

## Calendar No. 491

107<sup>TH</sup> CONGRESS  
2D SESSION**S. 812**

To amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals.

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IN THE SENATE OF THE UNITED STATES

MAY 1, 2001

Mr. SCHUMER (for himself, Mr. MCCAIN, Mr. JOHNSON, Mrs. CLINTON, Ms. STABENOW, Mrs. CARNAHAN, Mr. KOHL, Mr. DASCHLE, Mr. DURBIN, Mr. WELLSTONE, Mr. EDWARDS, and Mr. MILLER) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

JULY 11 (legislative day, JULY 10), 2002

Reported by Mr. KENNEDY, with an amendment

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**A BILL**

To amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Greater Access to Af-  
5       fordable Pharmaceuticals Act of 2001”.

1 **SEC. 2. FINDINGS; PURPOSES.**

2 (a) FINDINGS.—Congress finds that—

3 (1) prescription drug costs are increasing at an  
4 alarming rate and are a major worry of American  
5 families and senior citizens;

6 (2) enhancing competition between generic drug  
7 manufacturers and brand-name manufacturers can  
8 significantly reduce prescription drug costs for  
9 American families;

10 (3) the pharmaceutical market has become in-  
11 creasingly competitive during the last decade be-  
12 cause of the increasing availability and accessibility  
13 of generic pharmaceuticals, but competition must be  
14 further stimulated and strengthened;

15 (4) the Federal Trade Commission has discov-  
16 ered that there are increasing opportunities for drug  
17 companies owning patents on brand-name drugs and  
18 generic drug companies to enter into private finan-  
19 cial deals in a manner that could restrain trade and  
20 greatly reduce competition and increase prescription  
21 drug costs for consumers;

22 (5) generic pharmaceuticals are approved by the  
23 Food and Drug Administration on the basis of sci-  
24 entific testing and other information establishing  
25 that pharmaceuticals are therapeutically equivalent  
26 to brand-name pharmaceuticals, ensuring consumers

1 a safe, efficacious, and cost-effective alternative to  
2 brand-name innovator pharmaceuticals;

3 (6) the Congressional Budget Office estimates  
4 that—

5 (A) the use of generic pharmaceuticals for  
6 brand-name pharmaceuticals could save pur-  
7 chasers of pharmaceuticals between  
8 \$8,000,000,000 and \$10,000,000,000 each  
9 year; and

10 (B) generic pharmaceuticals cost between  
11 25 percent and 60 percent less than brand-  
12 name pharmaceuticals, resulting in an esti-  
13 mated average savings of \$15 to \$30 on each  
14 prescription;

15 (7) generic pharmaceuticals are widely accepted  
16 by consumers and the medical profession, as the  
17 market share held by generic pharmaceuticals com-  
18 pared to brand-name pharmaceuticals has more than  
19 doubled during the last decade, from approximately  
20 19 percent to 43 percent, according to the Congres-  
21 sional Budget Office;

22 (8) expanding access to generic pharmaceuticals  
23 can help consumers, especially senior citizens and  
24 the uninsured, have access to more affordable pre-  
25 scription drugs;

1           (9) Congress should ensure that measures are  
2       taken to effectuate the amendments made by the  
3       Drug Price Competition and Patent Term Restora-  
4       tion Act of 1984 (98 Stat. 1585) (referred to in this  
5       section as the “Hatch-Waxman Act”) to make ge-  
6       neric drugs more accessible, and thus reduce health  
7       care costs; and

8           (10) it would be in the public interest if patents  
9       on drugs for which applications are approved under  
10      section 505(c) of the Federal Food, Drug, and Cos-  
11      metic Act (21 U.S.C. 355(c)) were extended only  
12      through the patent extension procedure provided  
13      under the Hatch-Waxman Act rather than through  
14      the attachment of riders to bills in Congress.

15      (b) PURPOSES.—The purposes of this Act are—

16           (1) to increase competition, thereby helping all  
17      Americans, especially seniors and the uninsured, to  
18      have access to more affordable medication; and

19           (2) to ensure fair marketplace practices and  
20      deter pharmaceutical companies (including generic  
21      companies) from engaging in anticompetitive action  
22      or actions that tend to unfairly restrain trade.

1 **SEC. 3. ACCELERATED GENERIC DRUG COMPETITION.**

2       (a) ~~IN GENERAL.~~—Section 505(j)(5) of the Federal  
3 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) is  
4 amended—

5           (1) in subparagraph (B)(iv), by striking sub-  
6 clause (II) and inserting the following:

7               “(II) the earlier of—

8                   “(aa) the date of a final decision of a  
9 court in an action described in clause (iii)  
10 (from which no appeal can or has been  
11 taken); or

12                   “(bb) the date of a settlement order  
13 or consent decree signed by a Federal  
14 judge that enters a final judgment and in-  
15 cludes a finding that the patents that are  
16 the subject of the certification are invalid  
17 or not infringed;”;

18           (2) by redesignating subparagraphs (C) and  
19 (D) as subparagraphs (E) and (F), respectively; and

20           (3) by inserting after subparagraph (B) the fol-  
21 lowing:

22               “(C) **FORFEITURE OF 180-DAY PERIOD.**—

23                   “(i) ~~IN GENERAL.~~—The 180-day pe-  
24 riod described in subparagraph (B)(iv)  
25 shall be forfeited by the previous applicant  
26 and become available to the next applicant

1 submitting an application containing a cer-  
2 tification described in paragraph  
3 (2)(A)(vii)(IV) if—

4 “(I) the previous applicant fails  
5 to market the drug within 90 days  
6 after the date on which the approval  
7 of the application for the drug is  
8 made effective under subparagraph  
9 (B)(iii);

10 “(II) the previous applicant with-  
11 draws the application;

12 “(III) the previous applicant  
13 amends the certification from a cer-  
14 tification under subelause (IV) to a  
15 certification under paragraph  
16 (2)(A)(vii)(III), either voluntarily or  
17 as a result of a settlement or defeat in  
18 patent litigation;

19 “(IV) the previous applicant fails  
20 to get tentative approval of the appli-  
21 cation within 30 months after the  
22 date on which the application is filed;  
23 unless the failure is caused by—

24 “(aa) a change in the re-  
25 quirements for tentative approval

1 of the application imposed after  
2 the date on which the application  
3 was filed; or

4 “(bb) other extraordinary or  
5 unusual circumstances, as deter-  
6 mined by the Secretary;

7 “(V) in a case in which, after the  
8 date on which the previous application  
9 was submitted under this subsection,  
10 new patent information is submitted  
11 for the drug under subsection (e)(2)  
12 for a patent for which certification is  
13 required under paragraph  
14 (2)(A)(vii)(IV), the previous applicant  
15 fails to challenge the patent that is  
16 the subject of the information within  
17 60 days after the date on which the  
18 patent information is submitted; or

19 “(VI) the previous applicant is  
20 determined by the Secretary, after a  
21 fair and sufficient hearing and in con-  
22 sultation with the Federal Trade  
23 Commission, to have engaged in anti-  
24 competitive or collusive conduct, or  
25 any other conduct intended to unfairly

1 monopolize the commercial manufac-  
2 turing of the drug of the application.

3 ~~“(ii) AVAILABILITY.—The 180-day pe-~~  
4 ~~riod described in subparagraph (B)(iv)~~  
5 ~~shall be available only to—~~

6 ~~“(I) the previous applicant sub-~~  
7 ~~mitting an application for a drug~~  
8 ~~under this subsection containing a~~  
9 ~~certification described in paragraph~~  
10 ~~(2)(A)(vii)(IV) with respect to any~~  
11 ~~patent; or~~

12 ~~“(II) under clause (i), the next~~  
13 ~~applicant submitting an application~~  
14 ~~for a drug under this subsection con-~~  
15 ~~taining such a certification with re-~~  
16 ~~spect to any patent;~~

17 ~~even if an application has been submitted~~  
18 ~~for the drug under this subsection con-~~  
19 ~~taining such a certification with respect to~~  
20 ~~a different patent.~~

21 ~~“(iii) APPLICABILITY.—The 180-day~~  
22 ~~period described in subparagraph (B)(iv)~~  
23 ~~shall apply only if—~~



1                   “(I) the application contains a  
2                   certification described in paragraph  
3                   (2)(A)(vii)(IV); and

4                   “(H) an action is brought for in-  
5                   fringement of a patent that is the  
6                   subject of the certification or the ap-  
7                   plicant brings an action (not later  
8                   than 50 days after the date on which  
9                   the notice provided under paragraph  
10                  (2)(B)(ii) was received), against the  
11                  holder of the approved application for  
12                  the listed drug.”.

13           (b) **EFFECTIVE DATE.**—The amendment made by  
14 this section shall be effective only with respect to an appli-  
15 cation filed under section 505(j) of the Federal Food,  
16 Drug, and Cosmetic Act (21 U.S.C. 355(j)) for a listed  
17 drug for which no certification under section  
18 505(j)(2)(A)(vii)(IV) of that Act was made before the date  
19 of enactment of this Act.

20 **SEC. 4. BIOEQUIVALENCE TESTING METHODS.**

21           Section 505(j)(8)(B) of the Federal Food, Drug, and  
22 Cosmetic Act (21 U.S.C. 355(j)(8)(B)) is amended—

23                   (1) in clause (i), by striking “or” at the end;  
24                   (2) in clause (ii), by striking the period at the  
25                  end and inserting “; or”; and

1           ~~(3)~~ by adding at the end the following:

2                   ~~“(iii)(I) clauses (i) and (ii) are not applica-~~  
 3           ~~ble, as determined by the Secretary;~~

4                   ~~“(II) the effects of the drug and the listed~~  
 5           ~~drug do not show a significant difference based~~  
 6           ~~on tests (other than tests that assess rate and~~  
 7           ~~extent of absorption); including—~~

8                   ~~“(aa) a bioequivalence study with a~~  
 9                   ~~pharmacodynamic endpoint;~~

10                   ~~“(bb) a bioequivalence study with a~~  
 11           ~~clinical endpoint;~~

12                   ~~“(cc) in vitro methods; or~~

13                   ~~“(dd) any other methodology that~~  
 14           ~~demonstrates that no significant dif-~~  
 15           ~~ferences in therapeutic effects of active in-~~  
 16           ~~gredients are expected; and~~

17                   ~~“(III) limited confirmatory studies to sup-~~  
 18           ~~plement the bioequivalence testing are consid-~~  
 19           ~~ered necessary by the Secretary.”.~~

20   **SEC. 5. CITIZEN PETITIONS.**

21           Section 505(j)(5) of the Federal Food, Drug, and  
 22   Cosmetic Act (21 U.S.C. 355(j)(5)) (as amended by sec-  
 23   tion 3(a)) is amended by inserting after subparagraph (C)  
 24   the following:

25                   ~~“(D) CITIZEN PETITIONS.—~~

1           “(i) ~~IN GENERAL.—~~Notwithstanding  
 2           any other provision of law, any petition  
 3           submitted under section 10.30 of title 21,  
 4           Code of Federal Regulations (or any suc-  
 5           cessor regulation), shall include a state-  
 6           ment that to the best knowledge and belief  
 7           of the petitioner, the petition—

8                       “(I) includes all information and  
 9                       views on which the petitioner relies;

10                      “(II) is well grounded in fact and  
 11                      is warranted by law (including regula-  
 12                      tions);

13                      “(III) is not submitted for any  
 14                      improper purpose, such as to harass  
 15                      or cause unnecessary delay;

16                      “(IV) does not contain a materi-  
 17                      ally false, misleading, or fraudulent  
 18                      statement that the petitioner has  
 19                      knowingly and willingly included; and

20                      “(V) includes all representative  
 21                      data and information known to the  
 22                      petitioner that is favorable or unfavor-  
 23                      able to the petition.

24           “(ii) ~~APPLICABILITY OF CRIMINAL~~  
 25           ~~PROVISION.—~~Section 1001 of title 18,

1 United States Code, shall apply to a per-  
 2 son that submits a petition under section  
 3 ~~10.30~~ of title 21, Code of Federal Regula-  
 4 tions (or any successor regulation).

5 “(iii) INVESTIGATIONS.—

6 “(I) IN GENERAL.—The Federal  
 7 Trade Commission shall investigate,  
 8 on receipt of a complaint or upon its  
 9 own initiative, any petition submitted  
 10 under section ~~10.30~~ of title 21, Code  
 11 of Federal Regulations (or any suc-  
 12 cessor regulation), that may have been  
 13 submitted for an improper purpose,  
 14 such as to delay competition or agen-  
 15 cy action.

16 “(II) REFERRAL.—If the Com-  
 17 mission finds that a petitioner has en-  
 18 gaged in conduct that may be illegal,  
 19 the Commission shall refer the peti-  
 20 tion to the Antitrust Division of the  
 21 Department of Justice for further ac-  
 22 tion.

23 “(iv) NOTICE OF RECEIPT OF CONSID-  
 24 ERATION.—

1           “(I) IN GENERAL.—A person  
 2           that submits a petition under section  
 3           ~~10.30~~ of title 21, Code of Federal  
 4           Regulations (or any successor regula-  
 5           tion), shall provide a written notice to  
 6           the Federal Trade Commission if the  
 7           person receives any consideration for  
 8           submitting the petition.

9           “(H) A notice under subclause  
 10          (I) shall include—

11           “(aa) the name of the per-  
 12           son or entity that provided the  
 13           consideration;

14           “(bb) the dollar value of the  
 15           consideration, if provided in cash,  
 16           or a description of such consider-  
 17           ation;

18           “(cc) the date on which the  
 19           consideration was provided; and

20           “(dd) any other information  
 21           that the Commission requires to  
 22           be disclosed.”.

23 **SEC. 6. PATENT CERTIFICATION.**

24           (a) ABBREVIATED NEW DRUG APPLICATIONS.—See  
 25          tion ~~505(j)(5)~~ of the Federal Food, Drug, and Cosmetic

1 Act (21 U.S.C. 355(j)(5)) (as amended by section 3(a)(2))  
 2 is amended—

3 (1) in subparagraph (B), by striking clause (iii)  
 4 and inserting the following:

5 “(iii) CERTIFICATION THAT PATENT  
 6 IS INVALID OR WILL NOT BE INFRINGED.—

7 “(I) IN GENERAL.—Except as  
 8 provided in subclauses (II) and (III),  
 9 if the applicant made a certification  
 10 described in paragraph  
 11 (2)(A)(vii)(IV), the approval shall be  
 12 made effective on the expiration of 45  
 13 days after the date on which the no-  
 14 tice provided under paragraph  
 15 (2)(B)(ii) was received.

16 “(II) ACTION FOR PATENT IN-  
 17 FRINGEMENT.—If an action is  
 18 brought for infringement of a patent  
 19 that is the subject of the certification  
 20 before the expiration of the 45-day pe-  
 21 riod beginning on the date on which  
 22 the notice provided under paragraph  
 23 (2)(B)(ii) was received, the approval  
 24 shall be made effective on the expira-  
 25 tion of the 45-day period unless the

1 court grants a preliminary injunction  
2 prohibiting the applicant from engag-  
3 ing in the commercial manufacture or  
4 sale of the drug until the court de-  
5 cides the issues of patent validity and  
6 infringement.

7 “(III) PATENT INVALID OR NOT  
8 INFRINGED.—If the court decides that  
9 the patent is invalid or was not in-  
10 fringed, the approval shall be made ef-  
11 fective on the date of the court deci-  
12 sion.

13 “(IV) PATENT INFRINGED.—If  
14 the court decides that the patent was  
15 infringed, the approval shall be made  
16 effective on such date as the court or-  
17 ders under section 271(e)(4)(A) of  
18 title 35, United States Code.

19 “(V) PROCEDURE.—In an action  
20 described in subclause (II)—

21 “(aa) each of the parties  
22 shall reasonably cooperate in ex-  
23 pediting the action;

24 “(bb) until the expiration of  
25 45 days after the date the notice

1 provided under paragraph  
2 (2)(B)(i) was received, no civil  
3 action may be brought under sec-  
4 tion 2201 of title 28, United  
5 States Code, for a declaratory  
6 judgment with respect to the pat-  
7 ent, except as provided in sub-  
8 paragraph (H); and

9 “(cc) any such civil action  
10 shall be brought in the judicial  
11 district in which the defendant  
12 has its principal place of business  
13 or a regular and established place  
14 of business.”; and

15 (2) by adding at the end the following:

16 “(G) CIVIL ACTION FOR DECLARATORY  
17 JUDGMENT.—A person that files an abbreviated  
18 application for a new drug under this para-  
19 graph may bring a civil action against the hold-  
20 er of an approved application for a listed drug  
21 for a declaratory judgment to determine wheth-  
22 er the patent that claims the listed drug or a  
23 method of using the drug is invalid or will not  
24 be infringed.



1           “(H) CIVIL ACTION TO DETERMINE LEGAL  
 2           STATUS.—Notwithstanding any other provision  
 3           of law, if information on a patent for a listed  
 4           drug has been published under subsection (c)(2)  
 5           for at least 1 year after the date on which an  
 6           abbreviated application for approval of a new  
 7           drug was filed under this subsection in relation  
 8           to the listed drug, the person that filed the ab-  
 9           breviated application or the holder of the ap-  
 10          proved application for the listed drug may im-  
 11          mediately bring a civil action to determine the  
 12          legal status of the patent for the listed drug.”.

13          (b) NEW DRUG APPLICATIONS.—Section 505(c)(3)  
 14          of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
 15          355(c)(3)) is amended by striking subparagraph (C) and  
 16          inserting the following:

17               “(C) CERTIFICATION THAT PATENT IS IN-  
 18               VALID OR WILL NOT BE INFRINGED.—

19               “(i) IN GENERAL.—Except as pro-  
 20               vided in clauses (ii) and (iii), if the appli-  
 21               cant made a certification described in sub-  
 22               section (b)(2)(A)(iv), the approval shall be  
 23               made effective on the expiration of 45 days  
 24               after the date on which the notice provided  
 25               under subsection (b)(3)(B) was received.

1           “(ii) ACTION BROUGHT BEFORE EXPI-  
2           RATION OF 45 DAYS.—If an action is  
3           brought for infringement of a patent that  
4           is the subject of the certification before the  
5           expiration of the 45-day period beginning  
6           on the date the notice provided under sub-  
7           section (b)(3)(B) was received, the ap-  
8           proval shall be made effective on the expi-  
9           ration of the 45-day period unless the  
10          court grants a preliminary injunction pro-  
11          hibiting the applicant from engaging in the  
12          commercial manufacture or sale of the  
13          drug until the court decides the issues of  
14          patent validity and infringement.

15          “(iii) PATENT INVALID OR NOT IN-  
16          FRINGED.—If the court decides that the  
17          patent is invalid or not infringed, the ap-  
18          proval shall be made effective on the date  
19          of the court decision.

20          “(iv) PATENT INFRINGED.—If the  
21          court decides that the patent has been in-  
22          fringed, the approval may be made effec-  
23          tive on such date as the court orders under  
24          section 271(e)(4)(A) of title 35, United  
25          States Code.

1                   “(v) PROCEDURE.—In an action de-  
2                   scribed in clause (ii)—

3                   “(I) each of the parties shall rea-  
4                   sonably cooperate in expediting the  
5                   action;

6                   “(II) until the expiration of 45  
7                   days after the date the notice provided  
8                   under subsection (b)(3)(B) was re-  
9                   ceived, no civil action may be brought  
10                  under section 2201 of title 28, United  
11                  States Code, for a declaratory judg-  
12                  ment with respect to the patent, ex-  
13                  cept as provided in subsection  
14                  (j)(5)(H); and

15                  “(III) any such civil action shall  
16                  be brought in the judicial district  
17                  where the defendant has its principal  
18                  place of business or a regular and es-  
19                  tablished place of business.”.

20           (e) EFFECTIVE DATE.—The amendments made by  
21 this section shall not apply to an application submitted  
22 under section 505 of the Federal Food, Drug, and Cos-  
23 metic Act (21 U.S.C. 355) before the date of enactment  
24 of this Act.

1 **SEC. 7. PATENT INFORMATION.**

2 Section 505 of the Federal Food, Drug, and Cosmetic  
3 Act (~~21 U.S.C. 355~~) is amended—

4 (1) in subsection (b), by striking “(b)(1) Any  
5 person” and all that follows through paragraph (1)  
6 and inserting the following:

7 “(b) APPLICATIONS.—

8 “(1) IN GENERAL.—

9 “(A) FILING.—Any person may file with  
10 the Secretary an application with respect to any  
11 drug subject to subsection (a).

12 “(B) CONTENTS.—A person that files an  
13 application shall submit to the Secretary as a  
14 part of the application with respect to a drug—

15 “(i) full reports of investigations that  
16 have been made to show whether or not  
17 such drug is safe for use and whether the  
18 drug is effective in use;

19 “(ii) a full list of the articles used as  
20 components of the drug;

21 “(iii) a full statement of the composi-  
22 tion of the drug;

23 “(iv) a full description of the methods  
24 used in, and the facilities and controls  
25 used for, the manufacture, processing, and  
26 packing of the drug;

1           “(v) such samples of the drug and of  
2           the articles used as components of the  
3           drug as the Secretary may require; and

4           “(vi) specimens of the labeling pro-  
5           posed to be used for the drug.

6           ~~“(C) PATENT INFORMATION.—~~

7           ~~“(i) IN GENERAL.—~~The applicant  
8           shall file with the application the patent  
9           number and expiration date of any patent  
10          that claims a drug or method of using a  
11          drug and with respect to which a claim of  
12          patent infringement could reasonably be  
13          asserted if a person not licensed by the  
14          owner engaged in the manufacture, use, or  
15          sale of the drug for which the applicant  
16          submitted the application.

17          ~~“(ii) AMENDMENT OF APPLICATION.—~~  
18          If an application is filed with respect to a  
19          drug and a patent as described in clause  
20          (i) is issued after the filing date but before  
21          approval of the application, the applicant  
22          shall amend the application to include the  
23          information required by clause (i).

24          ~~“(iii) PUBLICATION OF INFORMA-~~  
25          ~~TION.—~~On approval of the application, the

1 Secretary shall publish information sub-  
 2 mitted under clauses (i) and (ii).

3 ~~“(D) GUIDANCE.—~~The Secretary shall, in  
 4 consultation with the Director of the National  
 5 Institutes of Health and with representatives of  
 6 the drug manufacturing industry, review and  
 7 develop guidance, as appropriate, on the inclu-  
 8 sion of women and minorities in clinical trials  
 9 required by subparagraph (B)(i).”;

10 ~~(2) in paragraph (2)(A)—~~

11 (A) by striking “which claims” the first  
 12 place it appears and all that follows through  
 13 “subsection and”; and

14 (B) by striking “subsection (c)—” and in-  
 15 serting “and with respect to which a claim of  
 16 patent infringement could reasonably be as-  
 17 serted if a person not licensed by the owner en-  
 18 gaged in the manufacture, use, or sale of the  
 19 drug for which the investigations were con-  
 20 ducted—”;

21 ~~(3) in the first sentence of subsection (c)(2)—~~

22 (A) by inserting “such patent information”  
 23 after “shall file”; and

24 (B) by striking “Secretary,” and all that  
 25 follows and inserting “Secretary.”;

1           (4) in subsection (j)(2)(vii), by striking “which  
 2       claims the listed drug” and all that follows through  
 3       “under this subsection and” and inserting “for the  
 4       listed drug referred to in clause (i)”; and

5           (5) by adding at the end the following:

6       ~~“(o) PATENT INFORMATION.—~~

7           ~~“(1) APPLICABILITY.—This subsection applies~~  
 8       ~~to a holder of an approved application under sub-~~  
 9       ~~section (e) that files a patent—~~

10           ~~“(A) that claims, with regard to a drug of~~  
 11       ~~the application, a drug or method of using a~~  
 12       ~~drug; and~~

13           ~~“(B) for which a claim of patent infringe-~~  
 14       ~~ment could reasonably be asserted if a person~~  
 15       ~~not licensed by the owner engaged in the manu-~~  
 16       ~~facture, use, or sale of the drug, after the date~~  
 17       ~~of approval of the application.~~

18           ~~“(2) CERTIFICATION.—A holder of a patent de-~~  
 19       ~~scribed in paragraph (1) shall—~~

20           ~~“(A) inform the Secretary of the filing of~~  
 21       ~~the patent; and~~

22           ~~“(B) certify that the information is a com-~~  
 23       ~~plete and accurate listing of all such patents.~~

1           ~~“(3) SECRETARY.—The Secretary shall list the~~  
 2           ~~information provided under paragraph (2) in accord-~~  
 3           ~~ance with subsection (j)(7).”.~~

4   **SEC. 8. REPORT.**

5           ~~(a) IN GENERAL.—Not later than the date that is~~  
 6   ~~5 years after the date of enactment of this Act, the Fed-~~  
 7   ~~eral Trade Commission shall submit to Congress a report~~  
 8   ~~describing the extent to which implementation of the~~  
 9   ~~amendments made by this Act—~~

10           ~~(1) has enabled products to come to market in~~  
 11           ~~a fair and expeditious manner, consistent with the~~  
 12           ~~rights of patent owners under intellectual property~~  
 13           ~~law; and~~

14           ~~(2) has promoted lower prices of drugs and~~  
 15           ~~greater access to drugs through price competition.~~

16           ~~(b) AUTHORIZATION OF APPROPRIATIONS.—There is~~  
 17   ~~authorized to be appropriated to carry out this section~~  
 18   ~~\$5,000,000.~~

19   **SEC. 3. FILING OF PATENT INFORMATION WITH THE FOOD**  
 20           **AND DRUG ADMINISTRATION.**

21           ~~(a) FILING AFTER APPROVAL OF AN APPLICATION.—~~

22           ~~(1) IN GENERAL.—Section 505 of the Federal~~  
 23   ~~Food, Drug, and Cosmetic Act (21 U.S.C. 355) (as~~  
 24   ~~amended by section 9(a)(2)(B)(ii)) is amended in~~



1 subsection (c) by striking paragraph (2) and insert-  
 2 ing the following:

3 “(2) *PATENT INFORMATION.*—

4 “(A) *IN GENERAL.*—Not later than the date  
 5 that is 30 days after the date of an order ap-  
 6 proving an application under subsection (b) (un-  
 7 less the Secretary extends the date because of ex-  
 8 traordinary or unusual circumstances), the hold-  
 9 er of the application shall file with the Secretary  
 10 the patent information described in subpara-  
 11 graph (C) with respect to any patent—

12 “(i)(I) that claims the drug for which  
 13 the application was approved; or

14 “(II) that claims an approved method  
 15 of using the drug; and

16 “(ii) with respect to which a claim of  
 17 patent infringement could reasonably be as-  
 18 serted if a person not licensed by the owner  
 19 engaged in the manufacture, use, or sale of  
 20 the drug.

21 “(B) *SUBSEQUENTLY ISSUED PATENTS.*—In  
 22 a case in which a patent described in subpara-  
 23 graph (A) is issued after the date of an order ap-  
 24 proving an application under subsection (b), the  
 25 holder of the application shall file with the Sec-

retary the patent information described in subparagraph (C) not later than the date that is 30 days after the date on which the patent is issued (unless the Secretary extends the date because of extraordinary or unusual circumstances).

“(C) *PATENT INFORMATION.*—The patent information required to be filed under subparagraph (A) or (B) includes—

“(i) the patent number;

“(ii) the expiration date of the patent;

“(iii) with respect to each claim of the patent—

“(I) whether the patent claims the drug or claims a method of using the drug; and

“(II) whether the claim covers—

“(aa) a drug substance;

“(bb) a drug formulation;

“(cc) a drug composition; or

“(dd) a method of use;

“(iv) if the patent claims a method of use, the approved use covered by the claim;

“(v) the identity of the owner of the patent (including the identity of any agent of the patent owner); and

1           “(vi) a declaration that the applicant,  
 2           as of the date of the filing, has provided  
 3           complete and accurate patent information  
 4           for all patents described in subparagraph  
 5           (A).

6           “(D) PUBLICATION.—On filing of patent  
 7           information required under subparagraph (A) or  
 8           (B), the Secretary shall—

9           “(i) immediately publish the informa-  
 10          tion described in clauses (i) through (iv) of  
 11          subparagraph (C); and

12          “(ii) make the information described  
 13          in clauses (v) and (vi) of subparagraph (C)  
 14          available to the public on request.

15          “(E) CIVIL ACTION FOR CORRECTION OR  
 16          DELETION OF PATENT INFORMATION.—

17          “(i) IN GENERAL.—A person that has  
 18          filed an application under subsection (b)(2)  
 19          or (j) for a drug may bring a civil action  
 20          against the holder of the approved applica-  
 21          tion for the drug seeking an order requiring  
 22          that the holder of the application amend the  
 23          application—

24                 “(I) to correct patent information  
 25                 filed under subparagraph (A); or

1                   “(II) to delete the patent informa-  
 2                   tion in its entirety for the reason  
 3                   that—

4                   “(aa) the patent does not  
 5                   claim the drug for which the ap-  
 6                   plication was approved; or

7                   “(bb) the patent does not  
 8                   claim an approved method of  
 9                   using the drug.

10                  “(ii) LIMITATIONS.—Clause (i) does  
 11                  not authorize—

12                  “(I) a civil action to correct pat-  
 13                  ent information filed under subpara-  
 14                  graph (B); or

15                  “(II) an award of damages in a  
 16                  civil action under clause (i).

17                  “(F) NO CLAIM FOR PATENT INFRINGE-  
 18                  MENT.—An owner of a patent with respect to  
 19                  which a holder of an application fails to file in-  
 20                  formation on or before the date required under  
 21                  subparagraph (A) or (B) shall be barred from  
 22                  bringing a civil action for infringement of the  
 23                  patent against a person that—

24                  “(i) has filed an application under  
 25                  subsection (b)(2) or (j); or

1                   “(ii) manufactures, uses, offers to sell,  
2                   or sells a drug approved under an applica-  
3                   tion under subsection (b)(2) or (j).”.

4                   (2) *TRANSITION PROVISION.*—

5                   (A) *FILING OF PATENT INFORMATION.*—

6                   Each holder of an application for approval of a  
7                   new drug under section 505(b) of the Federal  
8                   Food, Drug, and Cosmetic Act (21 U.S.C.  
9                   355(b)) that has been approved before the date of  
10                  enactment of this Act shall amend the applica-  
11                  tion to include the patent information required  
12                  under the amendment made by paragraph (1)  
13                  not later than the date that is 30 days after the  
14                  date of enactment of this Act (unless the Sec-  
15                  retary of Health and Human Services extends  
16                  the date because of extraordinary or unusual cir-  
17                  cumstances).

18                  (B) *NO CLAIM FOR PATENT INFRINGE-*  
19                  *MENT.*—An owner of a patent with respect to  
20                  which a holder of an application under sub-  
21                  section (b) of section 505 of the Federal Food,  
22                  Drug, and Cosmetic Act (21 U.S.C. 355) fails to  
23                  file information on or before the date required  
24                  under subparagraph (A) shall be barred from

1           *bringing a civil action for infringement of the*  
 2           *patent against a person that—*

3                     *(i) has filed an application under sub-*  
 4                     *section (b)(2) or (j) of that section; or*

5                     *(ii) manufactures, uses, offers to sell, or*  
 6                     *sells a drug approved under an application*  
 7                     *under subsection (b)(2) or (j) of that section.*

8           ***(b) FILING WITH AN APPLICATION.***—*Section 505 of the*  
 9           *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is*  
 10          *amended—*

11                    *(1) in subsection (b)(2)—*

12                             *(A) in subparagraph (A), by striking “and”*  
 13                             *at the end;*

14                             *(B) in subparagraph (B), by striking the*  
 15                             *period at the end and inserting “; and”; and*

16                             *(C) by adding at the end the following:*

17                             *“(C) with respect to a patent that claims*  
 18                             *both the drug and a method of using the drug or*  
 19                             *claims more than 1 method of using the drug for*  
 20                             *which the application is filed—*

21                                     *“(i) a certification under subpara-*  
 22                                     *graph (A)(iv) on a claim-by-claim basis;*  
 23                                     *and*

1                   “(ii) a statement under subparagraph  
2                   (B) regarding the method of use claim.”;  
3                   and

4                   (2) in subsection (j)(2)(A), by inserting after  
5                   clause (viii) the following:

6    “With respect to a patent that claims both the drug and  
7    a method of using the drug or claims more than 1 method  
8    of using the drug for which the application is filed, the ap-  
9    plication shall contain a certification under clause (vii)(IV)  
10   on a claim-by-claim basis and a statement under clause  
11   (viii) regarding the method of use claim.”.

12   **SEC. 4. LIMITATION OF 30-MONTH STAY TO CERTAIN PAT-**  
13                   **ENTS.**

14           (a) *ABBREVIATED NEW DRUG APPLICATIONS.*—Sec-  
15   tion 505(j)(5) of the Federal Food, Drug, and Cosmetic Act  
16   (21 U.S.C. 355(j)(5)) is amended—

17                   (1) in subparagraph (B)—

18                           (A) in clause (iii)—

19                                   (i) by striking “(iii) If the applicant  
20                                   made a certification described in subclause  
21                                   (IV) of paragraph (2)(A)(vii),” and insert-  
22                                   ing the following:

23                                           “(iii) *SUBCLAUSE (IV) CERTIFICATION*  
24                                           *WITH RESPECT TO CERTAIN PATENTS.*—If  
25                                           the applicant made a certification described

1           *in paragraph (2)(A)(vii)(IV) with respect to*  
 2           *a patent (other than a patent that claims a*  
 3           *process for manufacturing the listed drug)*  
 4           *for which patent information was filed with*  
 5           *the Secretary under subsection (c)(2)(A),”;*  
 6           *and*

7           *(ii) by adding at the end the following:*  
 8           *“The 30-month period provided under the*  
 9           *second sentence of this clause shall not*  
 10           *apply to a certification under paragraph*  
 11           *(2)(A)(vii)(IV) made with respect to a pat-*  
 12           *ent for which patent information was filed*  
 13           *with the Secretary under subsection*  
 14           *(c)(2)(B).”;*

15           *(B) by redesignating clause (iv) as clause*  
 16           *(v); and*

17           *(C) by inserting after clause (iii) the fol-*  
 18           *lowing:*

19           *“(iv) SUBCLAUSE (IV) CERTIFICATION*  
 20           *WITH RESPECT TO OTHER PATENTS.—*

21           *“(I) IN GENERAL.—If the appli-*  
 22           *cant made a certification described in*  
 23           *paragraph (2)(A)(vii)(IV) with respect*  
 24           *to a patent not described in clause (iii)*  
 25           *for which patent information was pub-*



lished by the Secretary under subsection (c)(2)(D), the approval shall be made effective on the date that is 45 days after the date on which the notice provided under paragraph (2)(B) was received, unless a civil action for infringement of the patent, accompanied by a motion for preliminary injunction to enjoin the applicant from engaging in the commercial manufacture or sale of the drug, was filed on or before the date that is 45 days after the date on which the notice was received, in which case the approval shall be made effective—

“(aa) on the date of a court action declining to grant a preliminary injunction; or

“(bb) if the court has granted a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug—

“(AA) on issuance by a court of a determination that

1                   the patent is invalid or is  
2                   not infringed;

3                   “(BB) on issuance by a  
4                   court of an order revoking  
5                   the preliminary injunction  
6                   or permitting the applicant  
7                   to engage in the commercial  
8                   manufacture or sale of the  
9                   drug; or

10                  “(CC) on the date speci-  
11                  fied in a court order under  
12                  section 271(e)(4)(A) of title  
13                  35, United States Code, if the  
14                  court determines that the  
15                  patent is infringed.

16                  “(II) COOPERATION.—Each of the  
17                  parties shall reasonably cooperate in  
18                  expediting a civil action under sub-  
19                  clause (I).

20                  “(III) EXPEDITED NOTIFICA-  
21                  TION.—If the notice under paragraph  
22                  (2)(B) contains an address for the re-  
23                  ceipt of expedited notification of a civil  
24                  action under subclause (I), the plaintiff  
25                  shall, on the date on which the com-

1                    *plaint is filed, simultaneously cause a*  
 2                    *notification of the civil action to be de-*  
 3                    *livered to that address by the next*  
 4                    *business day.”; and*

5                    *(2) by inserting after subparagraph (B) the fol-*  
 6                    *lowing:*

7                    *“(C) FAILURE TO BRING INFRINGEMENT AC-*  
 8                    *TION.—If, in connection with an application*  
 9                    *under this subsection, the applicant provides an*  
 10                    *owner of a patent notice under paragraph (2)(B)*  
 11                    *with respect to the patent, and the owner of the*  
 12                    *patent fails to bring a civil action against the*  
 13                    *applicant for infringement of the patent on or*  
 14                    *before the date that is 45 days after the date on*  
 15                    *which the notice is received, the owner of the pat-*  
 16                    *ent shall be barred from bringing a civil action*  
 17                    *for infringement of the patent in connection with*  
 18                    *the development, manufacture, use, offer to sell,*  
 19                    *or sale of the drug for which the application was*  
 20                    *filed or approved under this subsection.”.*

21                    *(b) OTHER APPLICATIONS.—Section 505(c) of the*  
 22                    *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c))*  
 23                    *(as amended by section 9(a)(3)(A)(iii)) is amended—*

24                    *(1) in paragraph (3)—*

25                    *(A) in subparagraph (C)—*

1                   (i) by striking “(C) If the applicant  
2                   made a certification described in clause (iv)  
3                   of subsection (b)(2)(A),” and inserting the  
4                   following:

5                   “(C) *CLAUSE (iv) CERTIFICATION WITH RE-*  
6                   *SPECT TO CERTAIN PATENTS.—If the applicant*  
7                   *made a certification described in subsection*  
8                   *(b)(2)(A)(iv) with respect to a patent (other than*  
9                   *a patent that claims a process for manufacturing*  
10                  *the listed drug) for which patent information*  
11                  *was filed with the Secretary under paragraph*  
12                  *(2)(A),”*; and

13                  (ii) by adding at the end the following:

14                  *“The 30-month period provided under the*  
15                  *second sentence of this subparagraph shall*  
16                  *not apply to a certification under sub-*  
17                  *section (b)(2)(A)(iv) made with respect to a*  
18                  *patent for which patent information was*  
19                  *filed with the Secretary under paragraph*  
20                  *(2)(B).”*; and

21                  (B) by inserting after subparagraph (C) the  
22                  following:

23                  “(D) *CLAUSE (iv) CERTIFICATION WITH RE-*  
24                  *SPECT TO OTHER PATENTS.—*

1           “(i) *IN GENERAL.*—If the applicant  
2           made a certification described in subsection  
3           (b)(2)(A)(iv) with respect to a patent not  
4           described in subparagraph (C) for which  
5           patent information was published by the  
6           Secretary under paragraph (2)(D), the ap-  
7           proval shall be made effective on the date  
8           that is 45 days after the date on which the  
9           notice provided under subsection (b)(3) was  
10          received, unless a civil action for infringe-  
11          ment of the patent, accompanied by a mo-  
12          tion for preliminary injunction to enjoin  
13          the applicant from engaging in the commer-  
14          cial manufacture or sale of the drug, was  
15          filed on or before the date that is 45 days  
16          after the date on which the notice was re-  
17          ceived, in which case the approval shall be  
18          made effective—

19                 “(I) on the date of a court action  
20                 declining to grant a preliminary in-  
21                 junction; or

22                 “(II) if the court has granted a  
23                 preliminary injunction prohibiting the  
24                 applicant from engaging in the com-

mercials manufacture or sale of the  
drug—

“(aa) on issuance by a court  
of a determination that the patent  
is invalid or is not infringed;

“(bb) on issuance by a court  
of an order revoking the prelimi-  
nary injunction or permitting the  
applicant to engage in the com-  
mercial manufacture or sale of the  
drug; or

“(cc) on the date specified in  
a court order under section  
271(e)(4)(A) of title 35, United  
States Code, if the court deter-  
mines that the patent is infringed.

“(ii) COOPERATION.—Each of the par-  
ties shall reasonably cooperate in expediting  
a civil action under clause (i).

“(iii) EXPEDITED NOTIFICATION.—If  
the notice under subsection (b)(3) contains  
an address for the receipt of expedited noti-  
fication of a civil action under clause (i),  
the plaintiff shall, on the date on which the  
complaint is filed, simultaneously cause a

1                   *notification of the civil action to be deliv-*  
 2                   *ered to that address by the next business*  
 3                   *day.”; and*

4                   (2) *by inserting after paragraph (3) the fol-*  
 5                   *lowing:*

6                   “(4) *FAILURE TO BRING INFRINGEMENT AC-*  
 7                   *TION.—If, in connection with an application under*  
 8                   *subsection (b)(2), the applicant provides an owner of*  
 9                   *a patent notice under subsection (b)(3) with respect*  
 10                   *to the patent, and the owner of the patent fails to*  
 11                   *bring a civil action against the applicant for in-*  
 12                   *fringement of the patent on or before the date that is*  
 13                   *45 days after the date on which the notice is received,*  
 14                   *the owner of the patent shall be barred from bringing*  
 15                   *a civil action for infringement of the patent in con-*  
 16                   *nection with the development, manufacture, use, offer*  
 17                   *to sell, or sale of the drug for which the application*  
 18                   *was filed or approved under subsection (b)(2).”.*

19                   (c) *EFFECTIVE DATE.—*

20                   (1) *IN GENERAL.—The amendments made by*  
 21                   *subsections (a) and (b) shall be effective with respect*  
 22                   *to any certification under subsection (b)(2)(A)(iv) or*  
 23                   *(j)(2)(A)(vii)(IV) of section 505 of the Federal Food,*  
 24                   *Drug, and Cosmetic Act (21 U.S.C. 355) made after*

1        *the date of enactment of this Act in an application*  
 2        *filed under subsection (b)(2) or (j) of that section.*

3            (2) *TRANSITION PROVISION.—In the case of ap-*  
 4        *plications under section 505(b) of the Federal Food,*  
 5        *Drug, and Cosmetic Act (21 U.S.C. 355(b)) filed be-*  
 6        *fore the date of enactment of this Act—*

7            (A) *a patent (other than a patent that*  
 8        *claims a process for manufacturing a listed*  
 9        *drug) for which information was submitted to*  
 10       *the Secretary of Health and Human Services*  
 11       *under section 505(b)(1) of the Federal Food,*  
 12       *Drug, and Cosmetic Act (as in effect on the day*  
 13       *before the date of enactment of this Act) shall be*  
 14       *subject to subsections (c)(3)(C) and (j)(5)(B)(iii)*  
 15       *of section 505 of the Federal Food, Drug, and*  
 16       *Cosmetic Act (as amended by this section); and*

17           (B) *any other patent (including a patent*  
 18        *for which information was submitted to the Sec-*  
 19        *retary under section 505(c)(2) of that Act (as in*  
 20        *effect on the day before the date of enactment of*  
 21        *this Act)) shall be subject to subsections (c)(3)(D)*  
 22        *and (j)(5)(B)(iv) of section 505 of the Federal*  
 23        *Food, Drug, and Cosmetic Act (as amended by*  
 24        *this section).*



1 **SEC. 5. EXCLUSIVITY FOR ACCELERATED GENERIC DRUG**  
 2 **APPLICANTS.**

3 (a) *IN GENERAL.*—Section 505(j)(5) of the Federal  
 4 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) (as  
 5 amended by section 4(a)) is amended—

6 (1) in subparagraph (B)(v), by striking sub-  
 7 clause (II) and inserting the following:

8 “(II) the earlier of—

9 “(aa) the date of a final deci-  
 10 sion of a court (from which no  
 11 appeal has been or can be taken,  
 12 other than a petition to the Su-  
 13 preme Court for a writ of certio-  
 14 rari) holding that the patent that  
 15 is the subject of the certification is  
 16 invalid or not infringed; or

17 “(bb) the date of a settlement  
 18 order or consent decree signed by  
 19 a Federal judge that enters a final  
 20 judgment and includes a finding  
 21 that the patent that is the subject  
 22 of the certification is invalid or  
 23 not infringed;”; and

24 (2) by inserting after subparagraph (C) the fol-  
 25 lowing:

26 “(D) *FORFEITURE OF 180-DAY PERIOD.*—

1 “(i) *DEFINITIONS.*—*In this subpara-*  
 2 *graph:*

3 “(I) *APPLICATION.*—*The term*  
 4 *‘application’ means an application for*  
 5 *approval of a drug under this sub-*  
 6 *section containing a certification*  
 7 *under paragraph (2)(A)(vii)(IV) with*  
 8 *respect to a patent.*

9 “(II) *FIRST APPLICATION.*—*The*  
 10 *term ‘first application’ means the first*  
 11 *application to be filed for approval of*  
 12 *the drug.*

13 “(III) *FORFEITURE EVENT.*—*The*  
 14 *term ‘forfeiture event’, with respect to*  
 15 *an application under this subsection,*  
 16 *means the occurrence of any of the fol-*  
 17 *lowing:*

18 “(aa) *FAILURE TO MAR-*  
 19 *KET.*—*The applicant fails to mar-*  
 20 *ket the drug by the later of—*

21 “(AA) *the date that is*  
 22 *60 days after the date on*  
 23 *which the approval of the ap-*  
 24 *plication for the drug is*  
 25 *made effective under clause*

1                                    *(iii) or (iv) of subparagraph*  
2                                    *(B) (unless the Secretary ex-*  
3                                    *tends the date because of ex-*  
4                                    *traordinary or unusual cir-*  
5                                    *cumstances); or*

6                                    *“(BB) if 1 or more civil*  
7                                    *actions have been brought*  
8                                    *against the applicant for in-*  
9                                    *fringement of a patent sub-*  
10                                   *ject to a certification under*  
11                                   *paragraph (2)(A)(vii)(IV) or*  
12                                   *1 or more civil actions have*  
13                                   *been brought by the appli-*  
14                                   *cant for a declaratory judg-*  
15                                   *ment that such a patent is*  
16                                   *invalid or not infringed, the*  
17                                   *date that is 60 days after the*  
18                                   *date of a final decision (from*  
19                                   *which no appeal has been or*  
20                                   *can be taken, other than a*  
21                                   *petition to the Supreme*  
22                                   *Court for a writ of certio-*  
23                                   *rari) in the last of those civil*  
24                                   *actions to be decided (unless*  
25                                   *the Secretary extends the*

1                   *date because of extraordinary*  
 2                   *or unusual circumstances).*

3                   “(bb) *WITHDRAWAL OF AP-*  
 4                   *PLICATION.—The applicant with-*  
 5                   *draws the application.*

6                   “(cc) *AMENDMENT OF CER-*  
 7                   *TIFICATION.—The applicant, vol-*  
 8                   *untarily or as a result of a settle-*  
 9                   *ment or defeat in patent litiga-*  
 10                  *tion, amends the certification*  
 11                  *from a certification under para-*  
 12                  *graph (2)(A)(vii)(IV) to a certifi-*  
 13                  *cation under paragraph*  
 14                  *(2)(A)(vii)(III).*

15                  “(dd) *FAILURE TO OBTAIN*  
 16                  *APPROVAL.—The applicant fails*  
 17                  *to obtain tentative approval of an*  
 18                  *application within 30 months*  
 19                  *after the date on which the appli-*  
 20                  *cation is filed, unless the failure is*  
 21                  *caused by—*

22                         “(AA) *a change in the*  
 23                         *requirements for approval of*  
 24                         *the application imposed after*

1                   the date on which the appli-  
2                   cation is filed; or

3                   “(BB) other extraor-  
4                   dinary circumstances war-  
5                   ranting an exception, as de-  
6                   termined by the Secretary.

7                   “(ee) *FAILURE TO CHAL-*  
8                   *LENGE PATENT.*—In a case in  
9                   which, after the date on which the  
10                  applicant submitted the applica-  
11                  tion, new patent information is  
12                  submitted under subsection (c)(2)  
13                  for the listed drug for a patent for  
14                  which certification is required  
15                  under paragraph (2)(A), the ap-  
16                  plicant fails to submit, not later  
17                  than the date that is 60 days after  
18                  the date on which the Secretary  
19                  publishes the new patent informa-  
20                  tion under paragraph (7)(A)(iii)  
21                  (unless the Secretary extends the  
22                  date because of extraordinary or  
23                  unusual circumstances)—

24                  “(AA) a certification de-  
25                  scribed in paragraph

1                   (2)(A)(vii)(IV) with respect  
 2                   to the patent to which the  
 3                   new patent information re-  
 4                   lates; or

5                   “(BB) a statement that  
 6                   any method of use claim of  
 7                   that patent does not claim a  
 8                   use for which the applicant  
 9                   is seeking approval under  
 10                  this subsection in accordance  
 11                  with paragraph (2)(A)(viii).

12                  “(ff) UNLAWFUL CONDUCT.—  
 13                  The Federal Trade Commission  
 14                  determines that the applicant en-  
 15                  gaged in unlawful conduct with  
 16                  respect to the application in vio-  
 17                  lation of section 1 of the Sherman  
 18                  Act (15 U.S.C. 1).

19                  “(IV) SUBSEQUENT APPLICA-  
 20                  TION.—The term ‘subsequent applica-  
 21                  tion’ means an application for ap-  
 22                  proval of a drug that is filed subse-  
 23                  quent to the filing of a first applica-  
 24                  tion for approval of that drug.

1                   “(ii) *FORFEITURE OF 180-DAY PE-*  
2                   *RIOD.*—

3                   “(I) *IN GENERAL.*—*Except as pro-*  
4                   *vided in subclause (II), if a forfeiture*  
5                   *event occurs with respect to a first*  
6                   *application—*

7                   “(aa) *the 180-day period*  
8                   *under subparagraph (B)(v) shall*  
9                   *be forfeited by the first applicant;*  
10                  *and*

11                  “(bb) *any subsequent appli-*  
12                  *cation shall become effective as*  
13                  *provided under clause (i), (ii),*  
14                  *(iii), or (iv) of subparagraph (B),*  
15                  *and clause (v) of subparagraph*  
16                  *(B) shall not apply to the subse-*  
17                  *quent application.*

18                  “(II) *FORFEITURE TO FIRST SUB-*  
19                  *SEQUENT APPLICANT.*—*If the subse-*  
20                  *quent application that is the first to be*  
21                  *made effective under subclause (I) was*  
22                  *the first among a number of subsequent*  
23                  *applications to be filed—*

24                  “(aa) *that first subsequent*  
25                  *application shall be treated as the*

1           *first application under this sub-*  
 2           *paragraph (including subclause*  
 3           *(I)) and as the previous applica-*  
 4           *tion under subparagraph (B)(v);*  
 5           *and*

6                   “(bb) any other subsequent  
 7           *applications shall become effective*  
 8           *as provided under clause (i), (ii),*  
 9           *(iii), or (iv) of subparagraph (B),*  
 10           *but clause (v) of subparagraph*  
 11           *(B) shall apply to any such subse-*  
 12           *quent application.*

13                   “(iii) *AVAILABILITY.—The 180-day pe-*  
 14           *riod under subparagraph (B)(v) shall be*  
 15           *available to a first applicant submitting an*  
 16           *application for a drug with respect to any*  
 17           *patent without regard to whether an appli-*  
 18           *cation has been submitted for the drug*  
 19           *under this subsection containing such a cer-*  
 20           *tification with respect to a different patent.*

21                   “(iv) *APPLICABILITY.—The 180-day*  
 22           *period described in subparagraph (B)(v)*  
 23           *shall apply to an application only if a civil*  
 24           *action is brought against the applicant for*



1                    *infringement of a patent that is the subject*  
 2                    *of the certification.”.*

3            (b) *APPLICABILITY.—The amendment made by sub-*  
 4            *section (a) shall be effective only with respect to an applica-*  
 5            *tion filed under section 505(j) of the Federal Food, Drug,*  
 6            *and Cosmetic Act (21 U.S.C. 355(j)) after the date of enact-*  
 7            *ment of this Act for a listed drug for which no certification*  
 8            *under section 505(j)(2)(A)(vii)(IV) of that Act was made*  
 9            *before the date of enactment of this Act, except that if a*  
 10           *forfeiture event described in section 505(j)(5)(D)(i)(III)(ff)*  
 11           *of that Act occurs in the case of an applicant, the applicant*  
 12           *shall forfeit the 180-day period under section*  
 13           *505(j)(5)(B)(v) of that Act without regard to when the ap-*  
 14           *plicant made a certification under section*  
 15           *505(j)(2)(A)(vii)(IV) of that Act.*

16    **SEC. 6. FAIR TREATMENT FOR INNOVATORS.**

17            (a) *BASIS FOR APPLICATION.—Section 505 of the Fed-*  
 18            *eral Food, Drug, and Cosmetic Act (21 U.S.C. 355) is*  
 19            *amended—*

20                    (1) *in subsection (b)(3)(B), by striking the sec-*  
 21                    *ond sentence and inserting “The notice shall include*  
 22                    *a detailed statement of the factual and legal basis of*  
 23                    *the applicant’s opinion that, as of the date of the no-*  
 24                    *tice, the patent is not valid or is not infringed, and*  
 25                    *shall include, as appropriate for the relevant patent,*

1     *a description of the applicant’s proposed drug sub-*  
2     *stance, drug formulation, drug composition, or meth-*  
3     *od of use. All information disclosed under this sub-*  
4     *paragraph shall be treated as confidential and may*  
5     *be used only for purposes relating to patent adjudica-*  
6     *tion. Nothing in this subparagraph precludes the ap-*  
7     *plicant from amending the factual or legal basis on*  
8     *which the applicant relies in patent litigation.”; and*

9             *(2) in subsection (j)(2)(B)(ii), by striking the*  
10     *second sentence and inserting “The notice shall in-*  
11     *clude a detailed statement of the factual and legal*  
12     *basis of the opinion of the applicant that, as of the*  
13     *date of the notice, the patent is not valid or is not*  
14     *infringed, and shall include, as appropriate for the*  
15     *relevant patent, a description of the applicant’s pro-*  
16     *posed drug substance, drug formulation, drug com-*  
17     *position, or method of use. All information disclosed*  
18     *under this subparagraph shall be treated as confiden-*  
19     *tial and may be used only for purposes relating to*  
20     *patent adjudication. Nothing in this subparagraph*  
21     *precludes the applicant from amending the factual or*  
22     *legal basis on which the applicant relies in patent*  
23     *litigation.”.*

1       (b) *INJUNCTIVE RELIEF*.—Section 505(j)(5)(B) of the  
 2       *Federal Food, Drug, and Cosmetic Act* (21 U.S.C.  
 3       355(j)(5)(B)) (as amended by section 4(a)(1)) is amended—

4               (1) in clause (iii), by adding at the end the fol-  
 5       lowing: “A court shall not regard the extent of the  
 6       ability of an applicant to pay monetary damages as  
 7       a whole or partial basis on which to deny a prelimi-  
 8       nary or permanent injunction under this clause.”;  
 9       and

10              (2) in clause (iv), by adding at the end the fol-  
 11      lowing:

12                       “(IV) *INJUNCTIVE RELIEF*.—A court shall  
 13                      not regard the extent of the ability of an appli-  
 14                      cant to pay monetary damages as a whole or  
 15                      partial basis on which to deny a preliminary or  
 16                      permanent injunction under this clause.”.

17   **SEC. 7. BIOEQUIVALENCE.**

18       (a) *IN GENERAL*.—The amendments to part 320 of  
 19       title 21, Code of Federal Regulations, promulgated by the  
 20       Commissioner of Food and Drugs on July 17, 1991 (57 Fed.  
 21       Reg. 17997 (April 28, 1992)), shall continue in effect as  
 22       an exercise of authorities under sections 501, 502, 505, and  
 23       701 of the *Federal Food, Drug, and Cosmetic Act* (21 U.S.C.  
 24       351, 352, 355, 371).

1       (b) *EFFECT.*—Subsection (a) does not affect the au-  
 2       thority of the Commissioner of Food and Drugs to amend  
 3       part 320 of title 21, Code of Federal Regulations.

4       (c) *EFFECT OF SECTION.*—This section shall not be  
 5       construed to alter the authority of the Secretary of Health  
 6       and Human Services to regulate biological products under  
 7       the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301  
 8       et seq.). Any such authority shall be exercised under that  
 9       Act as in effect on the day before the date of enactment of  
 10      this Act.

11   **SEC. 8. REPORT.**

12       (a) *IN GENERAL.*—Not later than the date that is 5  
 13      years after the date of enactment of this Act, the Federal  
 14      Trade Commission shall submit to Congress a report de-  
 15      scribing the extent to which implementation of the amend-  
 16      ments made by this Act—

17               (1) has enabled products to come to market in a  
 18               fair and expeditious manner, consistent with the  
 19               rights of patent owners under intellectual property  
 20               law; and

21               (2) has promoted lower prices of drugs and  
 22               greater access to drugs through price competition.

23       (b) *AUTHORIZATION OF APPROPRIATIONS.*—There is  
 24      authorized to be appropriated to carry out this section  
 25      \$5,000,000.

1 **SEC. 9. CONFORMING AND TECHNICAL AMENDMENTS.**

2 (a) *SECTION 505.*—Section 505 of the Federal Food,  
3 Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

4 (1) in subsection (a), by striking “(a) No per-  
5 son” and inserting “(a) *IN GENERAL.*—No person”;

6 (2) in subsection (b)—

7 (A) by striking “(b)(1) Any person” and in-  
8 serting the following:

9 “(b) *APPLICATIONS.*—

10 “(1) *REQUIREMENTS.*—

11 “(A) *IN GENERAL.*—Any person”;

12 (B) in paragraph (1)—

13 (i) in the second sentence—

14 (I) by redesignating subpara-  
15 graphs (A) through (F) as clauses (i)  
16 through (vi), respectively, and adjust-  
17 ing the margins appropriately;

18 (II) by striking “Such persons”  
19 and inserting the following:

20 “(B) *INFORMATION TO BE SUBMITTED WITH*  
21 *APPLICATION.*—A person that submits an appli-  
22 cation under subparagraph (A)”;

23 (III) by striking “application”  
24 and inserting “application—”;

25 (ii) by striking the third through fifth  
26 sentences; and

1                   (iii) in the sixth sentence—

2                   (I) by striking “The Secretary”

3                   and inserting the following:

4                   “(C) GUIDANCE.—The Secretary”; and

5                   (II) by striking “clause (A)” and

6                   inserting “subparagraph (B)(i)”; and

7                   (C) in paragraph (2)—

8                   (i) by striking “clause (A) of such

9                   paragraph” and inserting “paragraph

10                  (1)(B)(i)”; and

11                  (ii) in subparagraphs (A) and (B), by

12                  striking “paragraph (1) or”; and

13                  (iii) in subparagraph (B)—

14                  (I) by striking “paragraph

15                  (1)(A)” and inserting “paragraph

16                  (1)(B)(i)”; and

17                  (II) by striking “patent” each

18                  place it appears and inserting

19                  “claim”; and

20                  (3) in subsection (c)—

21                  (A) in paragraph (3)—

22                  (i) in subparagraph (A)—

23                  (I) by striking “(A) If the appli-

24                  cant” and inserting the following:

1 “(A) *CLAUSE (i) OR (ii) CERTIFICATION.—*

2 *If the applicant*”; and

3 (II) by striking “may” and in-

4 serting “shall”;

5 (ii) in subparagraph (B)—

6 (I) by striking “(B) *If the appli-*

7 *cant*” and inserting the following:

8 “(B) *CLAUSE (iii) CERTIFICATION.—If the*

9 *applicant*”; and

10 (II) by striking “may” and in-

11 serting “shall”;

12 (iii) by redesignating subparagraph

13 (D) as subparagraph (E); and

14 (iv) in subparagraph (E) (as redesign-

15 ated by clause (iii)), by striking “clause

16 (A) of subsection (b)(1)” each place it ap-

17 pears and inserting “subsection

18 (b)(1)(B)(i)”; and

19 (B) by redesignating paragraph (4) as

20 paragraph (5); and

21 (4) in subsection (j)—

22 (A) in paragraph (2)(A)—

23 (i) in clause (vi), by striking “clauses

24 (B) through ((F))” and inserting “subclauses

25 (ii) through (vi) of subsection (b)(1)”;

1                   (ii) in clause (vii), by striking “(b)  
2                   or”; and

3                   (iii) in clause (viii)—

4                   (I) by striking “(b) or”; and

5                   (II) by striking “patent” each  
6                   place it appears and inserting  
7                   “claim”; and

8                   (B) in paragraph (5)—

9                   (i) in subparagraph (B)—

10                  (I) in clause (i)—

11                   (aa) by striking “(i) If the  
12                   applicant” and inserting the fol-  
13                   lowing:

14                   “(i) SUBCLAUSE (I) OR (II) CERTIFI-  
15                   CATION.—If the applicant”; and

16                   (bb) by striking “may” and  
17                   inserting “shall”;

18                   (II) in clause (ii)—

19                   (aa) by striking “(ii) If the  
20                   applicant” and inserting the fol-  
21                   lowing:

22                   “(i) SUBCLAUSE (III) CERTIFI-  
23                   CATION.—If the applicant”; and

24                   (bb) by striking “may” and  
25                   inserting “shall”;



1                   (III) in clause (iii), by striking  
 2                   “(2)(B)(i)” each place it appears and  
 3                   inserting “(2)(B)”; and

4                   (IV) in clause (v) (as redesignated  
 5                   by section 4(a)(1)(B)), by striking  
 6                   “continuing” and inserting “con-  
 7                   taining”; and

8                   (ii) by redesignating subparagraphs  
 9                   (C) and (D) as subparagraphs (E) and (F),  
 10                   respectively.

11           (b) *SECTION 505A.*—*Section 505A of the Federal Food,*  
 12           *Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—*

13                   (1) in subsections (b)(1)(A)(i) and (c)(1)(A)(i)—  
 14                   (A) by striking “(c)(3)(D)(ii)” each place it  
 15                   appears and inserting “(c)(3)(E)(ii)”; and

16                   (B) by striking “(j)(5)(D)(ii)” each place it  
 17                   appears and inserting “(j)(5)(F)(ii)”;  
 18                   (2) in subsections (b)(1)(A)(ii) and

19                   (c)(1)(A)(ii)—

20                   (A) by striking “(c)(3)(D)” each place it  
 21                   appears and inserting “(c)(3)(E)”; and

22                   (B) by striking “(j)(5)(D)” each place it ap-  
 23                   pears and inserting “(j)(5)(F)”;  
 24                   (3) in subsections (e) and (l)—

1                   (A) by striking “505(c)(3)(D)” each place it  
2                   appears and inserting “505(c)(3)(E)”; and

3                   (B) by striking “505(j)(5)(D)” each place it  
4                   appears and inserting “505(j)(5)(F)”; and

5                   (4)     in     subsection     (k),     by     striking  
6                   “505(j)(5)(B)(iv)” and inserting “505(j)(5)(B)(v)”.

7           (c) SECTION 527.—Section 527(a) of the Federal Food,  
8   Drug, and Cosmetic Act (21 U.S.C. 360cc(a)) is amended  
9   in the second sentence by striking “505(c)(2)” and inserting  
10 “505(c)(1)(B)”.



**Calendar No. 491**

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

**S. 812**

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**A BILL**

To amend the Federal Food, Drug, and Cosmetic  
Act to provide greater access to affordable pharmaceuticals.

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JULY 11 (legislative day, JULY 10), 2002

Reported with an amendment