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98TH CONGRESS
2D SESSION

H. R. 3605

[Report No. 98-857, Parts I and II]

To amend the Federal Food, Drug, and Cosmetic Act to authorize an abbreviated new drug application under section 505 of that Act for generic new drugs equivalent to approved new drugs.

IN THE HOUSE OF REPRESENTATIVES

JULY 19, 1983

Mr. WAXMAN (for himself, Mr. MADIGAN, Mr. WYDEN, Mr. SIKORSKI, Mr. WIETH, Mr. LELAND, Mr. MARKEY, Mr. SWIFT, Mr. BRYANT, and Mr. WEISS) introduced the following bill; which was referred to the Committee on Energy and Commerce

JUNE 21, 1984

Additional sponsors: Mr. GORE, Ms. KAPTUR, Mr. OWENS, Mr. MARTINEZ, Mr. BEDELL, and Mr. SYNAR

JUNE 21, 1984

Reported with amendments, referred to the Committee on the Judiciary for a period ending not later than August 1, 1984, for consideration of such portions of the amendment as fall within that committee's jurisdiction pursuant to clause 1(m) of rule X, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

AUGUST 1, 1984

Reported from the Committee on the Judiciary with amendments and ordered to be printed

[Omit the part struck through in italic and insert the part printed in bold face]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to authorize an abbreviated new drug application under section 505 of that Act for generic new drugs equivalent to approved new drugs.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 *That this Act may be cited as the "Drug Price Competition*
4 *Act of 1983".*

5 **SEC. 2.** Section 505(b) of the Federal Food, Drug, and
6 Cosmetic Act (21 U.S.C. 355(b)) is amended by adding at the
7 end the following new sentence: "Clause (1) of the previous
8 sentence shall not apply in the case of an application for a
9 drug for which a previous application has been approved in
10 accordance with subsection (c), if the drug with respect to
11 which such subsequent application is filed meets appropriate
12 standards of identity, strength, quality, purity, stability, bio-
13 availability, and bioequivalence in relation to the drug ap-
14 proved in the previous application."

15 *That this Act may be cited as the "Drug Price Competition*
16 *and Patent Term Restoration Act of 1984".*

17 **TITLE I—ABBREVIATED NEW DRUG**
18 **APPLICATIONS**

19 **SEC. 101.** Section 505 of the Federal Food, Drug, and
20 Cosmetic Act (21 U.S.C. 355) is amended by redesignating

1 subsection (j) as subsection (k) and inserting after subsection
2 (i) the following:

3 “(j)(1) Any person may file with the Secretary an ab-
4 breviated application for the approval of a new drug.

5 “(2)(A) An abbreviated application for a new drug shall
6 contain—

7 “(i) information to show that the conditions of use
8 prescribed, recommended, or suggested in the labeling
9 proposed for the new drug have been previously ap-
10 proved for a drug listed under paragraph (6) (herein-
11 after in this subsection referred to as a ‘listed drug’);

12 “(ii)(I) if the listed drug referred to in clause (i)
13 has only one active ingredient, information to show
14 that the active ingredient of the new drug is the same
15 as that of the listed drug,

16 “(II) if the listed drug referred to in clause (i)
17 has more than one active ingredient, information to
18 show that the active ingredients of the new drug are the
19 same as those of the listed drug, or

20 “(III) if the listed drug referred to in clause (i)
21 has more than one active ingredient and if one of the
22 active ingredients of the new drug is different and the
23 application is filed pursuant to the approval of a peti-
24 tion filed under subparagraph (C), information to show
25 that the other active ingredients of the new drug are the

1 same as the active ingredients of the listed drug, infor-
2 mation to show that the different active ingredient is
3 an active ingredient of a listed drug or of a drug which
4 does not meet the requirements of section 201(p), and
5 such other information respecting the different active
6 ingredient with respect to which the petition was filed
7 as the Secretary may require;

8 “(iii) information to show that the route of admin-
9 istration, the dosage form, and the strength of the new
10 drug are the same as those of the listed drug referred to
11 in clause (i) or, if the route of administration, the
12 dosage form, or the strength of the new drug is differ-
13 ent and the application is filed pursuant to the approv-
14 al of a petition filed under subparagraph (C), such in-
15 formation respecting the route of administration,
16 dosage form, or strength with respect to which the peti-
17 tion was filed as the Secretary may require;

18 “(iv) information to show that the new drug is
19 bioequivalent to the listed drug referred to in clause (i),
20 except that if the application is filed pursuant to the
21 approval of a petition filed under subparagraph (C),
22 information to show that the active ingredients of the
23 new drug are of the same pharmacological or therapeutic
24 class as those of the listed drug referred to in clause
25 (i) and the new drug can be expected to have the same

1 *therapeutic effect as the listed drug when administered*
2 *to patients for a condition of use referred to in clause*
3 *(i);*

4 *“(v) information to show that the labeling pro-*
5 *posed for the new drug is the same as the labeling ap-*
6 *proved for the listed drug referred to in clause (i)*
7 *except for changes required because of differences ap-*
8 *proved under a petition filed under subparagraph (C)*
9 *or because the new drug and the listed drug are pro-*
10 *duced or distributed by different manufacturers;*

11 *“(vi) the items specified in clauses (B) through*
12 *(F) of subsection (b)(1);*

13 *“(vii) a certification, in the opinion of the appli-*
14 *cant and to the best of his knowledge, with respect to*
15 *each patent which claims the listed drug referred to in*
16 *clause (i) or which claims a use for such listed drug*
17 *for which the applicant is seeking approval under this*
18 *subsection and for which information is required to be*
19 *filed under subsection (b) or (c)—*

20 *“(I) that such patent information has not*
21 *been filed,*

22 *“(II) that such patent has expired,*

23 *“(III) of the date on which such patent will*
24 *expire, or*

1 “(IV) that such patent is invalid or will not
2 be infringed by the manufacture, use, or sale of
3 the new drug for which the application is submit-
4 ted; and

5 “(viii) if with respect to the listed drug referred to
6 in clause (i) information was filed under subsection (b)
7 or (c) for a method of use patent which does not claim
8 a use for which the applicant is seeking approval under
9 this subsection, a statement that the method of use
10 patent does not claim such a use.

11 The Secretary may not require that an abbreviated applica-
12 tion contain information in addition to that required by
13 clauses (i) through (viii).

14 “(B)(i) An applicant who makes a certification de-
15 scribed in subparagraph (A)(vii)(IV) shall include in the ap-
16 plication a statement that the applicant has given the notice
17 required by clause (ii) to—

18 “(I) each owner of the patent which is the subject
19 of the certification or the representative of such owner
20 designated to receive such notice, and

21 “(II) the holder of the approved application under
22 subsection (b) for the drug which is claimed by the
23 patent or a use of which is claimed by the patent or the
24 representative of such holder designated to receive such
25 notice.

1 “(i) The notice referred to in clause (i) shall state that
2 an application, which contains data from bioavailability or
3 bioequivalence studies, has been submitted under this subsec-
4 tion for the drug with respect to which the certification is
5 made to obtain approval to engage in the commercial manu-
6 facture, use, or sale of such drug before the expiration of the
7 patent referred to in the certification. Such notice shall in-
8 clude a detailed statement of the factual and legal basis of the
9 applicant’s opinion that the patent is not valid or will not be
10 infringed.

11 “(ii) If an application is amended to include a certifi-
12 cation described in subparagraph (A)(vii)(IV), the notice re-
13 quired by clause (i) shall be given when the amended appli-
14 cation is submitted.

15 “(C) If a person wants to submit an abbreviated appli-
16 cation for a new drug which has a different active ingredient
17 or whose route of administration, dosage form, or strength
18 differ from that of a listed drug, such person shall submit a
19 petition to the Secretary seeking permission to file such an
20 application. The Secretary shall approve or disapprove a pe-
21 tition submitted under this subparagraph within ninety days
22 of the date the petition is submitted. The Secretary shall ap-
23 prove such a petition unless the Secretary finds that investi-
24 gations must be conducted to show the safety and effective-
25 ness of the drug or of any of its active ingredients of the drug

1 *or of the route of administration, the dosage form, or strength*
2 *which differ from the listed drug.*

3 “(3) *Subject to paragraph (4), the Secretary shall ap-*
4 *prove an application for a drug unless the Secretary finds—*

5 “(A) *the methods used in, or the facilities and*
6 *controls used for, the manufacture, processing, and*
7 *packing of the drug are inadequate to assure and pre-*
8 *serve its identity, strength, quality, and purity;*

9 “(B) *information submitted with the application*
10 *is insufficient to show that each of the proposed condi-*
11 *tions of use have been previously approved for the*
12 *listed drug referred to in the application;*

13 “(C)(i) *if the listed drug has only one active in-*
14 *redient, information submitted with the application is*
15 *insufficient to show that the active ingredient is the*
16 *same as that of the listed drug,*

17 “(ii) *if the listed drug has more than one active*
18 *ingredient, information submitted with the application*
19 *is insufficient to show that the active ingredients are*
20 *the same as the active ingredients of the listed drug, or*

21 “(iii) *if the listed drug has more than one active*
22 *ingredient and if the application is for a drug which*
23 *has an active ingredient different from the listed drug,*
24 *information submitted with the application is insuffi-*
25 *cient to show—*

1 “(I) that the other active ingredients are the
2 same as the active ingredients of the listed drug,
3 or

4 “(II) that the different active ingredient is
5 an active ingredient of a listed drug or a drug
6 which does not meet the requirements of section
7 201(p),
8 or no petition to file an application for the drug with
9 the different ingredient was approved under paragraph
10 (2)(C);

11 “(D)(i) if the application is for a drug whose
12 route of administration, dosage form, or strength of the
13 drug is the same as the route of administration, dosage
14 form, or strength of the listed drug referred to in the
15 application, information submitted in the application is
16 insufficient to show that the route of administration,
17 dosage form, or strength is the same as that of the
18 listed drug, or

19 “(ii) if the application is for a drug whose route
20 of administration, dosage form, or strength of the drug
21 is different from that of the listed drug referred to in
22 the application, no petition to file an application for
23 the drug with the different route of administration,
24 dosage form, or strength was approved under paragraph
25 (2)(C);

1 “(E) if the application was filed pursuant to the
2 approval of a petition under paragraph (2)(C), the ap-
3 plication did not contain the information required by
4 the Secretary respecting the active ingredient, route of
5 administration, dosage form, or strength which is not
6 the same;

7 “(F) information submitted in the application is
8 insufficient to show that the drug is bioequivalent to
9 the listed drug referred to in the application or, if the
10 application was filed pursuant to a petition approved
11 under paragraph (2)(C), information submitted in the
12 application is insufficient to show that the active ingre-
13 dients of the new drug are of the same pharmacological
14 or therapeutic class as those of the listed drug referred
15 to in paragraph (2)(A)(i) and that the new drug can be
16 expected to have the same therapeutic effect as the
17 listed drug when administered to patients for a condi-
18 tion of use referred to in such paragraph;

19 “(G) information submitted in the application is
20 insufficient to show that the labeling proposed for the
21 drug is the same as the labeling approved for the listed
22 drug referred to in the application except for changes
23 required because of differences approved under a peti-
24 tion filed under paragraph (2)(C) or because the drug

1 *and the listed drug are produced or distributed by dif-*
2 *ferent manufacturers;*

3 *“(H) information submitted in the application or*
4 *any other information available to the Secretary shows*
5 *that (i) the inactive ingredients of the drug are unsafe*
6 *for use under the conditions prescribed, recommended,*
7 *or suggested in the labeling proposed for the drug, or*
8 *(ii) the composition of the drug is unsafe under such*
9 *conditions because of the type or quantity of inactive*
10 *ingredients included or the manner in which the inac-*
11 *tive ingredients are included;*

12 *“(I) the approval under subsection (c) of the listed*
13 *drug referred to in the application under this subsec-*
14 *tion has been withdrawn or suspended for grounds de-*
15 *scribed in the first sentence of subsection (e), the ap-*
16 *proval under this subsection of the listed drug referred*
17 *to in the application under this subsection has been*
18 *withdrawn or suspended under paragraph (5), or the*
19 *Secretary has determined that the listed drug has been*
20 *withdrawn from sale for safety or effectiveness reasons;*

21 *“(J) the application does not meet any other re-*
22 *quirement of paragraph (2)(A); or*

23 *“(K) the application contains an untrue statement*
24 *of material fact.*

1 “(4)(A) *Within one hundred and eighty days of the ini-*
2 *tial receipt of an application under paragraph (2) or within*
3 *such additional period as may be agreed upon by the Secre-*
4 *tary and the applicant, the Secretary shall approve or disap-*
5 *prove the application.*

6 “(B) *The approval of an application submitted under*
7 *paragraph (2) shall be made effective on the last applicable*
8 *date determined under the following:*

9 “(i) *If the applicant only made a certification de-*
10 *scribed in subclause (I) or (II) of paragraph*
11 *(2)(A)(vii) or in both such subclauses, the approval*
12 *may be made effective immediately.*

13 “(ii) *If the applicant made a certification de-*
14 *scribed in subclause (III) of paragraph (2)(A)(vii), the*
15 *approval may be made effective on the date certified*
16 *under subclause (III).*

17 “(iii) *If the applicant made a certification de-*
18 *scribed in subclause (IV) of paragraph (2)(A)(vii), the*
19 *approval shall be made effective immediately unless an*
20 *action is brought for infringement of a patent which is*
21 *the subject of the certification before the expiration of*
22 *forty-five days from the date the notice provided under*
23 *paragraph (2)(B)(i) is received. If such an action is*
24 *brought before the expiration of such days, the approval*
25 *shall be made effective upon the expiration of the eight-*

1 *een month period beginning on the date of the receipt*
2 *of the notice provided under paragraph (2)(B)(i) or*
3 *such shorter or longer period as the court may order*
4 *because either party to the action failed to reasonably*
5 *cooperate in expediting the action, except that—*

6 *“(I) if before the expiration of such period*
7 *the court decides that such patent is invalid or not*
8 *infringed, the approval shall be made effective on*
9 *the date of the court decision, or*

10 *“(II) if before the expiration of such period*
11 *the court decides that such patent has been in-*
12 *fringed, the approval shall be made effective on*
13 *such date as the court orders under section*
14 *271(e)(4)(A) of title 35, United States Code.*

15 *In such an action, each of the parties shall reasonably*
16 *cooperate in expediting the action. Until the expiration*
17 *of the forty-five-day period beginning on the date the*
18 *notice made under paragraph (2)(B)(i) is received, no*
19 *action may be brought under section 2201 of title 28,*
20 *United States Code, for a declaratory judgment with*
21 *respect to the patent. Any action brought under section*
22 *2201 shall be brought in the judicial district where the*
23 *defendant has its principal place of business or a regu-*
24 *lar and established place of business.*

1 “(iv) If the application contains a certification de-
2 scribed in subclause (IV) of paragraph (2)(A)(vii) and
3 is for a drug for which a previous application has been
4 submitted under this subsection containing such a cer-
5 tification, the application shall be made effective not
6 earlier than one hundred and eighty days after—

7 “(I) the date the Secretary receives notice
8 from the applicant under the previous application
9 of the first commercial marketing of the drug
10 under the previous application, or

11 “(II) the date of a decision of a court in an
12 action described in clause (iii) holding the patent
13 which is the subject of the certification to be in-
14 valid or not infringed,

15 whichever is earlier.

16 “(C) If the Secretary decides to disapprove an applica-
17 tion, the Secretary shall give the applicant notice of an op-
18 portunity for a hearing before the Secretary on the question
19 of whether such application is approvable. If the applicant
20 elects to accept the opportunity for hearing by written request
21 within thirty days after such notice, such hearing shall com-
22 mence not more than ninety days after the expiration of such
23 thirty days unless the Secretary and the applicant otherwise
24 agree. Any such hearing shall thereafter be conducted on an
25 expedited basis and the Secretary’s order thereon shall be

1 *issued within ninety days after the date fixed by the Secre-*
2 *tary for filing final briefs.*

3 “(D)(i) *If an application (other than an abbreviated*
4 *new drug application) submitted under subsection (b) for a*
5 *drug, no active ingredient (including any ester or salt of the*
6 *active ingredient) of which has been approved in any other*
7 *application under subsection (b), was approved during the*
8 *period beginning January 1, 1982, and ending on the date of*
9 *the enactment of this subsection, the Secretary may not make*
10 *the approval of an application submitted under this subsec-*
11 *tion which refers to the drug for which the subsection (b)*
12 *application was submitted effective before the expiration of*
13 *ten years from the date of the approval of the application*
14 *under subsection (b).*

15 “(ii) *If an application submitted under subsection (b)*
16 *for a drug, no active ingredient (including any ester or salt of*
17 *the active ingredient) of which has been approved in any*
18 *other application under subsection (b), is approved after the*
19 *date of the enactment of this subsection and if the holder of*
20 *the approved application certifies to the Secretary that no*
21 *patent has ever been issued to any person for such drug or for*
22 *a method of using such drug and that the holder cannot re-*
23 *ceive a patent for such drug or for a method of using such*
24 *drug because in the opinion of the holder a patent may not be*
25 *issued for such drug or for a method of using such drug for*

1 *any known therapeutic purposes the Secretary may not make*
2 *the approval of an application submitted under this subsec-*
3 *tion which refers to the drug for which the subsection (b)*
4 *application was submitted effective before the expiration of*
5 *four years from the date of the approval of the application*
6 *under subsection (b) unless the Secretary determines that an*
7 *adequate supply of such drug will not be available or the*
8 *holder of the application approved under subsection (b) con-*
9 *sents to an earlier effective date for an application under this*
10 *subsection.*

11 “(5) *If a drug approved under this subsection refers in*
12 *its approved application to a drug the approval of which was*
13 *withdrawn or suspended for grounds described in the first*
14 *sentence of subsection (e) or was withdrawn or suspended*
15 *under this paragraph or which, as determined by the Secre-*
16 *tary, has been withdrawn from sale for safety or effectiveness*
17 *reasons, the approval of the drug under this subsection shall*
18 *be withdrawn or suspended—*

19 “(A) *for the same period as the withdrawal or*
20 *suspension under subsection (e) or this paragraph, or*

21 “(B) *if the listed drug has been withdrawn from*
22 *sale, for the period of withdrawal from sale or, if*
23 *earlier, the period ending on the date the Secretary de-*
24 *termines that the withdrawal from sale is not for safety*
25 *or effectiveness reasons.*

1 “(6)(A)(i) *Within sixty days of the date of the enact-*
2 *ment of this subsection, the Secretary shall publish and make*
3 *available to the public—*

4 “(I) *a list in alphabetical order of the official and*
5 *proprietary name of each drug which has been ap-*
6 *proved for safety and effectiveness under subsection (c)*
7 *before the date of the enactment of this subsection;*

8 “(II) *the date of approval if the drug is approved*
9 *after 1981 and the number of the application which*
10 *was approved; and*

11 “(III) *whether in vitro or in vivo bioequivalence*
12 *studies, or both such studies, are required for applica-*
13 *tions filed under this subsection which will refer to the*
14 *drug published.*

15 “(ii) *Every thirty days after the publication of the first*
16 *list under clause (i) the Secretary shall revise the list to in-*
17 *clude each drug which has been approved for safety and effec-*
18 *tiveness under subsection (c) or approved under this subsec-*
19 *tion during the thirty-day period.*

20 “(iii) *When patent information submitted under subsec-*
21 *tion (b) or (c) respecting a drug included on the list is to be*
22 *published by the Secretary the Secretary shall, in revisions*
23 *made under clause (ii), include such information for such*
24 *drug.*

1 “(B) A drug approved for safety and effectiveness under
2 subsection (c) or approved under this subsection shall, for
3 purposes of this subsection, be considered to have been pub-
4 lished under subparagraph (A) on the date of its approval or
5 the date of enactment, whichever is later.

6 “(C) If the approval of a drug was withdrawn or sus-
7 pended for grounds described in the first sentence of subsec-
8 tion (e) or was withdrawn or suspended under paragraph (5)
9 or if the Secretary determines that a drug has been with-
10 drawn from sale for safety or effectiveness reasons, it may
11 not be published in the list under subparagraph (A) or, if the
12 withdrawal or suspension occurred after its publication in
13 such list, it shall be immediately removed from such list—

14 “(i) for the same period as the withdrawal or sus-
15 pension under subsection (e) or paragraph (5), or

16 “(ii) if the listed drug has been withdrawn from
17 sale, for the period of withdrawal from sale or, if ear-
18 lier, the period ending on the date the Secretary deter-
19 mines that the withdrawal from sale is not for safety or
20 effectiveness reasons.

21 A notice of the removal shall be published in the Federal
22 Register.

23 “(7) For purposes of this subsection:

24 “(A) The term ‘bioavailability’ means the rate
25 and extent to which the active ingredient or therapeutic

1 *ingredient is absorbed from a drug and becomes avail-*
2 *able at the site of drug action.*

3 *“(B) A drug shall be considered to be bioequiva-*
4 *lent to a listed drug if—*

5 *“(i) the rate and extent of absorption of the*
6 *drug do not show a significant difference from the*
7 *rate and extent of absorption of the listed drug*
8 *when administered at the same molar dose of the*
9 *therapeutic ingredient under similar experimental*
10 *conditions in either a single dose or multiple*
11 *doses; or*

12 *“(ii) the extent of absorption of the drug does*
13 *not show a significant difference from the extent*
14 *of absorption of the listed drug when administered*
15 *at the same molar dose of the therapeutic ingredi-*
16 *ent under similar experimental conditions in*
17 *either a single dose or multiple doses and the dif-*
18 *ference from the listed drug in the rate of absorp-*
19 *tion of the drug is intentional, is reflected in its*
20 *proposed labeling, is not essential to the attain-*
21 *ment of effective body drug concentrations on*
22 *chronic use, and is considered medically insignifi-*
23 *cant for the drug.”*

24 *SEC. 102. (a)(1) Section 505(b) of such Act is amended*
25 *by adding at the end the following: “The applicant shall file*

1 *with the application the patent number and the expiration*
2 *date of any patent which claims the drug for which the appli-*
3 *cant submitted the application or which claims a method of*
4 *using such drug and with respect to which a claim of patent*
5 *infringement could reasonably be asserted if a person not li-*
6 *censed by the owner engaged in the manufacture, use, or sale*
7 *of the drug. If an application is filed under this subsection*
8 *for a drug and a patent which claims such drug or a method*
9 *of using such drug is issued after the filing date but before*
10 *approval of the application, the applicant shall amend the*
11 *application to include the information required by the preced-*
12 *ing sentence. Upon approval of the application, the Secretary*
13 *shall publish information submitted under the two preceding*
14 *sentences.”.*

15 *(2) Section 505(c) of such Act is amended by inserting*
16 *“(1)” after “(c)”, by redesignating paragraphs (1) and (2) as*
17 *subparagraphs (A) and (B), respectively, and by adding at*
18 *the end the following:*

19 *“(2) If the patent information described in subsection*
20 *(b) could not be filed with the submission of an application*
21 *under subsection (b) because the application was filed before*
22 *the patent information was required under subsection (b) or a*
23 *patent was issued after the application was approved under*
24 *such subsection, the holder of an approved application shall*
25 *file with the Secretary the patent number and the expiration*

1 *date of any patent which claims the drug for which the appli-*
2 *cation was submitted or which claims a method of using such*
3 *drug and with respect to which a claim of patent infringe-*
4 *ment could reasonably be asserted if a person not licensed by*
5 *the owner engaged in the manufacture, use, or sale of the*
6 *drug. If the holder of an approved application could not file*
7 *patent information under subsection (b) because it was not*
8 *required at the time the application was approved, the holder*
9 *shall file such information under this subsection not later*
10 *than thirty days after the date of the enactment of this sen-*
11 *tence, and if the holder of an approved application could not*
12 *file patent information under subsection (b) because no*
13 *patent had been issued when the application was filed or ap-*
14 *proved, the holder shall file such information under this sub-*
15 *section not later than thirty days after the date the patent*
16 *involved is issued. Upon the submission of patent informa-*
17 *tion under this subsection, the Secretary shall publish it.”.*

18 (3)(A) *The first sentence of section 505(d) of such Act is*
19 *amended by redesignating clause (6) as clause (7) and insert-*
20 *ing after clause (5) the following: “(6) the application failed*
21 *to contain the patent information prescribed by subsection*
22 *(b); or”.*

23 (B) *The first sentence of section 505(e) of such Act is*
24 *amended by redesignating clause (4) as clause (5) and insert-*
25 *ing after clause (3) the following: “(4) the patent information*

1 *prescribed by subsection (c) was not filed within thirty days*
2 *after the receipt of written notice from the Secretary specify-*
3 *ing the failure to file such information; or”.*

4 *(b)(1) Section 505(a) of such Act is amended by insert-*
5 *ing “or (j)” after “subsection (b)”.*

6 *(2) Section 505(c) of such Act is amended by striking*
7 *out “this subsection” and inserting in lieu thereof “subsec-*
8 *tion (b)”.*

9 *(3) The second sentence of section 505(e) of such Act is*
10 *amended by inserting “submitted under subsection (b) or (j)”*
11 *after “an application”.*

12 *(4) The second sentence of section 505(e) is amended by*
13 *striking out “(j)” each place it occurs in clause (1) and in-*
14 *serting in lieu thereof “(k)”.*

15 *(5) Section 505(k)(1) of such Act (as so redesignated) is*
16 *amended by striking out “pursuant to this section” and in-*
17 *serting in lieu thereof “under subsection (b) or (j)”.*

18 *(6) Subsections (a) and (b) of section 527 of such Act*
19 *are each amended by striking out “505(b)” each place it*
20 *occurs and inserting in lieu thereof “505”.*

21 *SEC. 103. (a) Section 505(b) of such Act is amended*
22 *by inserting “(1)” after “(b)”, by redesignating clauses (1)*
23 *through (6) as clauses (A) through (F), respectively, and by*
24 *adding at the end the following:*

1 “(2) An application submitted under paragraph (1) for
2 a drug listed under subsection (j)(6) for which investigations
3 described in clause (A) of such paragraph and relied upon by
4 the applicant for approval of the application were not con-
5 ducted by or for the applicant or for which the applicant has
6 not obtained a right of reference or use from the person by or
7 for whom the investigations were conducted shall also
8 include—

9 “(A) a certification, in the opinion of the appli-
10 cant and to the best of his knowledge, with respect to
11 each patent which claims the drug for which such in-
12 vestigations were conducted or which claims a use for
13 such drug for which the applicant is seeking approval
14 under this subsection and for which information is re-
15 quired to be filed under paragraph (1) or subsection
16 (c)—

17 “(i) that such patent information has not
18 been filed,

19 “(ii) that such patent has expired,

20 “(iii) of the date on which such patent will
21 expire, or

22 “(iv) that such patent is invalid or will not
23 be infringed by the manufacture, use, or sale of
24 the new drug for which the application is submit-
25 ted; and

1 “(B) if with respect to the drug for which investi-
2 gations described in paragraph (1)(A) were conducted
3 information was filed under paragraph (1) or subsec-
4 tion (c) for a method of use patent which does not
5 claim a use for which the applicant is seeking approval
6 under this subsection, a statement that the method of
7 use patent does not claim such a use.

8 “(3)(A) An applicant who makes a certification de-
9 scribed in paragraph (2)(A)(iv) shall include in the applica-
10 tion a statement that the applicant has given the notice re-
11 quired by subparagraph (B) to—

12 “(i) each owner of the patent which is the subject
13 of the certification or the representative of such owner
14 designated to receive such notice, and

15 “(ii) the holder of the approved application under
16 subsection (b) for the drug which is claimed by the
17 patent or a use of which is claimed by the patent or the
18 representative of such holder designated to receive such
19 notice.

20 “(B) The notice referred to in subparagraph (A) shall
21 state that an application has been submitted under this sub-
22 section for the drug with respect to which the certification is
23 made to obtain approval to engage in the commercial manu-
24 facture, use, or sale of the drug before the expiration of the
25 patent referred to in the certification. Such notice shall in-

1 *clude a detailed statement of the factual and legal basis of the*
2 *applicant's opinion that the patent is not valid or will not be*
3 *infringed.*

4 *“(C) If an application is amended to include a certifica-*
5 *tion described in paragraph (2)(A)(iv), the notice required by*
6 *subparagraph (B) shall be given when the amended applica-*
7 *tion is submitted.”.*

8 *(b) Section 505(c) of such Act (as amended by section*
9 *102(a)(2)) is amended by adding at the end the following:*

10 *“(3) The approval of an application filed under subsec-*
11 *tion (b) which contains a certification required by paragraph*
12 *(2) of such subsection shall be made effective on the last ap-*
13 *plicable date determined under the following:*

14 *“(A) If the applicant only made a certification de-*
15 *scribed in clause (i) or (ii) of subsection (b)(2)(A) or*
16 *in both such clauses, the approval may be made effec-*
17 *tive immediately.*

18 *“(B) If the applicant made a certification de-*
19 *scribed in clause (iii) of subsection (b)(2)(A), the ap-*
20 *proval may be made effective on the date certified*
21 *under clause (iii).*

22 *“(C) If the applicant made a certification de-*
23 *scribed in clause (iv) of subsection (b)(2)(A), the ap-*
24 *proval shall be made effective immediately unless an*
25 *action is brought for infringement of a patent which is*

1 *the subject of the certification before the expiration of*
2 *forty-five days from the date the notice provided under*
3 *paragraph (3)(B) is received. If such an action is*
4 *brought before the expiration of such days, the approval*
5 *may be made effective upon the expiration of the eight-*
6 *een-month period beginning on the date of the receipt of*
7 *the notice provided under paragraph (3)(B) or such*
8 *shorter or longer period as the court may order because*
9 *either party to the action failed to reasonably cooperate*
10 *in expediting the action, except that—*

11 “(i) if before the expiration of such period
12 the court decides that such patent is invalid or not
13 infringed, the approval may be made effective on
14 the date of the court decision, or

15 “(ii) if before the expiration of such period
16 the court decides that such patent has been in-
17 fringed, the approval may be made effective on
18 such date as the court orders under section
19 271(e)(4)(A) of title 35, United States Code.

20 *In such an action, each of the parties shall reasonably*
21 *cooperate in expediting the action. Until the expiration*
22 *of the forty-five-day period beginning on the date the*
23 *notice made under paragraph (3)(B) is received, no*
24 *action may be brought under section 2201 of title 28,*
25 *United States Code, for a declaratory judgment with*

1 *respect to the patent. Any action brought under such*
2 *section 2201 shall be brought in the judicial district*
3 *where the defendant has its principal place of business*
4 *or a regular and established place of business.*

5 ~~“(D)(i)~~ *If an application (other than an abbrevi-*
6 *ated new drug application) submitted under subsection*
7 *(b) for a drug, no active ingredient (including any*
8 *ester or salt of the active ingredient) of which has been*
9 *approved in any other application under subsection (b),*
10 *was approved during the period beginning January 1,*
11 *1982, and ending on the date of the enactment of this*
12 *subsection, the Secretary may not make the approval of*
13 *another application for a drug for which investigations*
14 *described in clause (A) of subsection (b)(1) and relied*
15 *upon by the applicant for approval of the application*
16 *were not conducted by or for the applicant or which the*
17 *applicant has not obtained a right of reference or use*
18 *from the person by or for whom the investigations were*
19 *conducted effective before the expiration of ten years*
20 *from the date of the approval of the application previ-*
21 *ously approved under subsection (b).*

22 ~~“(ii)~~ *If an application submitted under subsection*
23 *(b) for a drug, no active ingredient (including any*
24 *ester or salt of the active ingredient) of which has been*
25 *approved in any other application under subsection (b),*

1 *is approved after the date of the enactment of this sub-*
2 *section and if the holder of the approved application*
3 *certifies to the Secretary that no patent has ever been*
4 *issued to any person for such drug or for a method of*
5 *using such drug and that the holder cannot receive a*
6 *patent for such drug or for a method of using such*
7 *drug because in the opinion of the holder a patent may*
8 *not be issued for such drug or for a method of using for*
9 *any known therapeutic purposes such drug, the Secre-*
10 *tary may not make the approval of another application*
11 *for a drug for which investigations described in clause*
12 *(A) of subsection (b)(1) and relied upon by the appli-*
13 *cant for approval of the application were not conducted*
14 *by or for the applicant or which the applicant has not*
15 *obtained a right of reference or use from the person by*
16 *or for whom the investigations were conducted effective*
17 *before the expiration of four years from the date of the*
18 *approval of the application previously approved under*
19 *subsection (b) unless the Secretary determines that an*
20 *adequate supply of such drug will not be available or*
21 *the holder of the application approved under subsection*
22 *(b) consents to an earlier effective date for an applica-*
23 *tion under this subsection.”.*

24 *SEC. 104. Section 505 of such Act is amended by*
25 *adding at the end the following:*

1 “(l) *Safety and effectiveness data and information*
2 *which has been submitted in an application under subsection*
3 *(b) for a drug and which has not previously been disclosed to*
4 *the public shall be made available to the public, upon request,*
5 *unless extraordinary circumstances are shown—*

6 “(1) *if no work is being or will be undertaken to*
7 *have the application approved,*

8 “(2) *if the Secretary has determined that the ap-*
9 *plication is not approvable and all legal appeals have*
10 *been exhausted,*

11 “(3) *if approval of the application under subsec-*
12 *tion (c) is withdrawn and all legal appeals have been*
13 *exhausted,*

14 “(4) *if the Secretary has determined that such*
15 *drug is not a new drug, or*

16 “(5) *upon the effective date of the approval of the*
17 *first application under subsection (j) which refers to*
18 *such drug or upon the date upon which the approval of*
19 *an application under subsection (j) which refers to*
20 *such drug could be made effective if such an applica-*
21 *tion had been submitted.*

22 “(m) *For purposes of this section, the term ‘patent’*
23 *means a patent issued by the Patent and Trademark Office*
24 *of the Department of Commerce.”.*

1 *SEC. 105. (a) The Secretary of Health and Human*
2 *Services shall promulgate, in accordance with the notice and*
3 *comment requirements of section 553 of title 5, United States*
4 *Code, such regulations as may be necessary for the adminis-*
5 *tration of section 505 of the Federal Food, Drug, and Cos-*
6 *metic Act, as amended by sections 101, 102, and 103 of this*
7 *Act, within one year of the date of enactment of this Act.*

8 *(b) During the period beginning on the date of the enact-*
9 *ment of this Act and ending on the date regulations promul-*
10 *gated under subsection (a) take effect, abbreviated new drug*
11 *applications may be submitted in accordance with the provi-*
12 *sions of section 314.2 of title 21 of the Code of Federal Regu-*
13 *lations and shall be considered as suitable for any drug*
14 *which has been approved for safety and effectiveness under*
15 *section 505(c) of the Federal Food, Drug, and Cosmetic Act*
16 *before the date of the enactment of this Act. If any such pro-*
17 *vision is inconsistent with the requirements of section 505(j)*
18 *of the Federal Food, Drug, and Cosmetic Act, the Secretary*
19 *shall consider the application under the applicable require-*
20 *ments of such section. The Secretary of Health and Human*
21 *Services may not approve such an abbreviated new drug ap-*
22 *plication which is filed for a drug which is described in sec-*
23 *tions 505(c)(3)(D) and 505(j)(4)(D) of the Federal Food,*
24 *Drug, and Cosmetic Act except in accordance with such*
25 *section.*

1 *SEC. 106. Section 2201 of title 28, United States*
2 *Code, is amended by inserting “(a)” before “In a case” and*
3 *by adding at the end the following:*

4 *“(b) For limitations on actions brought with respect to*
5 *drug patents see section 505 of the Federal Food, Drug, and*
6 *Cosmetic Act.”.*

7 *TITLE II—PATENT EXTENSION*

8 *SEC. 201. (a) Title 35 of the United States Code is*
9 *amended by adding the following new section immediately*
10 *after section 155A:*

11 *“§ 156. Extension of patent term*

12 *“(a) The term of a patent which claims a product, a*
13 *method of using a product, or a method of manufacturing a*
14 *product shall be extended in accordance with this section*
15 *from the original expiration date of the patent if—*

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

19 *“(2) the term of the patent has never been ex-*
20 *tended;*

21 *“(3) an application for extension is submitted by*
22 *the owner of record of the patent or its agent and in*
23 *accordance with the requirements of subsection (d);*

24 *“(4)(A) in the case of a patent which claims the*
25 *product or a method of using the product—*

1 “(i) the product is not claimed in another
2 patent having an earlier issuance date or which
3 was previously extended, and

4 “(ii) the product and the use approved for the
5 product in the applicable regulatory review period
6 are not identically disclosed or described in an-
7 other patent having an earlier issuance date or
8 which was previously extended; or

9 “(B) in the case of a patent which claims the
10 product, the product is also claimed in a patent which
11 has an earlier issuance date or which was previously
12 extended and which does not identically disclose or de-
13 scribe the product and—

14 “(i) the holder of the patent to be extended
15 has never been and will not become the holder of
16 the patent which has an earlier issuance date or
17 which was previously extended, and

18 “(ii) the holder of the patent which has an
19 earlier issuance date or which was previously ex-
20 tended has never been and will not become the
21 holder of the patent to be extended;

22 “(5)(A) in the case of a patent which claims a
23 method of manufacturing the product which does not
24 primarily use recombinant DNA technology in the
25 manufacture of the product—

1 “(i) no other patent has been issued which
2 claims the product or a method of using the prod-
3 uct and no other patent which claims a method of
4 using the product may be issued for any known
5 therapeutic purposes; and

6 “(ii) no other method of manufacturing the
7 product which does not primarily use recombinant
8 DNA technology in the manufacture of the prod-
9 uct is claimed in a patent having an earlier issu-
10 ance date;

11 “(B) in the case of a patent which claims a
12 method of manufacturing the product which primarily
13 uses recombinant DNA technology in the manufacture
14 of the product—

15 “(i) the holder of the patent for the method of
16 manufacturing the product (I) is not the holder of
17 a patent claiming the product or a method of
18 using the product, (II) is not owned or controlled
19 by a holder of a patent claiming the product or a
20 method of using the product or by a person who
21 owns or controls a holder of such a patent, and
22 (III) does not own or control the holder of such a
23 patent or a person who owns or controls a holder
24 of such a patent; and

1 “(i) no other method of manufacturing the
2 product primarily using recombinant DNA tech-
3 nology is claimed in a patent having an earlier
4 issuance.

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

7 “(7)(A) except as provided in subparagraph (B),
8 the permission for the commercial marketing or use of
9 the product after such regulatory review period is the
10 first permitted commercial marketing or use of the
11 product under the provision of law under which such
12 regulatory review period occurred; or

13 “(B) in the case of a patent which claims a
14 method of manufacturing the product which primarily
15 uses recombinant DNA technology in the manufacture
16 of the product, the permission for the commercial mar-
17 keting or use of the product after such regulatory
18 review period is the first permitted commercial market-
19 ing or use of a product manufactured under the process
20 claimed in the patent; and

21 “(8) the patent does not claim another product or
22 a method of using or manufacturing another product
23 which product received permission for commercial mar-
24 keting or use under such provision of law before the
25 filing of an application for extension.

1 *The product referred to in paragraphs (4), (5), (6), and (7) is*
2 *hereinafter in this section referred to as the 'approved prod-*
3 *uct'. For purposes of paragraphs (4)(B) (5)(B), the holder of*
4 *a patent is any person who is the owner of record of the*
5 *patent or is the exclusive licensee of the owner of record of the*
6 *patent.*

7 “(b) *The rights derived from any patent the term of*
8 *which is extended under this section shall during the period*
9 *during which the patent is extended—*

10 “(1) *in the case of a patent which claims a prod-*
11 *uct, be limited to any use approved for the approved*
12 *product before the expiration of the term of the patent*
13 *under the provision of law under which the applicable*
14 *regulatory review occurred;*

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

21 “(3) *in the case of a patent which claims a*
22 *method of manufacturing a product, be limited to the*
23 *method of manufacturing as used to make the approved*
24 *product.*

1 “(c) *The term of a patent eligible for extension under*
2 *subsection (a) shall be extended by the time equal to the regu-*
3 *latory review period for the approved product which period*
4 *occurs after the date the patent is issued, except that—*

5 “(1) *each period of the regulatory review period*
6 *shall be reduced by any period determined under sub-*
7 *section (d)(2)(B) during which the applicant for the*
8 *patent extension did not act with due diligence during*
9 *such period of the regulatory review period;*

10 “(2) *after any reduction required by paragraph*
11 *(1), the period of extension shall include only one-half*
12 *of the time remaining in the periods described in para-*
13 *graphs (1)(B)(i), (2)(B)(i), and (3)(B)(i) of subsection*
14 *(g); and*

15 “(3) *if the period remaining in the term of a*
16 *patent after the date of the approval of the approved*
17 *product under the provision of law under which such*
18 *regulatory review occurred when added to the regulato-*
19 *ry review period as revised under paragraphs (1) and*
20 *(2) exceeds fourteen years, the period of extension shall*
21 *be reduced so that the total of both such periods does*
22 *not exceed fourteen years.*

23 “(d)(1) *To obtain an extension of the term of a patent*
24 *under this section, the owner of record of the patent or its*
25 *agent shall submit an application to the Commissioner. Such*

1 *an application may only be submitted within the sixty-day*
2 *period beginning on the date the product received permission*
3 *under the provision of law under which the applicable regula-*
4 *tory review period occurred for commercial marketing or use.*

5 *The application shall contain—*

6 “(A) *the identity of the approved product;*

7 “(B) *the identity of the patent for which an exten-*
8 *sion is being sought and the identification of each*
9 *claim of such patent which claims the approved product*
10 *or a method of using or manufacturing the approved*
11 *product;*

12 “(C) *the identity of every other patent known to*
13 *the patent owner which claims or identically discloses*
14 *or describes the approved product or a method of using*
15 *or manufacturing the approved product;*

16 “(D) *the identity of all other products which have*
17 *received permission under the provision of law under*
18 *which the applicable regulatory review period occurred*
19 *for commercial marketing or use and which are*
20 *claimed in any of the patents identified in subpara-*
21 *graph (C);*

22 “(E) *information to enable the Commissioner to*
23 *determine under subsections (a) and (b) the eligibility*
24 *of a patent for extension and the rights that will be de-*
25 *rived from the extension and information to enable the*

1 *Commissioner and the Secretary of Health and*
2 *Human Services or the Secretary of Agriculture to de-*
3 *termine the period of the extension under subsection*
4 *(g);*

5 *“(F) a brief description of the activities undertak-*
6 *en by the applicant during the applicable regulatory*
7 *review period with respect to the approved product and*
8 *the significant dates applicable to such activities; and*

9 *“(G) such patent or other information as the*
10 *Commissioner may require.*

11 *“(2)(A) Within sixty days of the submittal of an appli-*
12 *cation for extension of the term of a patent under paragraph*
13 *(1), the Commissioner shall notify—*

14 *“(i) the Secretary of Agriculture if the patent*
15 *claims a drug product or a method of using or manu-*
16 *facturing a drug product and the drug product is sub-*
17 *ject to the ~~Virus-Serum-Toxin Act~~, and*

18 *“(ii) the Secretary of Health and Human Serv-*
19 *ices if the patent claims any other drug product, a*
20 *medical device, or a food additive or color additive or a*
21 *method of using or manufacturing such a product,*
22 *device, or additive and if the product, device, and addi-*
23 *tive are subject to the ~~Federal Food, Drug, and Cos-~~*
24 *metic Act,*

1 (1), the Commissioner shall notify the Secretary of
2 Health and Human Services if the patent claims
3 any human drug product, a medical device, or a
4 food additive or color additive or a method of
5 using or manufacturing such a product, device, or
6 additive and if the product, device, and additive
7 are subject to the Federal Food, Drug, and Cos-
8 metic Act of the extension application and shall submit to
9 the Secretary ~~who is so notified~~ a copy of the application.
10 Not later than thirty days after the receipt of an application
11 from the Commissioner, the Secretary ~~receiving the applica-~~
12 ~~tion~~ shall review the dates contained in the application pur-
13 suant to paragraph (1)(E) and determine the applicable regu-
14 latory review period, shall notify the Commissioner of the
15 determination, and shall publish in the Federal Register a
16 notice of such determination.

17 “(B)(i) If a petition is submitted to the Secretary
18 ~~making the determination~~ under subparagraph (A), not later
19 than one hundred and eighty days after the publication of the
20 determination under subparagraph (A), upon which it may
21 reasonably be determined that the applicant did not act with
22 due diligence during the applicable regulatory review period,
23 the Secretary ~~making the determination~~ shall, in accordance
24 with regulations promulgated by ~~such~~ the Secretary deter-
25 mine if the applicant acted with due diligence during the ap-

1 plicable regulatory review period. The Secretary shall make
2 such determination not later than ninety days after the re-
3 ceipt of such a petition. The Secretary of ~~Health and Human~~
4 ~~Services~~ may not delegate the authority to make the determi-
5 nation prescribed by this subparagraph to an office below the
6 Office of the Commissioner of Food and Drugs.

7 “(ii) The Secretary ~~making a determination under~~
8 ~~clause (i)~~ shall notify the Commissioner of the determination
9 and shall publish in the Federal Register a notice of such
10 determination together with the factual and legal basis for
11 such determination. Any interested person may request,
12 within the sixty day period beginning on the publication of a
13 determination, the Secretary ~~making the determination to~~
14 hold an informal hearing on the determination. If such a
15 request is made within such period, ~~such~~ **the** Secretary shall
16 hold such hearing not later than thirty days after the date of
17 the request, or at the request of the person making the request,
18 not later than sixty days after such date. The Secretary ~~who~~
19 ~~is holding the hearing~~ shall provide notice of the hearing to
20 the owner of the patent involved and to any interested person
21 and provide the owner and any interested person an opportu-
22 nity to participate in the hearing. Within thirty days after
23 the completion of the hearing, ~~such~~ **the** Secretary shall affirm
24 or revise the determination which was the subject of the
25 hearing and notify the Commissioner of any revision of the

1 determination and shall publish any such revision in the Fed-
2 eral Register.

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

8 “(4) An application for the extension of the term of a
9 patent is subject to the disclosure requirements prescribed by
10 the Commissioner.

11 “(e)(1) A determination that a patent is eligible for ex-
12 tension may be made by the Commissioner solely on the basis
13 of the information contained in the application for the exten-
14 sion. If the Commissioner determines that a patent is eligible
15 for extension under subsection (a) and that the requirements
16 of subsection (d) have been complied with, the Commissioner
17 shall issue to the applicant for the extension of the term of the
18 patent a certificate of extension, under seal, for the period
19 prescribed by subsection (c). Such certificate shall be record-
20 ed in the official file of the patent and shall be considered as
21 part of the original patent.

22 “(2) If the term of a patent for which an application has
23 been submitted under subsection (d) would expire before a
24 determination is made under paragraph (1) respecting the
25 application, the Commissioner shall extend, until such deter-

1 *mination is made, the term of the patent for periods of up to*
2 *one year if he determines that the patent is eligible for*
3 *extension.*

4 *“(f) For purposes of this section:*

5 *“(1) The term ‘product’ means:*

6 *“(A) A **human drug product.***

7 *“(B) Any medical device, food additive, or*
8 *color additive subject to regulation under the Fed-*
9 *eral Food, Drug, and Cosmetic Act.*

10 *“(2) The term ‘**human drug product**’ means the*
11 *active ingredient of a new drug, antibiotic drug, ~~new~~*
12 *animal drug, or human or veterinary biological product*
13 *(as those terms are used in the Federal Food, Drug,*
14 *and Cosmetic Act, the Public Health Service Act, and*
15 *the ~~Virus-Serum-Toxin Act~~) or **human biological***
16 *product (as those terms are used in the Fed-*
17 *eral Food, Drug, and Cosmetic Act and the*
18 ***Public Health Service Act**) including any salt or*
19 *ester of the active ingredient, as a single entity or in*
20 *combination with another active ingredient.*

21 *“(3) The term ‘major health or environmental ef-*
22 *fects test’ means a test which is reasonably related to*
23 *the evaluation of the health or environmental effects of*
24 *a product, which requires at least six months to con-*
25 *duct, and the data from which is submitted to receive*

1 *permission for commercial marketing or use. Periods of*
2 *analysis or evaluation of test results are not to be in-*
3 *cluded in determining if the conduct of a test required*
4 *at least six months.*

5 “(4)(A) *Any reference to section 351 is a refer-*
6 *ence to section 351 of the Public Health Service Act.*

7 “(B) *Any reference to section 503, 505, 507, ~~512,~~*
8 *or 515 is a reference to section 503, 505, 507, ~~512,~~ or*
9 *515 of the Federal Food, Drug, and Cosmetic Act.*

10 “~~(C) Any reference to the Virus-Serum-Toxin Act~~
11 *is a reference to the Act of March 4, 1913 (21 U.S.C.*
12 *~~151-158).~~*

13 “(5) *The term ‘informal hearing’ has the meaning*
14 *prescribed for such term by section 201(y) of the Fed-*
15 *eral Food, Drug, and Cosmetic Act.*

16 “(6) *The term ‘patent’ means a patent issued by*
17 *the United States Patent and Trademark Office.*

18 “(g) *For purposes of this section, the term ‘regulatory*
19 *review period’ has the following meanings:*

20 “(1)(A) *In the case of a product which is a*
21 **human drug product**, *the term means the period de-*
22 *scribed in subparagraph (B) to which the limitation*
23 *described in paragraph (4) applies.*

24 “(B) *The regulatory review period for a **human***
25 *drug product is the sum of—*

1 ~~“(i) the period beginning on the date—~~

2 ~~“(I) an exemption under subsection (i)~~
3 ~~of section 505, subsection (d) of section 507,~~
4 ~~or subsection (j) of section 512, or~~

5 ~~“(II) the authority to prepare an exper-~~
6 ~~imental drug product under the Virus-~~
7 ~~Serum-Toxin Act,~~

8 ~~became effective for the approved drug product~~
9 ~~and ending on the date an application was initial-~~
10 ~~ly submitted for such drug product under section~~
11 ~~351, 505, 507, or 512 or the Virus-Serum-Toxin~~
12 ~~Act, and~~

13 **“(i) the period beginning on the date**
14 **an exemption under subsection (i) of sec-**
15 **tion 505 or under subsection (d) of sec-**
16 **tion 507 became effective for the ap-**
17 **proved human drug product and ending**
18 **on the date an application was initially**
19 **submitted for such drug product under**
20 **section 351, 505, or 507, and**

21 ~~“(ii) the period beginning on the date the ap-~~
22 ~~plication was initially submitted for the approved~~
23 ~~drug product under section 351, subsection (b) of~~
24 ~~such section 505, section 507, section 512, or the~~
25 ~~Virus-Serum-Toxin Act and ending on the date~~

1 *such application was approved under such section*
2 *of Act* **human drug product under section**
3 **351, subsection (b) of section 505, or sec-**
4 **tion 507 and ending on the date such ap-**
5 **plication was approved under such**
6 **section.**

7 *“(2)(A) In the case of a product which is a food*
8 *additive or color additive, the term means the period*
9 *described in subparagraph (B) to which the limitation*
10 *described in paragraph (4) applies.*

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

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

20 *“(ii) the period beginning on the date a peti-*
21 *tion was initially submitted with respect to the*
22 *product under the Federal Food, Drug, and Cos-*
23 *metic Act requesting the issuance of a regulation*
24 *for use of the product, and ending on the date*
25 *such regulation became effective or, if objections*

1 *were filed to such regulation, ending on the date*
2 *such objections were resolved and commercial*
3 *marketing was permitted or, if commercial mar-*
4 *keting was permitted and later revoked pending*
5 *further proceedings as a result of such objections,*
6 *ending on the date such proceedings were finally*
7 *resolved and commercial marketing was permitted.*

8 “(3)(A) *In the case of a product which is a medi-*
9 *cal device, the term means the period described in sub-*
10 *paragraph (B) to which the limitation described in*
11 *paragraph (4) applies.*

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

14 “(i) *the period beginning on the date a clini-*
15 *cal investigation on humans involving the device*
16 *was begun and ending on the date an application*
17 *was initially submitted with respect to the device*
18 *under section 515, and*

19 “(ii) *the period beginning on the date an ap-*
20 *plication was initially submitted with respect to*
21 *the device under section 515 and ending on the*
22 *date such application was approved under such*
23 *Act or the period beginning on the date a notice of*
24 *completion of a product development protocol was*
25 *initially submitted under section 515(f)(5) and*

1 ending on the date the protocol was declared com-
2 pleted under section 515(f)(6).

3 “(4) A period determined under any of the preced-
4 ing paragraphs is subject to the following limitations:

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

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

12 “(i) no request for an exemption de-
13 scribed in paragraph (1)(B) was submitted,

14 “(ii) no request was submitted for the
15 preparation of an experimental drug product
16 described in paragraph (1)(B),

17 “(iii) (ii) no major health or environ-
18 mental effects test described in paragraph (2)
19 was initiated and no petition for a regulation
20 or application for registration described in
21 such paragraph was submitted, or

22 “(iv) (iii) no clinical investigation de-
23 scribed in paragraph (3) was begun or prod-
24 uct development protocol described in such
25 paragraph was submitted,

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

5 “(C) If the patent involved was issued before
6 the date of the enactment of this section and if an
7 action described in subparagraph (B) was taken
8 before the date of the enactment of this section
9 with respect to the approved product and the com-
10 mercial marketing or use of the product has not
11 been approved before such date, the period of ex-
12 tension determined on the basis of the regulatory
13 review period determined under such paragraph
14 may not exceed two years.

15 “(h) The Commissioner may establish such fees as the
16 Commissioner determines appropriate to cover the costs to the
17 Office of receiving and acting upon applications under this
18 section.”.

19 (b) The analysis for chapter 14 of title 35 of the United
20 States Code is amended by adding at the end thereof the
21 following:

“156. Extension of patent term.”.

22 SEC. 202. Section 271 of title 35, United States Code
23 is amended by adding at the end the following:

24 “(e)(1) It shall not be an act of infringement to make,
25 use, or sell a patented invention **(other than a new**

1 **animal drug or veterinary biological product (as**
2 **those terms are used in the Federal Food, Drug,**
3 **and Cosmetic Act and the Act of March 4, 1913))**
4 *solely for uses reasonably related to the development and sub-*
5 *mission of information under a Federal law which regulates*
6 *the manufacture, use, or sale of drugs.*

7 “(2) *It shall be an act of infringement to submit an*
8 *application under section 505(j) of the Federal Food, Drug,*
9 *and Cosmetic Act or described in section 505(b)(2) of such*
10 *Act for a drug claimed in a patent or the use of which is*
11 *claimed in a patent, if the purpose of such submission is to*
12 *obtain approval under such Act to engage in the commercial*
13 *manufacture, use, or sale of a drug claimed in a patent or the*
14 *use of which is claimed in a patent before the expiration of*
15 *such patent.*

16 “(3) *In any action for patent infringement brought*
17 *under this section, no injunctive or other relief may be grant-*
18 *ed which would prohibit the making, using, or selling of a*
19 *patented invention under paragraph (1).*

20 “(4) *For an act of infringement described in paragraph*
21 *(2)—*

22 “(A) *the court shall order the effective date of any*
23 *approval of the drug involved in the infringement to be*
24 *a date which is not earlier than the date of the expira-*
25 *tion of the patent which has been infringed,*

1 “(B) injunctive relief may be granted against an
2 infringer to prevent the commercial manufacture, use,
3 or sale of an approved drug, and

4 “(C) damages or other monetary relief may be
5 awarded against an infringer only if there has been
6 commercial manufacture, use, or sale of an approved
7 drug.

8 The remedies prescribed by subparagraphs (A), (B), and (C)
9 are the only remedies which may be granted by a court for an
10 act of infringement described in paragraph (2), except that a
11 court may award attorney fees under section 285.”

12 SEC. 203. Section 282 of title 35, United States Code,
13 is amended by adding at the end the following:

14 “Invalidity of the extension of a patent term or any
15 portion thereof under section 156 of this title because of the
16 material failure—

17 “(1) by the applicant for the extension, or

18 “(2) by the Commissioner,

19 to comply with the requirements of such section shall be a
20 defense in any action involving the infringement of a patent
21 during the period of the extension of its term and shall be

1 *pleaded. A due diligence determination under section*
2 *156(d)(2) is not subject to review in such an action."*

Amend the title so as to read: "A bill to amend the Federal Food, Drug, and Cosmetic Act to revise the procedures for new drug applications and to amend title 35, United States Code, to authorize the extension of the patents for certain regulated products, and for other purposes."

Union Calendar No. 531

98TH CONGRESS
2^D SESSION

H. R. 3605

[Report No. 98-857, Parts I and II]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to authorize an abbreviated new drug application under section 505 of that Act for generic new drugs equivalent to approved new drugs.

AUGUST 1, 1984

Reported from the Committee on the Judiciary with
amendments and ordered to be printed