made in the applicable Federal laws to reduce the costs of developing such drugs and to provide financial incentives to develop such drugs; and

''(6) it is in the public interest to provide such changes and incentives for the development of orphan drugs.''

§ 360bb. Designation of drugs for rare diseases or conditions

(a) Request by sponsor; preconditions; "rare disease or condition" defined

(1) The manufacturer or the sponsor of a drug may request the Secretary to designate the drug as a drug for a rare disease or condition. A request for designation of a drug shall be made before the submission of an application under section 355(b) of this title for the drug, or the submission of an application for licensing of the drug under section 262 of title 42. If the Secretary finds that a drug for which a request is submitted under this subsection is being or will be investigated for a rare disease or condition and—

(A) if an application for such drug is approved under section 355 of this title, or

(B) if a license for such drug is issued under section 262 of title 42,

the approval, certification, or license would be for use for such disease or condition, the Secretary shall designate the drug as a drug for such disease or condition. A request for a designation of a drug under this subsection shall contain the consent of the applicant to notice being given by the Secretary under subsection (b) respecting the designation of the drug.

(2) For purposes of paragraph (1), the term ''rare disease or condition'' means any disease or condition which (A) affects less than 200,000 persons in the United States, or (B) affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug. Determinations under the preceding sentence with respect to any drug shall be made on the basis of the facts and circumstances as of the date the request for designation of the drug under this subsection is made.

(b) Notification of discontinuance of drug or application as condition

A designation of a drug under subsection (a) shall be subject to the condition that—

(1) if an application was approved for the drug under section 355(b) of this title or a license was issued for the drug under section 262 of title 42, the manufacturer of the drug will notify the Secretary of any discontinuance of the production of the drug at least one year before discontinuance, and

(2) if an application has not been approved for the drug under section 355(b) of this title or a license has not been issued for the drug under section 262 of title 42 and if preclinical investigations or investigations under section 355(i) of this title are being conducted with the drug, the manufacturer or sponsor of the drug will notify the Secretary of any decision to discontinue active pursuit of approval of an application under section 355(b) of this title or approval of a license under section 262 of title 42.

(c) Notice to public

Notice respecting the designation of a drug under subsection (a) shall be made available to the public.

(d) Regulations

The Secretary shall by regulation promulgate procedures for the implementation of subsection (a).

(June 25, 1938, ch. 675, §526, as added Pub. L. 97–414, §2(a), Jan. 4, 1983, 96 Stat. 2050; amended Pub. L. 98–551, §4(a), Oct. 30, 1984, 98 Stat. 2817; Pub. L. 99–91, §3(a)(2), Aug. 15, 1985, 99 Stat. 387; Pub. L. 100–290, §2, Apr. 18, 1988, 102 Stat. 90; Pub. L. 105–115, title I, §125(b)(2)(H), (I), Nov. 21, 1997, 111 Stat. 2326.)

AMENDMENTS

1997—Subsec. (a)(1). Pub. L. 105–115, §125(b)(2)(H), struck out ''the submission of an application for certification of the drug under section 357 of this title,'' before ''or the submission of an application for licensing of the drug'' in introductory provisions, inserted ''or'' at end of subpar. (A), redesignated subpar. (C) as (B), and struck out former subpar. (B) which read as follows: ''if a certification for such drug is issued under section 357 of this title, or''.

Subsec. (b)(1). Pub. L. 105–115, §125(b)(2)(I)(i), struck out '', a certificate was issued for the drug under section 357 of this title,'' before ''or a license was issued''.

Subsec. (b)(2). Pub. L. 105–115, §125(b)(2)(I)(ii), struck out '', a certificate has not been issued for the drug under section 357 of this title,'' before ''or a license has not been issued'' and '', approval of an application for certification under section 357 of this title,'' before ''or approval of a license''.

1988—Subsec. (a)(1). Pub. L. 100–290, §2(a), inserted after first sentence ''A request for designation of a drug shall be made before the submission of an application under section 355(b) of this title for the drug, the submission of an application for certification of the drug under section 357 of this title, or the submission of an application for licensing of the drug under section 262 of title 42.''

Subsecs. (b) to (d). Pub. L. 100–290, §2(b), added subsec. (b) and redesignated former subsecs. (b) and (c) as (c) and (d), respectively.

1985—Subsec. (a)(1). Pub. L. 99–91 struck out ''or'' at end of subpar. (A), struck out subpar. (B) and substituted subpars. (B) and (C), and inserted '', certification,'' after ''approval''.

1984—Subsec. (a)(2). Pub. L. 98–551 substituted ''which (A) affects less than 200,000 persons in the United States, or (B) affects more than 200,000 in the United States and for which'' for ''which occurs so infrequently in the United States that''.

EFFECTIVE DATE OF 1985 AMENDMENT

Amendment by Pub. L. 99–91 effective Aug. 15, 1985, see section 8(b) of Pub. L. 99–91, set out as a note under section 360aa of this title.

§ 360cc. Protection for drugs for rare diseases or conditions

(a) Exclusive approval, certification, or license

Except as provided in subsection (b), if the Secretary—

(1) approves an application filed pursuant to section 355 of this title, or

(2) issues a license under section 262 of title 42