

107TH CONGRESS
2D SESSION

H. R. 5311

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

IN THE HOUSE OF REPRESENTATIVES

JULY 26, 2002

Mr. THUNE (for himself, Mrs. EMERSON, Mr. KINGSTON, Mr. GUTKNECHT, Mrs. NORTHUP, Mr. MANZULLO, Mr. CALVERT, Mr. GOODE, Mr. BEREUTER, Mr. HOEKSTRA, and Mr. GOODLATTE) introduced the following bill; which was referred to the Committee on Energy and Commerce

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 “Prescription Drug Af-
5 fordability Act”.

6 **SEC. 2. FINDINGS; PURPOSES.**

7 (a) FINDINGS.—Congress finds that—

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

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

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

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

20 (5) generic pharmaceuticals are approved by the
21 Food and Drug Administration on the basis of sci-
22 entific testing and other information establishing
23 that pharmaceuticals are therapeutically equivalent
24 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. FILING OF PATENT INFORMATION WITH THE FOOD**
2 **AND DRUG ADMINISTRATION.**

3 (a) FILING AFTER APPROVAL OF AN APPLICA-
4 TION.—

5 (1) IN GENERAL.—Section 505 of the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C. 355) (as
7 amended by section 9(a)(2)(B)(ii)) is amended in
8 subsection (c) by striking paragraph (2) and insert-
9 ing the following:

10 “(2) PATENT INFORMATION.—

11 “(A) IN GENERAL.—Not later than the
12 date that is 30 days after the date of an order
13 approving an application under subsection (b)
14 (unless the Secretary extends the date because
15 of extraordinary or unusual circumstances), the
16 holder of the application shall file with the Sec-
17 retary the patent information described in sub-
18 paragraph (C) with respect to any patent—

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

21 “(II) that claims an approved method
22 of using the drug; and

23 “(ii) with respect to which a claim of
24 patent infringement could reasonably be
25 asserted if a person not licensed by the

1 owner engaged in the manufacture, use, or
2 sale of the drug.

3 “(B) SUBSEQUENTLY ISSUED PATENTS.—

4 In a case in which a patent described in sub-
5 paragraph (A) is issued after the date of an
6 order approving an application under subsection
7 (b), the holder of the application shall file with
8 the Secretary the patent information described
9 in subparagraph (C) not later than the date
10 that is 30 days after the date on which the pat-
11 ent is issued (unless the Secretary extends the
12 date because of extraordinary or unusual cir-
13 cumstances).

14 “(C) PATENT INFORMATION.—The patent
15 information required to be filed under subpara-
16 graph (A) or (B) includes—

17 “(i) the patent number;

18 “(ii) the expiration date of the patent;

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

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

24 “(II) whether the claim covers—

25 “(aa) a drug substance;

1 “(bb) a drug formulation;

2 “(cc) a drug composition; or

3 “(dd) a method of use;

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

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

9 “(vi) a declaration that the applicant,
10 as of the date of the filing, has provided
11 complete and accurate patent information
12 for all patents described in subparagraph
13 (A).

14 “(D) PUBLICATION.—On filing of patent
15 information required under subparagraph (A)
16 or (B), the Secretary shall—

17 “(i) immediately publish the informa-
18 tion described in clauses (i) through (iv) of
19 subparagraph (C); and

20 “(ii) make the information described
21 in clauses (v) and (vi) of subparagraph (C)
22 available to the public on request.

23 “(E) CIVIL ACTION FOR CORRECTION OR
24 DELETION OF PATENT INFORMATION.—

1 “(i) IN GENERAL.—A person that has
2 filed an application under subsection (b)(2)
3 or (j) for a drug, or a person with standing
4 to bring an infringement action on a pat-
5 ent that claims an approved drug or claims
6 an approved method of using the drug,
7 may bring a civil action against the holder
8 of the approved application for the drug
9 seeking an order requiring that the holder
10 of the application amend the application—

11 “(I) to correct patent information
12 filed under subparagraph (A);

13 “(II) to add patent information
14 required under subparagraph (A) or
15 (B); or

16 “(III) to delete the patent infor-
17 mation in its entirety for the reason
18 that—

19 “(aa) the patent does not
20 claim the drug for which the ap-
21 plication was approved; or

22 “(bb) the patent does not
23 claim an approved method of
24 using the drug.

1 “(ii) LIMITATIONS.—Clause (i) does
2 not authorize—

3 “(I) a civil action to correct pat-
4 ent information filed under subpara-
5 graph (B); or

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

8 “(F) NO CLAIM FOR PATENT INFRINGE-
9 MENT.—A person with standing to bring an in-
10 fringement action on a patent with respect to
11 which a holder of an application fails to file in-
12 formation on or before the date required under
13 subparagraph (A) or (B) shall be barred from
14 bringing a civil action for infringement of the
15 patent against a person that—

16 “(i) has filed an application under
17 subsection (b)(2) or (j); or

18 “(ii) manufactures, uses, offers to sell,
19 or sells a drug approved under an applica-
20 tion under subsection (b)(2) or (j);

21 unless, neither the holder of the application nor
22 any of its affiliates has any rights under the
23 patent, including without limitation, ownership,
24 license, option, or right of refusal, in which case
25 an infringement action may be brought if the

1 person with standing to bring an infringement
2 action commences an action against the holder
3 of the application under subparagraph (E) to
4 compel the filing of the patent information
5 within 90 days of the approval of the holder's
6 application or the issuance of the patent, which-
7 ever occurs later, and obtains final judgment
8 requiring the listing.".

9 (2) TRANSITION PROVISION.—

10 (A) FILING OF PATENT INFORMATION.—

11 Each holder of an application for approval of a
12 new drug under section 505(b) of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C.
14 355(b)) that has been approved before the date
15 of enactment of this Act shall amend the appli-
16 cation to include the patent information re-
17 quired under the amendment made by para-
18 graph (1) not later than the date that is 30
19 days after the date of enactment of this Act
20 (unless the Secretary of Health and Human
21 Services extends the date because of extraor-
22 dinary or unusual circumstances).

23 (B) NO CLAIM FOR PATENT INFRINGE-

24 MENT.—A person with standing to bring an in-
25 fringement action on a patent with respect to

1 which a holder of an application under sub-
2 section (b) of section 505 of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 355) fails
4 to file information on or before the date re-
5 quired under subparagraph (A) shall be barred
6 from bringing a civil action for infringement of
7 the patent against a person that—

8 (i) has filed an application under sub-
9 section (b)(2) or (j) of that section; or

10 (ii) manufactures, uses, offers to sell,
11 or sells a drug approved under an applica-
12 tion under subsection (b)(2) or (j) of that
13 section;

14 unless, neither the holder of the application nor
15 any of its affiliates has any rights under the
16 patent, including without limitation, ownership,
17 license, option, or right of refusal, in which case
18 an infringement action may be brought if the
19 person with standing to bring an infringement
20 action commences an action against the holder
21 of the application under subsection
22 505(c)(2)(E) of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 355) to compel the fil-
24 ing of the patent information within 90 days of
25 the approval of the holder's application or the

1 issuance of the patent, whichever occurs later,
2 and obtains final judgment requiring the listing.

3 (b) FILING WITH AN APPLICATION.—Section 505 of
4 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
5 355) is amended—

6 (1) in subsection (b)(2)—

7 (A) in subparagraph (A), by striking
8 “and” at the end;

9 (B) in subparagraph (B), by striking the
10 period at the end and inserting “; and”; and

11 (C) by adding at the end the following:

12 “(C) with respect to a patent that claims
13 both the drug and a method of using the drug
14 or claims more than 1 method of using the drug
15 for which the application is filed—

16 “(i) a certification under subpara-
17 graph (A)(iv) on a claim-by-claim basis;
18 and

19 “(ii) a statement under subparagraph
20 (B) regarding the method of use claim.”;
21 and

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

24 “With respect to a patent that claims both the drug and
25 a method of using the drug or claims more than 1 method

1 of using the drug for which the application is filed, the
2 application shall contain a certification under clause
3 (vii)(IV) on a claim-by-claim basis and a statement under
4 clause (viii) regarding the method of use claim.”.

5 **SEC. 4. LIMITATION OF 30-MONTH STAY TO CERTAIN PAT-**
6 **ENTS.**

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

10 (1) in subparagraph (B)—

11 (A) in clause (iii)—

12 (i) by striking “(iii) If the applicant
13 made a certification described in subclause
14 (IV) of paragraph (2)(A)(vii),” and insert-
15 ing the following:

16 “(iii) SUBCLAUSE (IV) CERTIFICATION
17 WITH RESPECT TO CERTAIN PATENTS.—If
18 the applicant made a certification de-
19 scribed in paragraph (2)(A)(vii)(IV) with
20 respect to a patent (other than a patent
21 that claims a process for manufacturing
22 the listed drug) for which patent informa-
23 tion was filed with the Secretary under
24 subsection (c)(2)(A),”; and

1 (ii) by adding at the end the fol-
2 lowing: “The 30-month period provided
3 under the second sentence of this clause
4 shall not apply to a certification under
5 paragraph (2)(A)(vii)(IV) made with re-
6 spect to a patent for which patent informa-
7 tion was filed with the Secretary under
8 subsection (c)(2)(B).”;

9 (B) by redesignating clause (iv) as clause
10 (v); and

11 (C) by inserting after clause (iii) the fol-
12 lowing:

13 “(iv) SUBCLAUSE (IV) CERTIFICATION
14 WITH RESPECT TO OTHER PATENTS.—

15 “(I) IN GENERAL.—If the appli-
16 cant made a certification described in
17 paragraph (2)(A)(vii)(IV) with respect
18 to a patent not described in clause
19 (iii) for which patent information was
20 published by the Secretary under sub-
21 section (c)(2)(D), the approval shall
22 be made effective on the date that is
23 45 days after the date on which the
24 notice provided under paragraph
25 (2)(B) was received, unless a civil ac-

1 tion for infringement of the patent,
2 accompanied by a motion for prelimi-
3 nary injunction to enjoin the applicant
4 from engaging in the commercial
5 manufacture or sale of the drug, was
6 filed on or before the date that is 45
7 days after the date on which the no-
8 tice was received, in which case the
9 approval shall be made effective—

10 “(aa) on the date of a court
11 action declining to grant a pre-
12 liminary injunction; or

13 “(bb) if the court has grant-
14 ed a preliminary injunction pro-
15 hibiting the applicant from en-
16 gaging in the commercial manu-
17 facture or sale of the drug—

18 “(AA) on issuance by a
19 court of a determination
20 that the patent is invalid or
21 is not infringed;

22 “(BB) on issuance by a
23 court of an order revoking
24 the preliminary injunction or
25 permitting the applicant to

1 engage in the commercial
2 manufacture or sale of the
3 drug; or

4 “(CC) on the date spec-
5 ified in a court order under
6 section 271(e)(4)(A) of title
7 35, United States Code, if
8 the court determines that
9 the patent is infringed.

10 “(II) COOPERATION.—Each of
11 the parties shall reasonably cooperate
12 in expediting a civil action under sub-
13 clause (I).

14 “(III) EXPEDITED NOTIFICA-
15 TION.—If the notice under paragraph
16 (2)(B) contains an address for the re-
17 ceipt of expedited notification of a
18 civil action under subclause (I), the
19 plaintiff shall, on the date on which
20 the complaint is filed, simultaneously
21 cause a notification of the civil action
22 to be delivered to that address by the
23 next business day.”; and

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

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

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

19 (1) in paragraph (3)—

20 (A) in subparagraph (C)—

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

1 “(C) CLAUSE (iv) CERTIFICATION WITH
2 RESPECT TO CERTAIN PATENTS.—If the appli-
3 cant made a certification described in sub-
4 section (b)(2)(A)(iv) with respect to a patent
5 (other than a patent that claims a process for
6 manufacturing the listed drug) for which patent
7 information was filed with the Secretary under
8 paragraph (2)(A),”; and

9 (ii) by adding at the end the fol-
10 lowing: “The 30-month period provided
11 under the second sentence of this subpara-
12 graph shall not apply to a certification
13 under subsection (b)(2)(A)(iv) made with
14 respect to a patent for which patent infor-
15 mation was filed with the Secretary under
16 paragraph (2)(B).”; and

17 (B) by inserting after subparagraph (C)
18 the following:

19 “(D) CLAUSE (iv) CERTIFICATION WITH
20 RESPECT TO OTHER PATENTS.—

21 “(i) IN GENERAL.—If the applicant
22 made a certification described in sub-
23 section (b)(2)(A)(iv) with respect to a pat-
24 ent not described in subparagraph (C) for
25 which patent information was published by

1 the Secretary under paragraph (2)(D), the
2 approval shall be made effective on the
3 date that is 45 days after the date on
4 which the notice provided under subsection
5 (b)(3) was received, unless a civil action
6 for infringement of the patent, accom-
7 panied by a motion for preliminary injunc-
8 tion to enjoin the applicant from engaging
9 in the commercial manufacture or sale of
10 the drug, was filed on or before the date
11 that is 45 days after the date on which the
12 notice was received, in which case the ap-
13 proval shall be made effective—

14 “(I) on the date of a court action
15 declining to grant a preliminary in-
16 junction; or

17 “(II) if the court has granted a
18 preliminary injunction prohibiting the
19 applicant from engaging in the com-
20 mercial manufacture or sale of the
21 drug—

22 “(aa) on issuance by a court
23 of a determination that the pat-
24 ent is invalid or is not infringed;

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

7 “(cc) on the date specified
8 in a court order under section
9 271(e)(4)(A) of title 35, United
10 States Code, if the court deter-
11 mines that the patent is in-
12 fringed.

13 “(ii) COOPERATION.—Each of the
14 parties shall reasonably cooperate in expe-
15 diting a civil action under clause (i).

16 “(iii) EXPEDITED NOTIFICATION.—If
17 the notice under subsection (b)(3) contains
18 an address for the receipt of expedited no-
19 tification of a civil action under clause (i),
20 the plaintiff shall, on the date on which the
21 complaint is filed, simultaneously cause a
22 notification of the civil action to be deliv-
23 ered to that address by the next business
24 day.”; and

1 (2) by inserting after paragraph (3) the fol-
2 lowing:

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

17 (c) EFFECTIVE DATE.—

18 (1) IN GENERAL.—The amendments made by
19 subsections (a) and (b) shall be effective with re-
20 spect to any certification under subsection
21 (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of
22 the Federal Food, Drug, and Cosmetic Act (21
23 U.S.C. 355) made after the date of enactment of
24 this Act in an application filed under subsection
25 (b)(2) or (j) of that section.

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

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

16 (B) any other patent (including a patent
17 for which information was submitted to the
18 Secretary under section 505(e)(2) of that Act
19 (as in effect on the day before the date of en-
20 actment of this Act)) shall be subject to sub-
21 sections (c)(3)(D) and (j)(5)(B)(iv) of section
22 505 of the Federal Food, Drug, and Cosmetic
23 Act (as amended by 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 de-
10 cision 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
16 is invalid or not infringed; or

17 “(bb) the date of a settle-
18 ment order or consent decree
19 signed by a Federal judge that
20 enters a final judgment and in-
21 cludes a finding that the patent
22 that is the subject of the certifi-
23 cation is invalid or not in-
24 fringed;”; and

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

1 “(D) FORFEITURE OF 180-DAY PERIOD.—

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

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

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

14 “(III) FORFEITURE EVENT.—
15 The term ‘forfeiture event’, with re-
16 spect to an application under this sub-
17 section, means the occurrence of any
18 of the following:

19 “(aa) FAILURE TO MAR-
20 KET.—The applicant fails to
21 market the drug by the later of—

22 “(AA) the date that is
23 60 days after the date on
24 which the approval of the
25 application for the drug is

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

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

1 cided (unless the Secretary
2 extends the date because of
3 extraordinary or unusual
4 circumstances).

5 “(bb) WITHDRAWAL OF AP-
6 PLICATION.—The applicant with-
7 draws the application.

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

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

24 “(AA) a change in the
25 requirements for approval of

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

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

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

1 “(AA) a certification
2 described in paragraph
3 (2)(A)(vii)(IV) with respect
4 to the patent to which the
5 new patent information re-
6 lates; or

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

15 “(ff) UNLAWFUL CON-
16 DUCT.—The Federal Trade Com-
17 mission determines that the ap-
18 plicant engaged in unlawful con-
19 duct with respect to the applica-
20 tion in violation of section 1 of
21 the Sherman Act (15 U.S.C. 1).

22 “(IV) SUBSEQUENT APPLICA-
23 TION.—The term ‘subsequent applica-
24 tion’ means an application for ap-
25 proval of a drug that is filed subse-

1 quent to the filing of a first applica-
2 tion for approval of that drug.

3 “(ii) FORFEITURE OF 180-DAY PE-
4 RIOD.—

5 “(I) IN GENERAL.—Except as
6 provided in subclause (II), if a for-
7 feiture event occurs with respect to a
8 first application—

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

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

20 “(II) FORFEITURE TO FIRST
21 SUBSEQUENT APPLICANT.—If the sub-
22 sequent application that is the first to
23 be made effective under subclause (I)
24 was the first among a number of sub-
25 sequent applications to be filed—

1 “(aa) that first subsequent
2 application shall be treated as
3 the first application under this
4 subparagraph (including sub-
5 clause (I)) and as the previous
6 application under subparagraph
7 (B)(v); and

8 “(bb) any other subsequent
9 applications shall become effec-
10 tive as provided under clause (i),
11 (ii), (iii), or (iv) of subparagraph
12 (B), but clause (v) of subpara-
13 graph (B) shall apply to any such
14 subsequent application.

15 “(iii) AVAILABILITY.—The 180-day
16 period under subparagraph (B)(v) shall be
17 available to a first applicant submitting an
18 application for a drug with respect to any
19 patent without regard to whether an appli-
20 cation has been submitted for the drug
21 under this subsection containing such a
22 certification with respect to a different pat-
23 ent.

24 “(iv) APPLICABILITY.—The 180-day
25 period described in subparagraph (B)(v)

1 shall apply to an application only if a civil
2 action is brought against the applicant for
3 infringement of a patent that is the subject
4 of the certification.”.

5 (b) **APPLICABILITY.**—The amendment made by sub-
6 section (a) shall be effective only with respect to an appli-
7 cation filed under section 505(j) of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 355(j)) after the date
9 of enactment of this Act for a listed drug for which no
10 certification under section 505(j)(2)(A)(vii)(IV) of that
11 Act was made before the date of enactment of this Act,
12 except that if a forfeiture event described in section
13 505(j)(5)(D)(i)(III)(ff) of that Act occurs in the case of
14 an applicant, the applicant shall forfeit the 180-day period
15 under section 505(j)(5)(B)(v) of that Act without regard
16 to when the applicant made a certification under section
17 505(j)(2)(A)(vii)(IV) of that Act.

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

19 (a) **BASIS FOR APPLICATION.**—Section 505 of the
20 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)
21 is amended—

22 (1) in subsection (b)(3)(B), by striking the sec-
23 ond sentence and inserting “The notice shall include
24 a detailed statement of the factual and legal basis of
25 the applicant’s opinion that, as of the date of the no-

1 tice, the patent is not valid or is not infringed, and
2 shall include, as appropriate for the relevant patent,
3 a description of the applicant’s proposed drug sub-
4 stance, drug formulation, drug composition, or meth-
5 od of use. All information disclosed under this sub-
6 paragraph shall be treated as confidential and may
7 be used only for purposes relating to patent adju-
8 dication. Nothing in this subparagraph precludes the
9 applicant from amending the factual or legal basis
10 on which the applicant relies in patent litigation.”;
11 and

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

1 or legal basis on which the applicant relies in patent
2 litigation.”.

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

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

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

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

20 **SEC. 7. BIOEQUIVALENCE.**

21 (a) IN GENERAL.—The amendments to part 320 of
22 title 21, Code of Federal Regulations, promulgated by the
23 Commissioner of Food and Drugs on July 17, 1991 (57
24 Fed. Reg. 17997 (April 28, 1992)), shall continue in effect
25 as an exercise of authorities under sections 501, 502, 505,

1 and 701 of the Federal Food, Drug, and Cosmetic Act
2 (21 U.S.C. 351, 352, 355, 371).

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

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

13 **SEC. 8. REPORT.**

14 (a) IN GENERAL.—Not later than the date that is
15 5 years after the date of enactment of this Act, the Fed-
16 eral Trade Commission shall submit to Congress a report
17 describing the extent to which implementation of the
18 amendments made by this Act—

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

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

1 (b) AUTHORIZATION OF APPROPRIATIONS.—There is
2 authorized to be appropriated to carry out this section
3 \$5,000,000.

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

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

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

9 (2) in subsection (b)—

10 (A) by striking “(b)(1) Any person” and
11 inserting the following:

12 “(b) APPLICATIONS.—

13 “(1) REQUIREMENTS.—

14 “(A) IN GENERAL.—Any person”;

15 (B) in paragraph (1)—

16 (i) in the second sentence—

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

21 (II) by striking “Such persons”
22 and inserting the following:

23 “(B) INFORMATION TO BE SUBMITTED
24 WITH APPLICATION.—A person that submits an
25 application under subparagraph (A)”;

1 (III) by striking “application”
2 and inserting “application—”;

3 (ii) by striking the third through fifth
4 sentences; and

5 (iii) in the sixth sentence—

6 (I) by striking “The Secretary”
7 and inserting the following:

8 “(C) GUIDANCE.—The Secretary”; and

9 (II) by striking “clause (A)” and
10 inserting “subparagraph (B)(i)”; and

11 (C) in paragraph (2)—

12 (i) by striking “clause (A) of such
13 paragraph” and inserting “paragraph
14 (1)(B)(i)”; and

15 (ii) in subparagraphs (A) and (B), by
16 striking “paragraph (1) or”; and

17 (iii) in subparagraph (B)—

18 (I) by striking “paragraph
19 (1)(A)” and inserting “paragraph
20 (1)(B)(i)”; and

21 (II) by striking “patent” each
22 place it appears and inserting
23 “claim”; and

24 (3) in subsection (c)—

25 (A) in paragraph (3)—

1 (i) in subparagraph (A)—

2 (I) by striking “(A) If the appli-
3 cant” and inserting the following:

4 “(A) CLAUSE (i) OR (ii) CERTIFICATION.—
5 If the applicant”; and

6 (II) by striking “may” and in-
7 serting “shall”;

8 (ii) in subparagraph (B)—

9 (I) by striking “(B) If the appli-
10 cant” and inserting the following:

11 “(B) CLAUSE (iii) CERTIFICATION.—If the
12 applicant”; and

13 (II) by striking “may” and in-
14 serting “shall”;

15 (iii) by redesignating subparagraph
16 (D) as subparagraph (E); and

17 (iv) in subparagraph (E) (as redesi-
18 gnated by clause (iii)), by striking “clause
19 (A) of subsection (b)(1)” each place it ap-
20 pears and inserting “subsection
21 (b)(1)(B)(i)”; and

22 (B) by redesignating paragraph (4) as
23 paragraph (5); and

24 (4) in subsection (j)—

25 (A) in paragraph (2)(A)—

- 1 (i) in clause (vi), by striking “clauses
2 (B) through ((F)” and inserting “sub-
3 clauses (ii) through (vi) of subsection
4 (b)(1)”;
- 5 (ii) in clause (vii), by striking “(b)
6 or”; and
- 7 (iii) in clause (viii)—
- 8 (I) by striking “(b) or”; and
- 9 (II) by striking “patent” each
10 place it appears and inserting
11 “claim”; and
- 12 (B) in paragraph (5)—
- 13 (i) in subparagraph (B)—
- 14 (I) in clause (i)—
- 15 (aa) by striking “(i) If the
16 applicant” and inserting the fol-
17 lowing:
- 18 “(i) SUBCLAUSE (i) OR (ii) CERTIFI-
19 CATION.—If the applicant”; and
- 20 (bb) by striking “may” and
21 inserting “shall”;
- 22 (II) in clause (ii)—
- 23 (aa) by striking “(ii) If the
24 applicant” and inserting the fol-
25 lowing:

1 “(i) SUBCLAUSE (iii) CERTIFI-
2 CATION.—If the applicant”; and

3 (bb) by striking “may” and
4 inserting “shall”;

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

8 (IV) in clause (v) (as redesign-
9 ated by section 4(a)(1)(B)), by strik-
10 ing “continuing” and inserting “con-
11 taining”; and

12 (ii) by redesignating subparagraphs
13 (C) and (D) as subparagraphs (E) and
14 (F), respectively.

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

18 (1) in subsections (b)(1)(A)(i) and
19 (c)(1)(A)(i)—

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

22 (B) by striking “(j)(5)(D)(ii)” each place
23 it appears and inserting “(j)(5)(F)(ii)”;

24 (2) in subsections (b)(1)(A)(ii) and
25 (c)(1)(A)(ii)—

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

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

5 (3) in subsections (e) and (l)—

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

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

10 (4) in subsection (k), by striking
11 “505(j)(5)(B)(iv)” and inserting “505(j)(5)(B)(v)”.

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

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