3)(B). Pub. L. 107–273, § 13206(a)(9)(A), substituted ''paragraph'' for ''paragraphs''.

Subsec. (d). Pub. L. 107–273, § 13206(b)(1)(B), made technical correction to directory language of Pub. L. 106–113, § 1000(a)(9) [title IV, § 4732(a)(10)(A)]. See 1999 Amendment note below.

Subsec. (d)(2)(B)(i). Pub. L. 107–273, § 13206(a)(9)(B), substituted ''below the Office'' for ''below the office''.

Subsec. (e). Pub. L. 107–273, § 13206(b)(1)(B), made technical correction to directory language of Pub. L. 106–113, § 1000(a)(9) [title IV, § 4732(a)(10)(A)]. See 1999 Amendment note below.

Subsec. (g)(6)(B)(iii). Pub. L. 107–273, § 13206(a)(9)(C), substituted ''submitted'' for ''submittted''.

Subsec. (h). Pub. L. 107–273, § 13206(b)(1)(B), made technical correction to directory language of Pub. L. 106–113, § 1000(a)(9) [title IV, § 4732(a)(10)(A)]. See 1999 Amendment note below.

1999—Subsec. (a). Pub. L. 106–113, § 1000(a)(9) [title IV, § 4404], in introductory provisions, inserted '', which shall include any patent term adjustment granted under section 154(b),'' after ''the original expiration date of the patent''.

Subsecs. (d), (e), (h). Pub. L. 106–113, § 1000(a)(9) [title IV, § 4732(a)(10)(A)], as amended by Pub. L. 107–273, § 13206(b)(1)(B), substituted ''Director'' for ''Commissioner'' wherever appearing.

1997—Subsec. (f)(4)(B). Pub. L. 105–115, § 125(b)(2)(P), struck out ''507,'' after ''505,'' in two places.

1994—Subsec. (a)(2). Pub. L. 103–465 inserted ''under subsection (e)(1) of this section'' after ''extended''.

1993—Subsec. (a)(1). Pub. L. 103–179, § 6(1)(A), substituted ''subsection (d)(1)'' for ''subsection (d)''.

Subsec. (a)(3). Pub. L. 103–179, § 6(1)(B), substituted ''paragraphs (1) through (4) of subsection (d)'' for ''subsection (d)''.

Subsec. (b). Pub. L. 103–179, § 6(2), substituted ''Except as provided in subsection (d)(5)(F), the rights'' for ''The rights'' in introductory provisions.

Subsec. (c)(4). Pub. L. 103–179, § 5(1), substituted ''extended under subsection (e)(1)'' for ''extended''.

Subsec. (d)(1). Pub. L. 103–179, § 5(2), substituted ''Except as provided in paragraph (5), such'' for ''Such'' in second sentence.

Subsec. (d)(5). Pub. L. 103–179, § 5(3), added par. (5).

Subsec. (e)(1). Pub. L. 103–179, § 6(3)(A), substituted ''paragraphs (1) through (4) of subsection (d)'' for ''subsection (d)''.

Subsec. (e)(2). Pub. L. 103–179, § 6(3)(B), substituted ''subsection (d)(1)'' for ''subsection (d)''.

1988—Subsec. (a)(5)(A). Pub. L. 100–670, § 201(a)(1), inserted ''or (C)'' after ''in subparagraph (B)''.

Subsec. (a)(5)(C). Pub. L. 100–670, § 201(a)(2), (3), added subpar. (C).

Subsec. (b). Pub. L. 100–670, § 201(b), amended subsec. (b) generally. Prior to amendment, subsec. (b) read as follows: ''The rights derived from any patent the term of which is extended under this section shall during the period during which the patent is extended—

''(1) in the case of a patent which claims a product, be limited to any use approved for the approved product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred;

''(2) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent and approved for the approved product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred; and

''(3) in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make the approved product.''

Subsec. (c)(2). Pub. L. 100–670, §201(c), substituted ''(3)(B)(i), (4)(B)(i), and (5)(B)(i)'' for ''and (3)(B)(i)''.

Subsec. (d)(1)(C). Pub. L. 100–670, §201(d), inserted ''or the Secretary of Agriculture'' after ''and Human Services''.

Subsec. (d)(2)(A). Pub. L. 100–670, §201(e), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: ''Within sixty days of the submittal of an application for extension of the term of a patent under paragraph (1), the Commissioner shall notify the Secretary of Health and Human Services if the patent claims any human drug product, a medical device, or a food additive or color additive or a method of using or manufacturing such a product, device, or additive and if the product, device, and additive are subject to the Federal Food, Drug, and Cosmetic Act, of the extension application and shall submit to the Secretary a copy of the application. Not later than thirty days after the receipt of an application from the Commissioner, the Secretary shall review the dates contained in the application pursuant to paragraph (1)(C) and determine the applicable regulatory review period, shall notify the Commissioner of the determination, and shall publish in the Federal Register a notice of such determination.''

Subsec. (d)(2)(B). Pub. L. 100–670, §201(f), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows:

''(i) If a petition is submitted to the Secretary under subparagraph (A), not later than one hundred and eighty days after the publication of the determination under subparagraph (A), upon which it may reasonably be determined that the applicant did not act with due diligence during the applicable regulatory review period, the Secretary shall, in accordance with regulations promulgated by the Secretary determine if the applicant acted with due diligence during the applicable regulatory review period. The Secretary shall make such determination not later than ninety days after the receipt of such a petition. The Secretary may not delegate the authority to make the determination prescribed by this subparagraph to an office below the Office of the Commissioner of Food and Drugs.

''(ii) The Secretary shall notify the Commissioner of the determination and shall publish in the Federal Register a notice of such determination together with the factual and legal basis for such determination. Any interested person may request, within the sixty-day period beginning on the publication of a determination, the Secretary to hold an informal hearing on the determination. If such a request is made within such period, the Secretary shall hold such hearing not later than thirty days after the date of the request, or at the request of the person making the request, not later than sixty days after such date. The Secretary shall provide notice of the hearing to the owner of the patent involved and to any interested person and provide the owner and any interested person an opportunity to participate in the hearing. Within thirty days after the completion of the hearing, the Secretary shall affirm or revise the determination which was the subject of the hearing and notify the Commissioner of any revision of the determination and shall publish any such revision in the Federal Register.''

Subsec. (f)(1)(A). Pub. L. 100–670, §201(g)(1), struck out ''human'' before ''drug product''.

Subsec. (f)(2). Pub. L. 100–670, §201(g)(1), amended par. (2) generally. Prior to amendment, par. (2) read as follows: ''The term 'human drug product' means the active ingredient of a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act) including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.''

Subsec. (f)(4)(B), (C). Pub. L. 100–670, §201(g)(2), which directed general amendment of subpars. (B) and (C) of par. (4), was executed by amending subpar. (B) generally, and adding subpar. (C) as probable intent of Congress in light of absence of subpar. (C) in par. (4). Prior to amendment, subpar. (B) read as follows: ''Any reference to section 503, 505, 507, or 515 is a reference to section 503, 505, 507, or 515 of the Federal Food, Drug, and Cosmetic Act.''

Subsec. (f)(7), (8). Pub. L. 100–670, §201(g)(3), added pars. (7) and (8).

Subsec. (g)(1)(A). Pub. L. 100–670, §201(h)(1)(A), (2), substituted ''new drug, antibiotic drug, or human biological product'' for ''human drug product'' and ''paragraph (6)'' for ''paragraph (4)''.

Subsec. (g)(1)(B). Pub. L. 100–670, §201(h)(1)(B), substituted ''new drug, antibiotic drug, or human biological product'' for ''human drug product'' in introductory provisions and ''product'' for ''human drug product'' in cls. (i) and (ii).

Subsec. (g)(2)(A), (3)(A). Pub. L. 100–670, §201(h)(3), substituted ''paragraph (6)'' for ''paragraph (4)''.

Subsec. (g)(4), (5). Pub. L. 100–670, §201(h)(4), added pars. (4) and (5). Former par. (4) redesignated (6).

Subsec. (g)(6). Pub. L. 100–670, §201(h)(4), redesignated former par. (4) as (6).

Subsec. (g)(6)(B)(i). Pub. L. 100–670, §201(h)(5)(A), substituted ''paragraph (1)(B) or (4)(B) was submitted and no request for the authority described in paragraph (5)(B) was submitted'' for ''paragraph (1)(B) was submitted''.

Subsec. (g)(6)(B)(ii). Pub. L. 100–670, §201(h)(5)(B), substituted ''paragraph (2)(B) or (4)(B)'' for ''paragraph (2)''.

Subsec. (g)(6)(C). Pub. L. 100–670, §201(h)(5)(C), inserted ''or in the case of an approved product which is a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act or the Virus-Serum-Toxin Act), three years'' after ''exceed two years''.

EFFECTIVE DATE OF 1999 AMENDMENT

Amendment by section 1000(a)(9) [title IV, §4404] of Pub. L. 106–113 effective on date that is 6 months after Nov. 29, 1999, and, except for design patent application filed under chapter 16 of this title, applicable to any application filed on or after such date, see section 1000(a)(9) [title IV, §4405(a)] of Pub. L. 106–113, set out as a note under section 154 of this title.

Amendment by section 1000(a)(9) [title IV, §4732(a)(10)(A)] of Pub. L. 106–113 effective 4 months after Nov. 29, 1999, see section 1000(a)(9) [title IV, §4731] of Pub. L. 106–113, set out as a note under section 1 of this title.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–465 effective 6 months after Dec. 8, 1994, and applicable to all patent applications filed in the United States on or after that effective date, with provisions relating to earliest filed patent application, see section 534(b)(1), (3) of Pub. L. 103–465, set out as a note under section 154 of this title.

§157. Statutory invention registration

(a) Notwithstanding any other provision of this title, the Director is authorized to publish a statutory invention registration containing the specification and drawings of a regularly filed application for a patent without examination if the applicant—

(1) meets the requirements of section 112 of this title;

(2) has complied with the requirements for printing, as set forth in regulations of the Director;