

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 2011 AMENDMENT

Pub. L. 112-29, §37(b), Sept. 16, 2011, 125 Stat. 341, provided that: “The amendment made by subsection (a) [amending this section] shall apply to any application for extension of a patent term under section 156 of title 35, United States Code, that is pending on, that is filed after, or as to which a decision regarding the application is subject to judicial review on, the date of the enactment of this Act [Sept. 16, 2011].”

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. Repealed. Pub. L. 112-29, § 3(e)(1), Sept. 16, 2011, 125 Stat. 287]

Section, added Pub. L. 98-622, title I, §102(a), Nov. 8, 1984, 98 Stat. 3383; amended Pub. L. 106-113, div. B, §1000(a)(9) [title IV, §4732(a)(10)(A), (11)], Nov. 29, 1999, 113 Stat. 1536, 1501A-582, 1501A-583; Pub. L. 107-273, div. C, title III, §13206(b)(1)(B), Nov. 2, 2002, 116 Stat. 1906; Pub. L. 112-29, §20(j), Sept. 16, 2011, 125 Stat. 335, related to statutory invention registration.

EFFECTIVE DATE OF REPEAL

Repeal effective upon the expiration of the 18-month period beginning on Sept. 16, 2011, and applicable to any request for a statutory invention registration filed on or after that effective date, see section 3(e)(3) of Pub. L. 112-29, set out as an Effective Date of 2011 Amendment note under section 111 of this title.

CHAPTER 15—PLANT PATENTS

Sec.
161. Patents for plants.