

## Calendar No. 1115

98TH CONGRESS  
2D SESSION**S. 2926**

To amend the Federal Food, Drug, and Cosmetic Act to revise the procedures for new drug applications, to amend title 35, United States Code, to authorize the extension of the patents for certain regulated products, and for other purposes.

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**IN THE SENATE OF THE UNITED STATES**

AUGUST 9 (legislative day, AUGUST 6), 1984

Mr. STEVENS (for Mr. HATCH) (for himself, Mr. DECONCINI, and Mrs. HAWKINS) introduced the following bill; which was read twice and ordered to be placed on the calendar

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**A BILL**

To amend the Federal Food, Drug, and Cosmetic Act to revise the procedures for new drug applications, to amend title 35, United States Code, to authorize the extension of the patents for certain regulated products, and for other purposes.

- 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 and Patent Term Restoration Act of 1984".

1                   **TITLE I—ABBREVIATED NEW DRUG**  
2                                   **APPLICATIONS**

3           **SEC. 101.** Section 505 of the Federal Food, Drug, and  
4 Cosmetic Act (21 U.S.C. 355) is amended by redesignating  
5 subsection (j) as subsection (k) and inserting after subsection  
6 (i) the following:

7           “(j)(1) Any person may file with the Secretary an abbrevi-  
8 viated application for the approval of a new drug.

9           “(2)(A) An abbreviated application for a new drug shall  
10 contain—

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

16                   “(ii)(I) if the listed drug referred to in clause (i)  
17 has only one active ingredient, information to show  
18 that the active ingredient of the new drug is the same  
19 as that of the listed drug,

20                   “(II) if the listed drug referred to in clause (i) has  
21 more than one active ingredient, information to show  
22 that the active ingredients of the new drug are the  
23 same as those of the listed drug, or

24                   “(III) if the listed drug referred to in clause (i)  
25 has more than one active ingredient and if one of the

1 active ingredients of the new drug is different and the  
2 application is filed pursuant to the approval of a peti-  
3 tion filed under subparagraph (C), information to show  
4 that the other active ingredients of the new drug are  
5 the same as the active ingredients of the listed drug,  
6 information to show that the different active ingredient  
7 is an active ingredient of a listed drug or of a drug  
8 which does not meet the requirements of section  
9 201(p), and such other information respecting the dif-  
10 ferent active ingredient with respect to which the peti-  
11 tion was filed as the Secretary may require;

12 “(iii) information to show that the route of admin-  
13 istration, the dosage form, and the strength of the new  
14 drug are the same as those of the listed drug referred  
15 to in clause (i) or, if the route of administration, the  
16 dosage form, or the strength of the new drug is differ-  
17 ent and the application is filed pursuant to the approval  
18 of a petition filed under subparagraph (C), such infor-  
19 mation respecting the route of administration, dosage  
20 form, or strength with respect to which the petition  
21 was filed as the Secretary may require;

22 “(iv) information to show that the new drug is  
23 bioequivalent to the listed drug referred to in clause (i),  
24 except that if the application is filed pursuant to the  
25 approval of a petition filed under subparagraph (C), in-

1       formation to show that the active ingredients of the  
2       new drug are of the same pharmacological or therapeutic  
3       class as those of the listed drug referred to in clause  
4       (i) and the new drug can be expected to have the same  
5       therapeutic effect as the listed drug when administered  
6       to patients for a condition of use referred to in clause  
7       (i);

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

15              “(vi) the items specified in clauses (B) through (F)  
16      of subsection (b)(1);

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

24              “(I) that such patent information has not  
25              been filed,

1           “(II) that such patent has expired,

2           “(III) of the date on which such patent will  
3           expire, or

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

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

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

17          “(B)(i) An applicant who makes a certification described  
18   in subparagraph (A)(vii)(IV) shall include in the application a  
19   statement that the applicant will give the notice required by  
20   clause (ii) to—

21           “(I) each owner of the patent which is the subject  
22           of the certification or the representative of such owner  
23           designated to receive such notice, and

24           “(II) the holder of the approved application under  
25           subsection (b) for the drug which is claimed by the

1 patent or a use of which is claimed by the patent or  
2 the representative of such holder designated to receive  
3 such notice.

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

14 “(iii) If an application is amended to include a certifica-  
15 tion described in subparagraph (A)(vii)(IV), the notice re-  
16 quired by clause (ii) shall be given when the amended appli-  
17 cation is submitted.

18 “(C) If a person wants to submit an abbreviated applica-  
19 tion for a new drug which has a different active ingredient or  
20 whose route of administration, dosage form, or strength differ  
21 from that of a listed drug, such person shall submit a petition  
22 to the Secretary seeking permission to file such an applica-  
23 tion. The Secretary shall approve or disapprove a petition  
24 submitted under this subparagraph within ninety days of the

1 date the petition is submitted. The Secretary shall approve  
2 such a petition unless the Secretary finds—

3 “(i) that investigations must be conducted to show  
4 the safety and effectiveness of the drug or of any of its  
5 active ingredients or of the route of administration, the  
6 dosage form, or strength which differ from the listed  
7 drug; or

8 “(ii) that any drug with a different active ingredi-  
9 ent may not be adequately evaluated for approval as  
10 safe and effective on the basis of the information re-  
11 quired to be submitted in an abbreviated application.

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

14 “(A) the methods used in, or the facilities and  
15 controls used for, the manufacture, processing, and  
16 packing of the drug are inadequate to assure and pre-  
17 serve its identity, strength, quality, and purity;

18 “(B) information submitted with the application is  
19 insufficient to show that each of the proposed condi-  
20 tions of use have been previously approved for the  
21 listed drug referred to in the application;

22 “(C)(i) if the listed drug has only one active ingre-  
23 dient, information submitted with the application is in-  
24 sufficient to show that the active ingredient is the same  
25 as that of the listed drug,

1           “(ii) if the listed drug has more than one active  
2 ingredient, information submitted with the application  
3 is insufficient to show that the active ingredients are  
4 the same as the active ingredients of the listed drug, or

5           “(iii) if the listed drug has more than one active  
6 ingredient and if the application is for a drug which  
7 has an active ingredient different from the listed drug,  
8 information submitted with the application is insuffi-  
9 cient to show—

10           “(I) that the other active ingredients are the  
11 same as the active ingredients of the listed drug,  
12 or

13           “(II) that the different active ingredient is an  
14 active ingredient of a listed drug or a drug which  
15 does not meet the requirements of section 201(p),  
16 or no petition to file an application for the drug with  
17 the different ingredient was approved under paragraph  
18 (2)(C);

19           “(D)(i) if the application is for a drug whose route  
20 of administration, dosage form, or strength of the drug  
21 is the same as the route of administration, dosage  
22 form, or strength of the listed drug referred to in the  
23 application, information submitted in the application is  
24 insufficient to show that the route of administration,

1 dosage form, or strength is the same as that of the  
2 listed drug, or

3 “(ii) if the application is for a drug whose route of  
4 administration, dosage form, or strength of the drug is  
5 different from that of the listed drug referred to in the  
6 application, no petition to file an application for the  
7 drug with the different route of administration, dosage  
8 form, or strength was approved under paragraph  
9 (2)(C);

10 “(E) if the application was filed pursuant to the  
11 approval of a petition under paragraph (2)(C), the ap-  
12 plication did not contain the information required by  
13 the Secretary respecting the active ingredient, route of  
14 administration, dosage form, or strength which is not  
15 the same;

16 “(F) information submitted in the application is in-  
17 sufficient to show that the drug is bioequivalent to the  
18 listed drug referred to in the application or, if the ap-  
19 plication was filed pursuant to a petition approved  
20 under paragraph (2)(C), information submitted in the  
21 application is insufficient to show that the active ingre-  
22 dients of the new drug are of the same pharmacological  
23 or therapeutic class as those of the listed drug referred  
24 to in paragraph (2)(A)(i) and that the new drug can be  
25 expected to have the same therapeutic effect as the

1 listed drug when administered to patients for a condi-  
2 tion of use referred to in such paragraph;

3 “(G) information submitted in the application is  
4 insufficient to show that the labeling proposed for the  
5 drug is the same as the labeling approved for the listed  
6 drug referred to in the application except for changes  
7 required because of differences approved under a peti-  
8 tion filed under paragraph (2)(C) or because the drug  
9 and the listed drug are produced or distributed by dif-  
10 ferent manufacturers;

11 “(H) information submitted in the application or  
12 any other information available to the Secretary shows  
13 that (i) the inactive ingredients of the drug are unsafe  
14 for use under the conditions prescribed, recommended,  
15 or suggested in the labeling proposed for the drug, or  
16 (ii) the composition of the drug is unsafe under such  
17 conditions because of the type or quantity of inactive  
18 ingredients included or the manner in which the inac-  
19 tive ingredients are included;

20 “(I) the approval under subsection (c) of the listed  
21 drug referred to in the application under this subsection  
22 has been withdrawn or suspended for grounds de-  
23 scribed in the first sentence of subsection (e), the Sec-  
24 retary has published a notice of opportunity for hearing  
25 to withdraw approval of the listed drug under subsec-

1 tion (c) for grounds described under the first sentence  
2 of subsection (e), the approval under this subsection of  
3 the listed drug referred to in the application under this  
4 subsection has been withdrawn or suspended under  
5 paragraph (5), or the Secretary has determined that  
6 the listed drug has been withdrawn from sale for safety  
7 or effectiveness reasons;

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

10 “(K) the application contains an untrue statement  
11 of material fact.

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

17 “(B) The approval of an application submitted under  
18 paragraph (2) shall be made effective on the last applicable  
19 date determined under the following:

20 “(i) If the applicant only made a certification de-  
21 scribed in subclause (I) or (II) of paragraph (2)(A)(vii)  
22 or in both such subclauses, the approval may be made  
23 effective immediately.

24 “(ii) If the applicant made a certification described  
25 in subclause (III) of paragraph (2)(A)(vii), the approval

1        may be made effective on the date certified under sub-  
2        clause (III).

3            “(iii) If the applicant made a certification de-  
4        scribed in subclause (IV) of paragraph (2)(A)(vii), the  
5        approval shall be made effective immediately unless an  
6        action is brought for infringement of each patent which  
7        is the subject of the certification before the expiration  
8        of forty-five days from the date the notice provided  
9        under paragraph (2)(B)(i) is received. If such an action  
10       is brought before the expiration of such days, the ap-  
11       proval shall be made effective upon the expiration of  
12       the thirty-month period beginning on the date of the  
13       receipt of the notice provided under paragraph (2)(B)(i)  
14       or such shorter or longer period as the court may order  
15       because either party to the action failed to reasonably  
16       cooperate in expediting the action, except that—

17            “(I) if before the expiration of such period  
18        the court decides that each such patent is invalid  
19        or not infringed, the approval shall be made effec-  
20        tive on the date of the court decision,

21            “(II) if before the expiration of such period  
22        the court decides that any such patent has been  
23        infringed, the approval shall be made effective on  
24        such date as the court orders under section  
25        271(e)(4)(A) of title 35, United States Code, or

1           “(III) if before the expiration of such period  
2           the court grants a preliminary injunction prohibit-  
3           ing the applicant from engaging in the commercial  
4           manufacture or sale of the drug until the court de-  
5           cides the issues of patent validity and infringe-  
6           ment, the approval shall be made effective on the  
7           date of such court decision.

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

18          “(iv) If the application contains a certification de-  
19          scribed in subclause (IV) of paragraph (2)(A)(vii) and is  
20          for a drug for which a previous application has been  
21          submitted under this subsection containing such a certi-  
22          fication, the application shall be made effective not ear-  
23          lier than one hundred and eighty days after—

24                 “(I) the date the Secretary receives notice  
25                 from the applicant under the previous application

1 of the first commercial marketing of the drug  
2 under the previous application, or

3 “(II) the date of a decision of a court in an  
4 action described in clause (iii) holding the patent  
5 which is the subject of the certification to be in-  
6 valid or not infringed,  
7 which ever is earlier.

8 “(C) If the Secretary decides to disapprove an applica-  
9 tion, the Secretary shall give the applicant notice of an op-  
10 portunity for a hearing before the Secretary on the question  
11 of whether such application is approvable. If the applicant  
12 elects to accept the opportunity for hearing by written re-  
13 quest within thirty days after such notice, such hearing shall  
14 commence not more than ninety days after the expiration of  
15 such thirty days unless the Secretary and the applicant other-  
16 wise agree. Any such hearing shall thereafter be conducted  
17 on an expedited basis and the Secretary’s order thereon shall  
18 be issued within ninety days after the date fixed by the Sec-  
19 retary for filing final briefs.

20 “(D)(i) If an application (other than an abbreviated new  
21 drug application) submitted under subsection (b) for a drug,  
22 no active ingredient (including any ester or salt of the active  
23 ingredient) of which has been approved in any other applica-  
24 tion under subsection (b), was approved during the period  
25 beginning January 1, 1982, and ending on the date of the

1 enactment of this subsection, the Secretary may not make the  
2 approval of an application submitted under this subsection  
3 which refers to the drug for which the subsection (b) applica-  
4 tion was submitted effective before the expiration of ten years  
5 from the date of the approval of the application under subsec-  
6 tion (b).

7       “(ii) If an application submitted under subsection (b) for  
8 a drug, no active ingredient (including any ester or salt of the  
9 active ingredient) of which has been approved in any other  
10 application under subsection (b), is approved after the date of  
11 the enactment of this subsection no application may be sub-  
12 mitted under this subsection which refers to the drug for  
13 which the subsection (b) application was submitted before the  
14 expiration of five years from the date of the approval of the  
15 application under subsection (b).

16       “(iii) If an application (or supplement to an application)  
17 submitted under subsection (b) for a drug which includes an  
18 active ingredient that has been approved in any other appli-  
19 cation approved under subsection (b), is approved after the  
20 date of enactment of this subsection, the Secretary may not  
21 make the approval of an application submitted under this sub-  
22 section which refers to the drug for which the subsection (b)  
23 application was submitted effective before the expiration of  
24 three years from the date of the approval of the application  
25 (or supplement thereto) under subsection (b).

1           “(iv) If an application (or supplement to an application)  
2 submitted under subsection (b) for a drug which includes an  
3 active ingredient that has been approved in any other appli-  
4 cation under subsection (b), was approved during the period  
5 beginning January 1, 1982, and ending on the date of the  
6 enactment of this subsection, the Secretary may not make the  
7 approval of an application submitted under this subsection  
8 which refers to the drug for which the subsection (b) applica-  
9 tion was submitted effective before the expiration of two  
10 years from the date of enactment of this 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 earli-  
23 er, the period ending on the date the Secretary deter-  
24 mines that the withdrawal from sale is not for safety or  
25 effectiveness reasons.

1       “(6)(A)(i) Within sixty days of the date of the enactment  
2 of this subsection, the Secretary shall publish and make avail-  
3 able 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 ef-  
18 fectiveness under subsection (c) or approved under this sub-  
19 section 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 earli-  
18 er, 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 and  
25 extent to which the active ingredient or therapeutic in-

1        ingredient is absorbed from a drug and becomes available  
2        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 either  
17       a single dose or multiple doses and the difference  
18       from the listed drug in the rate of absorption of  
19       the drug is intentional, is reflected in its proposed  
20       labeling, is not essential to the attainment of ef-  
21       fective body drug concentrations on chronic use,  
22       and is considered medically insignificant for the  
23       drug.”.

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

1 shall file with the application the patent number and the ex-  
2 piration date of any patent which claims the drug for which  
3 the applicant submitted the application or which claims a  
4 method of using such drug and with respect to which a claim  
5 of patent infringement could reasonably be asserted if a  
6 person not licensed by the owner engaged in the manufac-  
7 ture, use, or sale of the drug. If an application is filed under  
8 this subsection for a drug and a patent which claims such  
9 drug or a method of using such drug is issued after the filing  
10 date but before approval of the application, the applicant  
11 shall amend the application to include the information re-  
12 quired by the preceding sentence. Upon approval of the appli-  
13 cation, the Secretary shall publish information submitted  
14 under the two preceding 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 the  
18 end thereof the following:

19       “(2) If the patent information described in subsection (b)  
20 could not be filed with the submission of an application under  
21 subsection (b) because the application was filed before the  
22 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 than  
10 thirty days after the date of the enactment of this sentence,  
11 and if the holder of an approved application could not file  
12 patent information under subsection (b) because no patent  
13 had been issued when the application was filed or approved,  
14 the holder shall file such information under this subsection  
15 not later than thirty days after the date the patent involved is  
16 issued. Upon the submission of patent information under this  
17 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 (b);  
22 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 specifying  
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 “subsection  
8 (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 insert-  
14 ing 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 are  
19 each amended by striking out “under section 505(b)” and  
20 inserting in lieu thereof “under section 505”.

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

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

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

15               “(i) that such patent information has not  
16       been filed,

17               “(ii) that such patent has expired,

18               “(iii) of the date on which such patent will  
19       expire, or

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

24               “(B) if with respect to the drug for which investi-  
25       gations described in paragraph (1)(A) were conducted

1 information was filed under paragraph (1) or subsection  
2 (c) for a method of use patent which does not claim a  
3 use for which the applicant is seeking approval under  
4 this subsection, a statement that the method of use  
5 patent does not claim such a use.

6 “(3)(A) An applicant who makes a certification de-  
7 scribed in paragraph (2)(A)(iv) shall include in the application  
8 a statement that the applicant has given the notice required  
9 by subparagraph (B) to—

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

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

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

1 applicant's opinion that the patent is not valid or will not be  
2 infringed.

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

7       (b) Section 505(c) of such Act (as amended by section  
8 102(a)(2)) is amended by adding at the end thereof the follow-  
9 ing:

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 in  
16 both such clauses, the approval may be made effective  
17 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 each patent which

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

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

15 “(ii) if before the expiration of such period  
16 the court decides that any such patent has been  
17 infringed, 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, or

20 “(iii) if before the expiration of such period  
21 the court grants a preliminary injunction prohibit-  
22 ing the applicant from engaging in the commercial  
23 manufacture or sale of the drug until the court de-  
24 cides the issues of patent validity and infringe-

1           ment, the approval shall be made effective on the  
2           date of such court decision.

3           In such an action, each of the parties shall reasonably  
4           cooperate in expediting the action. Until the expiration  
5           of the forty-five-day period beginning on the date the  
6           notice made under paragraph (3)(B) is received, no  
7           action may be brought under section 2201 of title 28,  
8           United States Code, for a declaratory judgment with  
9           respect to the patent. Any action brought under such  
10          section 2201 shall be brought in the judicial district  
11          where the defendant has its principal place of business  
12          or a regular and established place of business.

13           “(D)(i) If an application (other than an abbreviat-  
14          ed new drug application) submitted under subsection (b)  
15          for a drug, no active ingredient (including any ester or  
16          salt of the active ingredient) of which has been ap-  
17          proved in any other application under subsection (b),  
18          was approved during the period beginning January 1,  
19          1982, and ending on the date of the enactment of this  
20          subsection, the Secretary may not make the approval  
21          of another application for a drug for which investiga-  
22          tions described in clause (A) of subsection (b)(1) and  
23          relied upon by the applicant for approval of the appli-  
24          cation were not conducted by or for the applicant or  
25          which the applicant has not obtained a right of refer-

1           ence or use from the person by or for whom the inves-  
2           tigations were conducted effective before the expiration  
3           of ten years from the date of the approval of the appli-  
4           cation previously approved under subsection (b).

5           “(ii) If an application submitted under subsection  
6           (b) for a drug, no active ingredient (including any ester  
7           or salt of the active ingredient) of which has been ap-  
8           proved in any other application under subsection (b), is  
9           approved after the date of the enactment of this sub-  
10          section no application may be submitted under this sub-  
11          section which refers to the drug for which the subsec-  
12          tion (b) application was submitted before the expiration  
13          of five years from the date of the approval of the appli-  
14          cation under subsection (b).

15          “(iii) If an application (or supplement to an appli-  
16          cation) submitted under subsection (b) for a drug which  
17          includes an active ingredient that has been approved in  
18          any other application approved under subsection (b), is  
19          approved after the date of enactment of this subsection,  
20          the Secretary may not make the approval of an appli-  
21          cation submitted under this subsection which refers to  
22          the drug for which the subsection (b) application was  
23          submitted effective before the expiration of three years  
24          from the date of the approval of the application (or  
25          supplement thereto) under subsection (b).

1           “(iv) If an application (or supplement to an appli-  
2 cation) submitted under subsection (b) for a drug,  
3 which includes an active ingredient that has been ap-  
4 proved in any other application under subsection (b),  
5 was approved during the period beginning January 1,  
6 1982, and ending on the date of the enactment of this  
7 subsection, the Secretary may not make the approval  
8 of an application submitted under this subsection which  
9 refers to the drug for which the subsection (b) applica-  
10 tion was submitted effective before the expiration of  
11 two years from the date of enactment of this subsec-  
12 tion.”.

13       SEC. 104. Section 505 of such Act is amended by  
14 adding at the end thereof the following:

15       “(l) Safety and effectiveness data and information which  
16 has been submitted in an application under subsection (b) for  
17 a drug and which has not previously been disclosed to the  
18 public shall be made available to the public, upon request,  
19 unless extraordinary circumstances are shown, including that  
20 the data and information represent trade secret or confiden-  
21 tial commercial or financial information—

22           “(1) if no work is being or will be undertaken to  
23       have the application approved,

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

4           “(3) if approval of the application under subsec-  
5           tion (c) is withdrawn and all legal appeals have been  
6           exhausted,

7           “(4) if the Secretary has determined that such  
8           drug is not a new drug, or

9           “(5) upon the effective date of the approval of the  
10          first application under subsection (j) which refers to  
11          such drug or upon the date upon which the approval of  
12          an application under subsection (j) which refers to such  
13          drug could be made effective if such an application had  
14          been submitted.

15          “(m) For purposes of this section, the term ‘patent’  
16          means a patent issued by the Patent and Trademark Office of  
17          the Department of Commerce.”.

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

1           (b) During the period beginning on the date of the enact-  
2 ment of this Act and ending on the date regulations promul-  
3 gated under subsection (a) take effect, abbreviated new drug  
4 applications may be submitted in accordance with the provi-  
5 sions of section 314.2 of title 21 of the Code of Federal Reg-  
6 ulations and shall be considered as suitable for any drug  
7 which has been approved for safety and effectiveness under  
8 section 505(c) of the Federal Food, Drug, and Cosmetic Act  
9 before the date of the enactment of this Act. If any such  
10 provision is inconsistent with the requirements of section  
11 505(j) of the Federal Food, Drug, and Cosmetic Act, the  
12 Secretary shall consider the application under the applicable  
13 requirements of such section. The Secretary of Health and  
14 Human Services may not approve such an abbreviated new  
15 drug application which is filed for a drug which is described  
16 in sections 505(c)(3)(D) and 505(j)(4)(D) of the Federal Food,  
17 Drug, and Cosmetic Act except in accordance with such sec-  
18 tion.

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

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

## 1 TITLE II—PATENT EXTENSION

2 SEC. 201. (a) Title 35 of the United States Code is  
3 amended by adding the following new section immediately  
4 after section 155:

## 5 “§ 156. Extension of patent term

6 “(a) The term of a patent which claims a product, a  
7 method of using a product, or a method of manufacturing a  
8 product shall be extended in accordance with this section  
9 from the original expiration date of the patent if—

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

13 “(2) the term of the patent has never been ex-  
14 tended;

15 “(3) an application for extension is submitted by  
16 the owner of record of the patent or its agent and in  
17 accordance with the requirements of subsection (d);

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

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

1           “(B) in the case of a patent which claims a  
2           method of manufacturing the product which primarily  
3           uses recombinant DNA technology in the manufacture  
4           of the product, the permission for the commercial mar-  
5           keting or use of the product after such regulatory  
6           review period is the first permitted commercial market-  
7           ing or use of a product manufactured under the process  
8           claimed in the patent.

9           The product referred to in paragraphs (4) and (5) is herein-  
10          after in this section referred to as the ‘approved product’.

11          “(b) The rights derived from any patent the term of  
12          which is extended under this section shall during the period  
13          during which the patent is extended—

14                 “(1) in the case of a patent which claims a prod-  
15                 uct be limited to any use approved for the approved  
16                 product before the expiration of the term of the patent  
17                 under the provision of law under which the applicable  
18                 regulatory review occurred;

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

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

5           “(c) The term of a patent eligible for extension under  
6 subsection (a) shall be extended by the time equal to the reg-  
7 ulatory review period for the approved product which period  
8 occurs after the date the patent is issued, except that—

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

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

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

1           “(4) in no event shall more than one patent be ex-  
2           tended for the same regulatory review period for any  
3           product.

4           “(d)(1) to obtain an extension of the term of a patent  
5           under this section, the owner of record of the patent or its  
6           agent shall submit an application to the Commissioner. Such  
7           an application may only be submitted within the sixty-day  
8           period beginning on the date the product received permission  
9           under the provision of law under which the applicable regula-  
10          tory review period occurred for commercial marketing or use.  
11          The application shall contain—

12                 “(A) the identity of the approved product and the  
13                 Federal statute under which regulatory review oc-  
14                 curred;

15                 “(B) the identity of the patent for which an exten-  
16                 sion is being sought and the identity of each claim of  
17                 such patent which claims the approved product or a  
18                 method of using or manufacturing the approved prod-  
19                 uct;

20                 “(C) information to enable the Commissioner to  
21                 determine under subsections (a) and (b) the eligibility of  
22                 a patent for extension and the rights that will be de-  
23                 rived from the extension and information to enable the  
24                 Commissioner and the Secretary of Health and Human

1 Services to determine the period of the extension under  
2 subsection (g);

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

7 “(E) such patent or other information as the Com-  
8 missioner may require.

9 “(2)(A) Within sixty days of the submittal of an applica-  
10 tion for extension of the term of a patent under paragraph (1),  
11 the Commissioner shall notify the Secretary of Health and  
12 Human Services if the patent claims any human drug prod-  
13 uct, a medical device, or a food additive or color additive or a  
14 method of using or manufacturing such a product, device, or  
15 additive and if the product, device, and additive are subject to  
16 the Federal Food, Drug, and Cosmetic Act of the extension  
17 application and shall submit to the Secretary a copy of the  
18 application. Not later than thirty days after the receipt of an  
19 application from the Commissioner, the Secretary shall  
20 review the dates contained in the application pursuant to  
21 paragraph (1)(C) and determine the applicable regulatory  
22 review period, shall notify the Commissioner of the determi-  
23 nation, and shall publish in the Federal Register a notice of  
24 such determination.

1           “(B)(i) If a petition is submitted to the Secretary under  
2 subparagraph (A), not later than one hundred and eighty days  
3 after the publication of the determination under subparagraph  
4 (A), upon which it may reasonably be determined that the  
5 applicant did not act with due diligence during the applicable  
6 regulatory review period, the Secretary shall, in accordance  
7 with regulations promulgated by the Secretary determine if  
8 the applicant acted with due diligence during the applicable  
9 regulatory review period. The Secretary shall make such de-  
10 termination not later than ninety days after the receipt of  
11 such a petition. The Secretary may not delegate the author-  
12 ity to make the determination prescribed by this subpara-  
13 graph to an office below the Office of the Commissioner of  
14 Food and Drugs.

15           “(ii) The Secretary shall notify the Commissioner of the  
16 determination and shall publish in the Federal Register a  
17 notice of such determination together with the factual and  
18 legal basis for such determination. Any interested person may  
19 request, within the sixty-day period beginning on the publica-  
20 tion of a determination, the Secretary to hold an informal  
21 hearing on the determination. If such a request is made  
22 within such period, the Secretary shall hold such hearing not  
23 later than thirty days after the date of the request, or at the  
24 request of the person making the request, not later than sixty  
25 days after such date. The Secretary shall provide notice of

1 the hearing to the owner of the patent involved and to any  
2 interested person and provide the owner and any interested  
3 person an opportunity to participate in the hearing. Within  
4 thirty days after the completion of the hearing, the Secretary  
5 shall affirm or revise the determination which was the subject  
6 of the hearing and notify the Commissioner of any revision of  
7 the determination and shall publish any such revision in the  
8 Federal Register.

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

14       “(4) An application for the extension of the term of a  
15 patent is subject to the disclosure requirements prescribed by  
16 the Commissioner.

17       “(e)(1) A determination that a patent is eligible for ex-  
18 tension may be made by the Commissioner solely on the basis  
19 of the representations contained in the application for the ex-  
20 tension. If the Commissioner determines that a patent is eli-  
21 gible for extension under subsection (a) and that the require-  
22 ments of subsection (d) have been complied with, the Com-  
23 missioner shall issue to the applicant for the extension of the  
24 term of the patent a certificate of extension, under seal, for  
25 the period prescribed by subsection (c). Such certificate shall

1 be recorded in the official file of the patent and shall be con-  
2 sidered as part of the original patent.

3       “(2) If the term of a patent for which an application has  
4 been submitted under subsection (d) would expire before a  
5 certificate of extension was issued or denied, the Commis-  
6 sioner shall extend the term of the patent for periods of up to  
7 one year until such certificate is issued or denied.

8       “(f) For purposes of this section:

9           “(1) The term ‘product’ means:

10               “(A) A human drug product.

11               “(B) Any medical device, food additive, or  
12 color additive subject to regulation under the Fed-  
13 eral Food, Drug, and Cosmetic Act.

14           “(2) The term ‘human drug product’ means the  
15 active ingredient of a new drug, antibiotic drug, or  
16 human biological product (as those terms are used in  
17 the Federal Food, Drug, and Cosmetic Act and the  
18 Public Health Service Act) including any salt or ester  
19 of the active ingredient, as a single entity or in com-  
20 bination 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,  
8 512, or 515 is a reference to section 503, 505, 507,  
9 512, or 515 of the Federal Food, Drug, and Cosmetic  
10 Act.

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

14 “(6) The term ‘patent’ means a patent issued by  
15 the United States Patent and Trademark Office,

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

18 “(1)(A) In the case of a product which is a human  
19 drug product, the term means the period described in  
20 subparagraph (B) to which the limitation described in  
21 paragraph (4) applies.

22 “(B) The regulatory review period for a human  
23 drug product is the sum of—

24 “(i) the period beginning on the date an ex-  
25 emption under subsection (i) of section 505 or

1 under subsection (d) of section 507 became effec-  
2 tive for the approved human drug product and  
3 ending on the date an application was initially  
4 submitted for such drug product under section  
5 351, 505, or 507, and

6 “(ii) the period beginning on the date the ap-  
7 plication was initially submitted for the approved  
8 human drug product under section 351, subsection  
9 (b) of section 505, or section 507 and ending on  
10 the date such application was approved under  
11 such section.

12 “(2)(A) In the case of a product which is a food  
13 additive or color additive, the term means the period  
14 described in subparagraph (B) to which the limitation  
15 described in paragraph (4) applies.

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

18 “(i) the period beginning on the date a major  
19 health or environmental effects test on the addi-  
20 tive was initiated and ending 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

1           “(ii) the period beginning on the date a peti-  
2           tion was initially submitted with respect to the  
3           product under the Federal Food, Drug, and Cos-  
4           metic Act requesting the issuance of a regulation  
5           for use of the product, and ending on the date  
6           such regulation became effective or, if objections  
7           were filed to such regulation, ending on the date  
8           such objections were resolved and commercial  
9           marketing was permitted or, if commercial mar-  
10          keting was permitted and later revoked pending  
11          further proceedings as a result of such objections,  
12          ending on the date such proceedings were finally  
13          resolved and commercial marketing was permit-  
14          ted.

15          “(3)(A) In the case of a product which is a medi-  
16          cal device, the term means the period described in sub-  
17          paragraph (B) to which the limitation described in  
18          paragraph (4) applies.

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

21                 “(i) the period beginning on the date a clini-  
22                 cal investigation on humans involving the device  
23                 was begun and ending on the date an application  
24                 was initially submitted with respect to the device  
25                 under section 515, and

1           “(ii) the period beginning on the date an ap-  
2           plication was initially submitted with respect to  
3           the device under section 515 and ending on the  
4           date such application was approved under such  
5           Act or the period beginning on the date a notice  
6           of completion of a product development protocol  
7           was initially submitted under section 515(f)(5) and  
8           ending on the date the protocol was declared  
9           completed under section 515(f)(6).

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

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

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

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

21           “(ii) no major health or environmental  
22           effects test described in paragraph (2) was  
23           initiated and no petition for a regulation or  
24           application for registration described in such  
25           paragraph was submitted, or

1                   “(iii) no clinical investigation described  
2                   in paragraph (3) was begun or product devel-  
3                   opment protocol described in such paragraph  
4                   was submitted,

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

9                   “(C) If the patent involved was issued before  
10                  the date of the enactment of this section and if an  
11                  action described in subparagraph (b) was taken  
12                  before the date of the enactment of this section  
13                  with respect to the approved product and the  
14                  commercial marketing or use of the product has  
15                  not been approved before such date, the period of  
16                  extension determined on the basis of the regulato-  
17                  ry review period determined under such para-  
18                  graph may not exceed two years.

19                  “(h) The Commissioner may establish such fees as the  
20                  Commissioner determines appropriate to cover the costs to  
21                  the Office of receiving and acting upon applications under  
22                  this section.”.

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

“156. Extension of patent term.”.

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

3           “(e)(1) It shall not be an act of infringement to make,  
4 use, or sell a patented invention (other than a new animal  
5 drug or veterinary biological product (as those terms are used  
6 in the Federal Food, Drug, and Cosmetic Act and the Act of  
7 March 4, 1913)) solely for uses reasonably related to the de-  
8 velopment and submission of information under a Federal law  
9 which regulates the manufacture, use, or sale of drugs.

10           “(2) It shall be an act of infringement to submit an ap-  
11 plication under section 505(j) of the Federal Food, Drug, and  
12 Cosmetic Act for a drug claimed in a patent or the use of  
13 which is claimed in a patent, if the purpose of such submis-  
14 sion is to obtain approval under such Act to engage in the  
15 commercial manufacture, use, or sale of a drug claimed in a  
16 patent or the use of which is claimed in a patent before the  
17 expiration of such patent.

18           “(3) In any action for patent infringement brought under  
19 this section, no injunctive or other relief may be granted  
20 which would prohibit the making, using, or selling of a pat-  
21 ented invention under the paragraph (1).

22           “(4) For an act of infringement described in paragraph  
23 (2)—

24                   “(A) the court shall order the effective date of any  
25 approval of the drug involved in the infringement to be

1 a date which is not earlier than the date of the expira-  
2 tion of the patent which has been infringed,

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

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

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

14 SEC. 203. Section 282 of title 35, United States Code,  
15 is amended by adding at the end the following: “Invalidity of  
16 the extension of a patent term or any portion thereof under  
17 section 156 of this title because of the material failure—

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

19 “(2) by the Commissioner,

20 to comply with the requirements of such section shall be a  
21 defense in any action involving the infringement of a patent  
22 during the period of the extension of its term and shall be  
23 pleaded. A due diligence determination under section  
24 156(d)(2) is not subject to review in such an action.”

1           **TITLE III—SEPARABILITY CLAUSE**

2           **SEC. 301.** If any provision of this Act is declared uncon-  
3 stitutional, or the applicability thereof to any person or cir-  
4 cumstances is held invalid, the constitutionality of the re-  
5 mainder of this Act and the applicability thereof to other per-  
6 sons and circumstances shall not be affected thereby.

Calendar No. 1115

98<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

**S. 2926**

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**A BILL**

To amend the Federal Food, Drug, and Cosmetic Act to revise the procedures for new drug applications, to amend title 35, United States Code, to authorize the extension of the patents for certain regulated products, and for other purposes.

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AUGUST 9 (legislative day, AUGUST 6), 1984

Read twice and ordered to be placed on the calendar