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Strike out all after the enacting clause and insert in lieu thereof the following:

TITLE I--ABBREVIATED NEW DRUG APPLICATIONS

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

“(j)(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

“(2)(A) An abbreviated application for a new drug shall contain--

“(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (6) (hereinafter in this subsection referred to as a “listed drug”);

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

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

1- “(III) if the listed drug referred to in clause (i)
2 has more than one active ingredient and if one of the
3 active ingredients of the new drug is different and the
4 application is filed pursuant to the approval of a
5 petition filed under subparagraph (C), information to
6 show that the other active ingredients of the new drug
7 are the same as the active ingredients of the listed
8 drug, information to show that the different active
9 ingredient is an active ingredient of a listed drug or
10 of a drug which does not meet the requirements of
11 section 201(p), and such other information respecting
12 the different active ingredient with respect to which
13 the petition was filed as the Secretary may require;

14 “(III) information to show that the the route of
15 administration, the dosage form, and the strength of the
16 new drug are the same as those of the listed drug
17 referred to in clause (i) or, if the route of
18 administration, the dosage form, or the strength of the
19 new drug is different and the application is filed
20 pursuant to the approval of a petition filed under
21 subparagraph (C), such information respecting the route
22 of administration, dosage form, or strength with respect
23 to which the petition was filed as the Secretary may
24 require;

25 “(iv) information to show that the new drug is
26 bioequivalent to the listed drug referred to in clause
27 (i), except that if the application is filed pursuant to

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

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

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

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

25 "(I) that such patent information has not been
26 filed,

27 "(II) that such patent has expired,

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

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

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

12 The Secretary may not require that an abbreviated
13 application contain information in addition to that required
14 by clauses (I) through (VIII).

15 “(B)(1) An applicant who makes a certification
16 described in subparagraph (A)(vii)(IV) shall include in the
17 application a statement that the applicant has given the
18 notice required by clause (ii) to--

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

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

27 “(ii) The notice referred to in clause (i) shall state

1 that an application has been submitted under this subsection
2 for the drug with respect to which the certification is made
3 to obtain approval to engage in the commercial manufacture,
4 use, or sale of such drug before the expiration of the
5 patent referred to in the certification.

6 Such notice shall include a detailed statement of the
7 factual and legal basis of the applicant's opinion that the
8 patent is not valid or will not be infringed.

9 "(iii) If an application is amended to include a
10 certification described in subparagraph (A)(vii)(IV), the
11 notice required by clause (ii) shall be given when the
12 amended application is submitted.

13 "(C) If a person wants to submit an abbreviated
14 application for a new drug which has a different active
15 ingredient or whose route of administration, dosage form, or
16 strength differ from that of a listed drug, such person
17 shall submit a petition to the Secretary seeking permission
18 to file such an application. The Secretary shall approve or
19 disapprove a petition submitted under this subparagraph
20 within ninety days of the date the petition is submitted.

21 The Secretary shall approve such a petition unless the
22 Secretary finds that investigations must be conducted to
23 show the safety and effectiveness of the active ingredients
24 of the drug or of the route of administration, the dosage
25 form, or strength which differ from the listed drug.

26 "(3) Subject to paragraph (4), the Secretary shall
27 approve an application for a drug unless the Secretary

1 finds--

2 "(A) the methods used in, or the facilities and
3 controls used for, the manufacture, processing, and
4 packing of the drug are inadequate to assure and
5 preserve its identity, strength, quality, and purity;

6 "(B) information submitted with the application is
7 insufficient to show that each of the proposed
8 conditions of use have been previously approved for the
9 listed drug referred to in the application;

10 "(C)(1) if the listed drug has only one active
11 ingredient, information submitted with the application
12 is insufficient to show that the active ingredient is
13 the same as that of the listed drug,

14 "(11) if the listed drug has more than one active
15 ingredient, information submitted with the application
16 is insufficient to show that the active ingredients are
17 the same as the active ingredients of the listed drug,
18 or

19 "(111) if the listed drug has more than one active
20 ingredient and if the application is for a drug which
21 has an active ingredient different from the listed drug,
22 information submitted with the application is
23 insufficient to show--

24 "(I) that the other active ingredients are the
25 same as the active ingredients of the listed drug,
26 or

27 "(II) that the different active ingredient is

1 an active ingredient of a listed drug or a drug
2 which does not meet the requirements of section
3 201(p),

4 or no petition to file an application for the drug with
5 the different ingredient was approved under paragraph
6 (2)(C);

7 "(D)(i) if the application is for a drug whose
8 route of administration, dosage form, or strength of the
9 drug is the same as the route of administration, dosage
10 form, or strength of the listed drug referred to in the
11 application, information submitted in the application is
12 insufficient to show that the route of administration,
13 dosage form, or strength is the same as that of the
14 listed drug, or

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

22 "(E) if the application was filed pursuant to the
23 approval of a petition under paragraph (2)(C), the
24 application did not contain the information required by
25 the Secretary respecting the active ingredient, route of
26 administration, dosage form, or strength which is not
27 the same;

1 “(F) information submitted in the application is
2 insufficient to show that the drug is bioequivalent to
3 the listed drug referred to in the application or, if
4 the application was filed pursuant to a petition
5 approved under paragraph (2)(C), information submitted
6 in the application is insufficient to show that the
7 active ingredients of the new drug are of the same
8 pharmacological or therapeutic class as those of the
9 listed drug referred to in paragraph (2)(A)(1) and that
10 the new drug can be expected to have the same
11 therapeutic effect as the listed drug when administered
12 to patients for a condition of use referred to in such
13 paragraph;

14 “(G) information submitted in the application is
15 insufficient to show that the labeling proposed for the
16 drug is the same as the labeling approved for the listed
17 drug referred to in the application except for changes
18 required because of differences approved under a
19 petition filed under paragraph (2)(C) or because the
20 drug and the listed drug are produced or distributed by
21 different manufacturers;

22 “(H) information submitted in the application or
23 any other information available to the Secretary shows
24 that (i) the inactive ingredients of the drug are unsafe
25 for use under the conditions prescribed, recommended, or
26 suggested in the labeling proposed for the drug, or (ii)
27 the composition of the drug is unsafe under such

1 conditions because of the type or quantity of inactive
2 ingredients included or the manner in which the inactive
3 ingredients are included;

4 "(I) the approval under subsection (c) of the
5 listed drug referred to in the application under this
6 subsection has been withdrawn or suspended for grounds
7 described in the first sentence of subsection (e), the
8 approval under this subsection of the listed drug
9 referred to in the application under this subsection has
10 been withdrawn or suspended under paragraph (5), or the
11 Secretary has determined that the listed drug has been
12 withdrawn from sale for safety or effectiveness reasons;

13 "(J) the application does not meet any other
14 requirement of paragraph (2)(A); or

15 "(K) the application contains an untrue statement
16 of material fact.

17 "(4)(A) Within one hundred and eighty days of the
18 initial receipt of an application under paragraph (2) or
19 within such additional period as may be agreed upon by the
20 Secretary and the applicant, the Secretary shall approve or
21 disapprove the application.

22 "(B) The approval of an application submitted under
23 paragraph (2) shall be made effective on the last applicable
24 date determined under the following:

25 "(1) If the applicant only made a certification
26 described in subclause (I) or (II) of paragraph
27 (2)(A)(vii) or in both such subclauses, the approval may

1 be made effective immediately.

2 “(ii) If the applicant made a certification
3 described in subclause (III) of paragraph (2)(A)(vii),
4 the approval may be made effective on the date certified
5 under subclause (III).

6 “(iii) If the applicant made a certification
7 described in subclause (IV) of paragraph (2)(A)(vii),
8 the approval shall be made effective immediately unless
9 an action is brought for infringement of each patent
10 which is the subject of the certification before the
11 expiration of forty-five days from the date the notice
12 provided under paragraph (2)(B)(1) is received. If such
13 an action is brought before the expiration of such days,
14 the approval shall be made effective upon the expiration
15 of the eighteen month period beginning on the date of
16 the receipt of the notice provided under paragraph
17 (2)(B)(1) or such shorter or longer period as the court
18 may order because either party to the action failed to
19 reasonably cooperate in expediting the action, except
20 that--

21 “(I) If before the expiration of such period
22 the court decides that each such patent is invalid
23 or not infringed, the approval shall be made
24 effective on the date of the court decision, or

25 “(II) if before the expiration of such period
26 the court decides that any such patent has been
27 infringed, the approval shall be made effective on

1 such date as the court orders under section
2 271(e)(4)(A) of title 35, United States Code.

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

13 "(iv) If the application contains a certification
14 described in subclause (IV) of paragraph (2)(A)(vii) and
15 is for a drug for which a previous application has been
16 submitted under this subsection containing such a
17 certification, the application shall be made effective
18 not earlier than one hundred and eighty days after--

19 "(I) the date the Secretary receives notice
20 from the applicant under the previous application of
21 the first commercial marketing of the drug under the
22 previous application, or

23 "(II) the date of a decision of a court in an
24 action described in clause (iii) holding the patent
25 which is the subject of the certification to be
26 invalid or not infringed,

27 whichever is earlier.

1 “(C) If the Secretary decides to disapprove an
2 application, the Secretary shall give the applicant notice
3 of an opportunity for a hearing before the Secretary on the
4 question of whether such application is approvable. If the
5 applicant elects to accept the opportunity for hearing by
6 written request within thirty days after such notice, such
7 hearing shall commence not more than ninety days after the
8 expiration of such thirty days unless the Secretary and the
9 applicant otherwise agree. Any such hearing shall thereafter
10 be conducted on an expedited basis and the Secretary's order
11 thereon shall be issued within ninety days after the date
12 fixed by the Secretary for filing final briefs.

13 “(D)(i) If an application (other than an abbreviated
14 new drug application) submitted under subsection (b) for a
15 drug, no active ingredient (including any ester or salt of
16 the active ingredient) of which has been approved in any
17 other application under subsection (b), was approved during
18 the period beginning January 1, 1982, and ending on the date
19 of the enactment of this subsection, the Secretary may not
20 make the approval of an application submitted under this
21 subsection which refers to the drug for which the subsection
22 (b) application was submitted effective before the
23 expiration of ten years from the date of the approval of the
24 application under subsection (b).

25 “(ii) If an application submitted under subsection (b)
26 for a drug, no active ingredient (including any ester or
27 salt of the active ingredient) of which has been approved in

1 any other application under subsection (b), is approved
2 after the date of the enactment of this subsection and if
3 the holder of the approved application certifies to the
4 Secretary that no patent has ever been issued to any person
5 for such drug or for a method of using such drug and that
6 the holder cannot receive a patent for such drug or for a
7 method of using such drug because in the opinion of the
8 holder a patent may not be issued for such drug or for a
9 method of using such drug for any known therapeutic purposes
10 the Secretary may not make the approval of an application
11 submitted under this subsection which refers to the drug for
12 which the subsection (b) application was submitted effective
13 before the expiration of four years from the date of the
14 approval of the application under subsection (b) unless the
15 Secretary determines that an adequate supply of such drug
16 will not be available or the holder of the application
17 approved under subsection (b) consents to an earlier
18 effective date for an application under this subsection.

19 "(5) If a drug approved under this subsection refers in
20 its approved application to a drug the approval of which was
21 withdrawn or suspended for grounds described in the first
22 sentence of subsection (e) or was withdrawn or suspended
23 under this paragraph or which, as determined by the
24 Secretary, has been withdrawn from sale for safety or
25 effectiveness reasons, the approval of the drug under this
26 subsection shall be withdrawn or suspended--

27 "(A) for the same period as the withdrawal or

1 suspension under subsection (a) or this paragraph, or

2 “(B) if the listed drug has been withdrawn from
3 sale, for the period of withdrawal from sale or, if
4 earlier, the period ending on the date the Secretary
5 determines that the withdrawal from sale is not for
6 safety or effectiveness reasons.

7 “(6)(A)(1) Within sixty days of the date of the
8 enactment of this subsection, the Secretary shall publish
9 and make available to the public--

10 “(I) a list in alphabetical order of the official
11 and proprietary name of each drug which has been
12 approved for safety and effectiveness under subsection
13 (c) before the date of the enactment of this subsection;

14 “(II) the date of approval if the drug is approved
15 after 1981 and the number of the application which was
16 approved; and

17 “(III) whether in vitro or in vivo bioequivalence
18 studies, or both such studies, are required for
19 applications filed under this subsection which will
20 refer to the drug published.

21 “(ii) Every thirty days after the publication of the
22 first list under clause (1) the Secretary shall revise the
23 list to include each drug which has been approved for safety
24 and effectiveness under subsection (c) or approved under
25 this subsection during the thirty day-period.

26 “(iii) When patent information submitted under
27 subsection (b) or (c) respecting a drug included on the list

1 is to be published by the Secretary the Secretary shall, in
2 revisions made under clause (ii), include such information
3 for such drug.

4 “(B) A drug approved for safety and effectiveness under
5 subsection (c) or approved under this subsection shall, for
6 purposes of this subsection, be considered to have been
7 published under subparagraph (A) on the date of its approval
8 or the date of enactment, whichever is later.

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

18 “(i) for the same period as the withdrawal or
19 suspension under subsection (e) or paragraph (5), or

20 “(ii) if the listed drug has been withdrawn from
21 sale, for the period of withdrawal from sale or, if
22 earlier, the period ending on the date the Secretary
23 determines that the withdrawal from sale is not for
24 safety or effectiveness reasons.

25 A notice of the removal shall be published in the Federal
26 register.

27 “(7) For purposes of this subsection:

1 “(A) The term ‘bioavailability’ means the rate and
2 extent to which the active ingredient or therapeutic
3 ingredient is absorbed from a drug and becomes available
4 at the site of drug action.

5 “(B) A drug shall be considered to be bioequivalent
6 to a listed drug if--

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

14 “(ii) the extent of absorption of the drug does
15 not show a significant difference from the extent of
16 absorption of the listed drug when administered at
17 the same molar dose of the therapeutic ingredient
18 under similar experimental conditions in either a
19 single dose or multiple doses and the difference
20 from the listed drug in the rate of absorption of
21 the drug is intentional, is reflected in its
22 proposed labeling, is not essential to the
23 attainment of effective body drug concentrations on
24 chronic use, and is considered medically
25 insignificant for the drug.”.

26 Sec. 102. (a)(1) Section 505(b) of such Act is amended
27 by adding at the end the following: “The applicant shall

1 file with the application the patent number and the
2 expiration date of any patent which claims the drug for
3 which the applicant submitted the application or which
4 claims a method of using such drug and with respect to which
5 a claim of patent infringement could reasonably be asserted
6 if a person not licensed by the owner engaged in the
7 manufacture, use, or sale of the drug. If an application is
8 filed under this subsection for a drug and a patent which
9 claims such drug or a method of using such drug is issued
10 after the filing date but before approval of the
11 application, the applicant shall amend the application to
12 include the information required by the preceding sentence.
13 Upon approval of the application, the Secretary shall
14 publish information submitted under the two preceding
15 sentences.''.
16

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

21 '(2) If the patent information described in subsection
22 (b) could not be filed with the submission of an application
23 under subsection (b) because the application was filed
24 before the patent information was required under subsection
25 (b) or a patent was issued after the application was
26 approved under such subsection, the holder of an approved
27 application shall file with the Secretary the patent number
and the expiration date of any patent which claims the drug

1 for which the application was submitted or which claims a
2 method of using such drug and with respect to which a claim
3 of patent infringement could reasonably be asserted if a
4 person not licensed by the owner engaged in the manufacture,
5 use, or sale of the drug. If the holder of an approved
6 application could not file patent information under
7 subsection (b) because it was not required at the time the
8 application was approved, the holder shall file such
9 information under this subsection not later than thirty days
10 after the date of the enactment of this sentence, and if the
11 holder of an approved application could not file patent
12 information under subsection (b) because no patent had been
13 issued when the application was filed or approved, the
14 holder shall file such information under this subsection not
15 later than thirty days after the date the patent involved is
16 issued. Upon the submission of patent information under this
17 subsection, the Secretary shall publish it.''.
18

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

24 (B) The first sentence of section 505(e) of such Act is
25 amended by redesignating clause (4) as clause (5) and
26 inserting after clause (3) the following: ''(4) the patent
27 information prescribed by subsection (c) was not filed
within thirty days after the receipt of written notice from

1 the Secretary specifying the failure to file such
2 information; or''.

3 (d)(1) Section 505(a) of such Act is amended by
4 inserting ''or (j)'' after ''subsection (b)''.

5 (2) Section 505(c) of such Act is amended by striking
6 out ''this subsection '' and inserting in lieu thereof
7 ''subsection (b)''.

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

11 (4) The second sentence of section 505(e) is amended by
12 striking out ''(j)'' each place it occurs in clause (1) and
13 inserting in lieu thereof ''(k)''.

14 (5) Section 505(k)(1) of such Act (as so redesignated)
15 is amended by striking out ''pursuant to this section'' and
16 inserting in lieu thereof ''under subsection (b) or (j)''.

17 (6) Subsections (a) and (b) of section 527 of such Act
18 are each amended by striking out ''under section 505(b)''
19 and inserting in lieu thereof ''under section 505''.

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

24 ''(2) An application submitted under paragraph (1) for a
25 drug for which investigations described in clause (A) of
26 such paragraph and called upon by the applicant for approval
27 of the application were not conducted by or for the

1 applicant or for which the applicant has not obtained a
2 right of reference or use from the person by or for whom the
3 investigations were conducted shall also include--

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

12 “(i) that such patent information has not been
13 filed,

14 “(ii) that such patent has expired,

15 “(iii) of the date on which such patent will
16 expire, or

17 “(iv) that such patent is invalid or will not
18 be infringed by the manufacture, use, or sale of the
19 new drug for which the application is submitted; and

20 “(B) if with respect to the drug for which
21 investigations described in paragraph (1)(A) were
22 conducted information was filed under paragraph (1) or
23 subsection (c) for a method of use patent which does not
24 claim a use for which the applicant is seeking approval
25 under this subsection, a statement that the method of
26 use patent does not claim such a use.

27 “(3)(A) An applicant who makes a certification

1 described in paragraph (2)(A)(iv) shall include in the
2 application a statement that the applicant has given the
3 notice required by subparagraph (B) to--

4 “(1) each owner of the patent which is the subject
5 of the certification or the representative of such owner
6 designated to receive such notice, and

7 “(11) the holder of the approved application under
8 subsection (b) for the drug which is claimed by the
9 patent or a use of which is claimed by the patent or the
10 representative of such holder designated to receive such
11 notice.

12 “(B) The notice referred to in subparagraph (A) shall
13 state that an application has been submitted under this
14 subsection for the drug with respect to which the
15 certification is made to obtain approval to engage in the
16 commercial manufacture, use, or sale of the drug before the
17 expiration of the patent referred to in the certification.
18 Such notice shall include a detailed statement of the
19 factual and legal basis of the applicant's opinion that the
20 patent is not valid or will not be infringed.

21 “(C) If an application is amended to include a
22 certification described in paragraph (2)(A)(iv), the notice
23 required by subparagraph (B) shall be given when the amended
24 application is submitted.”.

25 (b) Section 505(c) of such Act (as amended by section
26 102(a)(2)) is amended by adding at the end the following:

27 “(3) The approval of an application filed under

1 subsection (b) which contains a certification required by
2 paragraph (2) of such subsection shall be made effective on
3 the last applicable date determined under the following:

4 “(A) If the applicant only made a certification
5 described in clause (i) or (ii) of subsection (b)(2)(A)
6 or in both such clauses, the approval may be made
7 effective immediately.

8 “(B) If the applicant made a certification
9 described in clause (iii) of subsection (b)(2)(A), the
10 approval may be made effective on the date certified
11 under clause (iii).

12 “(C) If the applicant made a certification
13 described in clause (iv) of subsection (b)(2)(A), the
14 approval shall be made effective immediately unless an
15 action is brought for infringement of each patent which
16 is the subject of the certification before the
17 expiration of forty-five days from the date the notice
18 provided under paragraph (3)(B) is received. If such an
19 action is brought before the expiration of such days,
20 the approval may be made effective upon the expiration
21 of the eighteen month period beginning on the date of
22 the receipt of the notice provided under paragraph
23 (3)(B) or such shorter or longer period as the court may
24 order because either party to the action failed to
25 reasonably cooperate in expediting the action, except
26 that--

27 “(1) If before the expiration of such period

1 the court decides that each such patent is invalid
2 or not infringed, the approval may be made effective
3 on the date of the court decision, or

4 "(11) If before the expiration of such period
5 the court decides that any such patent has been
6 infringed, the approval may be made effective on
7 such date as the court orders under section
8 271(e)(4)(A) of title 35, United States Code.

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

19 "(D)(1) If an application (other than an
20 abbreviated new drug application) submitted under
21 subsection (b) for a drug, no active ingredient
22 (including any ester or salt of the active ingredient)
23 of which has been approved in any other application
24 under subsection (b), was approved during the period
25 beginning January 1, 1982, and ending on the date of the
26 enactment of this subsection, the Secretary may not make
27 the approval of another application for a drug for which

1 investigations described in clause (A) of subsection
2 (b)(1) and relied upon by the applicant for approval of
3 the application were not conducted by or for the
4 applicant or which the applicant has not obtained a
5 right of reference or use from the person by or for whom
6 the investigations were conducted effective before the
7 expiration of ten years from the date of the approval of
8 the application previously approved under subsection

9 (b).

10 "(11) If an application submitted under subsection
11 (b) for a drug, no active ingredient (including any
12 ester or salt of the active ingredient) of which has
13 been approved in any other application under subsection
14 (c), is approved after the date of the enactment of this
15 subsection and if the holder of the approved application
16 certifies to the Secretary that no patent has ever been
17 issued to any person for such drug or for a method of
18 using such drug and that the holder cannot receive a
19 patent for such drug or for a method of using such drug
20 because in the opinion of the holder a patent may not be
21 issued for such drug or for a method of using for any
22 known therapeutic purposes such drug, the Secretary may
23 not make the approval of another application for a drug
24 for which investigations described in clause (A) of
25 subsection (b)(1) and relied upon by the applicant for
26 approval of the application were not conducted by or for
27 the applicant or which the applicant has not obtained a

1 right of reference or use from the person by or for whom
2 the investigations were conducted effective before the
3 expiration of four years from the date of the approval
4 of the application previously approved under subsection
5 (b) unless the Secretary determines that an adequate
6 supply of such drug will not be available or the holder
7 of the application approved under subsection (b)
8 consents to an earlier effective date for an application
9 under this subsection.''.
10

11 Sec. 104. Section 505 of such Act is amended by adding
12 at the end the following:

13 ''(1) Safety and effectiveness data and information
14 which has been submitted in an application under subsection
15 (b) for a drug and which has not previously been disclosed
16 to the public shall be made available to the public, upon
17 request, unless extraordinary circumstances are shown--

18 ''(1) if no work is being or will be undertaken to
19 have the application approved,

20 ''(2) if the Secretary has determined that the
21 application is not approvable and all legal appeals have
22 been exhausted,

23 ''(3) if approval of the application under
24 subsection (c) is withdrawn and all legal appeals have
25 been exhausted,

26 ''(4) if the Secretary has determined that such drug
27 is not a new drug, or

''(5) upon the effective date of the approval of the

1 first application under subsection (j) which refers to
2 such drug or upon the date upon which the approval of an
3 application under subsection (j) which refers to such
4 drug could be made effective if such an application had
5 been submitted.

6 "(n) For purposes of this section, the term 'patent'
7 means a patent issued by the Patent and Trademark Office of
8 the Department of Commerce."

9 Sec. 105. (a) The Secretary of Health and Human Services
10 shall promulgate, in accordance with the notice and comment
11 requirements of section 553 of title 5, United States Code,
12 such regulations as may be necessary for the administration
13 of section 505 of the Federal Food, Drug, and Cosmetic Act,
14 as amended by sections 101, 102, and 103 of this Act, within
15 one year of the date of enactment of this Act.

16 (b) During the period beginning on the date of the
17 enactment of this Act and ending on the date regulations
18 promulgated under subsection (a) take effect, abbreviated
19 new drug applications may be submitted in accordance with
20 the provisions of section 314.2 of title 21 of the Code of
21 Federal Regulations and shall be considered as suitable for
22 any drug which has been approved for safety and
23 effectiveness under section 505(c) of the Federal Food,
24 Drug, and Cosmetic Act before the date of the enactment of
25 this Act. If any such provision is inconsistent with the
26 requirements of section 505(j) of the Federal Food, Drug,
27 and Cosmetic Act, the Secretary shall consider the

1 application under the applicable requirements of such
2 section. The Secretary of Health and Human Services may not
3 approve such an abbreviated new drug application which is
4 filed for a drug which is described in sections 505(c)(3)(D)
5 and 505(j)(4)(D) of the Federal Food, Drug, and Cosmetic Act
6 except in accordance with such section.

7 Sec. 106. Section 2201 of title 28, United States Code,
8 is amended by inserting "(a)" before "In a case" and by
9 adding at the end the following:

10 "(b) For limitations on actions brought with respect to
11 drug patents see section 505 of the Federal Food, Drug, and
12 Cosmetic Act."

13 TITLE II--PATENT EXTENSION

14 Sec. 201. (a) Title 35 of the United States Code is
15 amended by adding the following new section immediately
16 after section 155:

17 "\$156. Extension of patent term

18 "(a) The term of a patent which claims a product, a
19 method of using a product, or a method of manufacturing a
20 product shall be extended in accordance with this section
21 from the original expiration date of the patent if--

22 "(1) the term of the patent has not expired before
23 an application is submitted under subsection (d) for its
24 extension;

25 "(2) the term of the patent has never been
26 extended;

27 "(3) an application for extension is submitted by

1 the owner of record of the patent or its agent and in
2 accordance with the requirements of subsection (d);

3 "(4)(A) in the case of a patent which claims the
4 product or a method of using the product--

5 "(1) the product is not claimed in another
6 patent having an earlier issuance date or which was
7 previously extended, and

8 "(11) the product and the use approved for the
9 product in the applicable regulatory review period
10 are not identically disclosed or described in
11 another patent having an earlier issuance date or
12 which was previously extended; or

13 "(B) in the case of a patent which claims the
14 product, the product is also claimed in a patent which
15 has an earlier issuance date or which was previously
16 extended and which does not identically disclose or
17 describe the product and--

18 "(1) the holder of the patent to be extended
19 has never been and will not become the holder of the
20 patent which has an earlier issuance date or which
21 was previously extended, and

22 "(11) the holder of the patent which has an
23 earlier issuance date or which was previously
24 extended has never been and will not become the
25 holder of the patent to be extended;

26 "(5)(A) in the case of a patent which claims a
27 method of manufacturing the product which does not

1 primarily use recombinant DNA technology in the
2 manufacture of the product--

3 "(1) no other patent has been issued which
4 claims the product or a method of using the product
5 and no other patent which claims a method of using
6 the product may be issued for any known therapeutic
7 purposes; and

8 "(11) no other method of manufacturing the
9 product is claimed in a patent having an earlier
10 issuance date;

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

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

24 "(11) no other method of manufacturing the
25 product primarily using recombinant DNA technology
26 is claimed in a patent having an earlier issuance.

27 "(6) the product has been subject to a regulatory

1 review period before its commercial marketing or use;

2 "(7)(A) except as provided in subparagraph (B), the
3 permission for the commercial marketing or use of the
4 product after such regulatory review period is the first
5 permitted commercial marketing or use of the product
6 under the provision of law under which such regulatory
7 review period occurred; or

8 "(8) in the case of a patent which claims a method
9 of manufacturing the product which primarily uses
10 recombinant DNA technology in the manufacture of the
11 product, the permission for the commercial marketing or
12 use of the product after such regulatory review period
13 is the first permitted commercial marketing or use of a
14 product manufactured under the process claimed in the
15 patent; and

16 "(9) the patent does not claim another product or a
17 method of using or manufacturing another product which
18 product received permission for commercial marketing or
19 use under such provision of law before the filing of an
20 application for extension.

21 The product referred to in paragraphs (4), (5), (6), and (7)
22 is hereinafter in this section referred to as the 'approved
23 product'. For purposes of paragraphs (4)(B) (5)(B), the
24 holder of a patent is any person who is the owner of record
25 of the patent or is the exclusive licensee of the owner of
26 record of the patent.

27 "(b) The rights derived from any patent the term of

1 which is extended under this section shall during the period
2 during which the patent is extended--

3 “(1) In the case of a patent which claims a
4 product, be limited to any use approved for the approved
5 product before the expiration of the term of the patent
6 under the provision of law under which the applicable
7 regulatory review occurred;

8 “(2) In the case of a patent which claims a method
9 of using a product, be limited to any use claimed by the
10 patent and approved for the approved product before the
11 expiration of the term of the patent under the provision
12 of law under which the applicable regulatory review
13 occurred; and

14 “(3) In the case of a patent which claims a method
15 of manufacturing a product, be limited to the method of
16 manufacturing as used to make the approved product.

17 “(c) The term of a patent eligible for extension under
18 subsection (a) shall be extended by the time equal to the
19 regulatory review period for the approved product which
20 period occurs after the date the patent is issued, except
21 that--

22 “(1) each period of the regulatory review period
23 shall be reduced by any period determined under
24 subsection (d)(2)(B) during which the applicant for the
25 patent extension did not act with due diligence during
26 such period of the regulatory review period;

27 “(2) after any reduction required by paragraph (1),

1 the period of extension shall include only one-half of
2 the time remaining in the periods described in
3 paragraphs (1)(2)(1), (2)(3)(1), and (3)(3)(1) of
4 subsection (g); and

5 "(3) if the period remaining in the term of a
6 patent after the date of the approval of the approved
7 product under the provision of law under which such
8 regulatory review occurred when added to the regulatory
9 review period as revised under paragraphs (1) and (2)
10 exceeds fourteen years, the period of extension shall be
11 reduced so that the total of both such periods does not
12 exceed fourteen years.

13 "(d)(1) To obtain an extension of the term of a patent
14 under this section, the owner of record of the patent or its
15 agent shall submit an application to the Commissioner. Such
16 an application may only be submitted within the sixty-day
17 period beginning on the date the product received permission
18 under the provision of law under which the applicable
19 regulatory review period occurred for commercial marketing or
20 use. The application shall contain--

21 "(A) the identity of the approved product;

22 "(B) the identity of the patent for which an
23 extension is being sought and the identification of each
24 claim of such patent which claims the approved product
25 or a method of using or manufacturing the approved
26 product;

27 "(C) the identity of every other patent known to

1 the patent owner which claims or identically discloses
2 or describes the approved product or a method of using
3 or manufacturing the approved product;

4 "(D) the identity of all other products which have
5 received permission under the provision of law under
6 which the applicable regulatory review period occurred
7 for commercial marketing or use and which are claimed in
8 any of the patents identified in subparagraph (C);

9 "(E) information to enable the Commissioner to
10 determine under subsections (a) and (b) the eligibility
11 of a patent for extension and the rights that will be
12 derived from the extension and information to enable the
13 Commissioner and the Secretary of Health and Human
14 Services or the Secretary of Agriculture to determine
15 the period of the extension under subsection (g);

16 "(F) a brief description of the activities
17 undertaken by the applicant during the applicable
18 regulatory review period with respect to the approved
19 product and the significant dates applicable to such
20 activities; and

21 "(G) such patent or other information as the
22 Commissioner may require.

23 "(2)(A) Within sixty days of the submittal of an
24 application for extension of the term of a patent under
25 paragraph (1), the Commissioner shall notify--

26 "(1) the Secretary of Agriculture if the patent
27 claims a drug product or a method of using or

1 manufacturing a drug product and the drug product is
2 subject to the Virus-Serum-Toxin Act, and

3 "(11) the Secretary of Health and Human Services if
4 the patent claims any other drug product, a medical
5 device, or a food additive or color additive or a method
6 of using or manufacturing such a product, device, or
7 additive and if the product, device, and additive are
8 subject to the Federal Food, Drug, and Cosmetic Act,
9 of the extension application and shall submit to the
10 Secretary who is so notified a copy of the application. Not
11 later than 30 days after the receipt of an application from
12 the Commissioner, the Secretary receiving the application
13 shall review the dates contained in the application pursuant
14 to paragraph (1)(E) and determine the applicable regulatory
15 review period, shall notify the Commissioner of the
16 determination, and shall publish in the Federal Register a
17 notice of such determination.

18 "(3)(1) If a petition is submitted to the Secretary
19 making the determination under subparagraph (A), not later
20 than one hundred and eighty days after the publication of
21 the determination under subparagraph (A), upon which it may
22 reasonably be determined that the applicant did not act with
23 due diligence during the applicable regulatory review
24 period, the Secretary making the determination shall, in
25 accordance with regulations promulgated by such Secretary
26 determine if the applicant acted with due diligence during
27 the applicable regulatory review period. The Secretary shall

1 make such determination not later 90 days after the receipt
2 of such a petition. The Secretary of Health and Human
3 Services may not delegate the authority to make the
4 determination prescribed by this subparagraph to an office
5 below the Office of the Commissioner of Food and Drugs.

6 “(ii) The Secretary making a determination under clause
7 (i) shall notify the Commissioner of the determination and
8 shall publish in the Federal Register a notice of such
9 determination together with the factual and legal basis for
10 such determination. Any interested person may request,
11 within the 60 day period beginning on the publication of a
12 determination, the Secretary making the determination to
13 hold an informal hearing on the determination. If such a
14 request is made within such period, such Secretary shall
15 hold such hearing not later than thirty days after the date
16 of the request, or at the request of the person making the
17 request, not later than sixty days after such date. The
18 Secretary who is holding the hearing shall provide notice of
19 the hearing to the owner of the patent involved and to any
20 interested person and provide the owner and any interested
21 person an opportunity to participate in the hearing. Within
22 thirty days after the completion of the hearing, such
23 Secretary shall affirm or revise the determination which was
24 the subject of the hearing and notify the Commissioner of
25 any revision of the determination and shall publish any such
26 revision in the Federal Register.

27 “(3) For purposes of paragraph (2)(B), the term ‘due

1 diligence' means that degree of attention, continuous
2 directed effort, and timeliness as may reasonably be
3 expected from, and are ordinarily exercised by, a person
4 during a regulatory review period.

5 "(4) An application for the extension of the term of a
6 patent is subject to the disclosure requirements prescribed
7 by the Commissioner.

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

20 "(2) If the term of a patent for which an application
21 has been submitted under subsection (d) would expire before
22 a determination is made under paragraph (1) respecting the
23 application, the Commissioner shall extend, until such
24 determination is made, the term of the patent for periods of
25 up to one year if he determines that the patent is eligible
26 for extension.

27 "(f) For purposes of this section:

1 “(1) The term ‘product’ means any machine,
2 manufacture, or composition of matter for which a patent
3 may be obtained and includes the following:

4 “(A) A drug product.

5 “(B) Any medical device, food additive, or
6 color additive subject to regulation under the
7 Federal Food, Drug, and Cosmetic Act.

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

16 “(3) The term ‘major health or environmental
17 effects test’ means a test which is reasonably related
18 to the evaluation of the health or environmental effects
19 of a product, which requires at least six months to
20 conduct, and the data from which is submitted to receive
21 permission for commercial marketing or use. Periods of
22 analysis or evaluation of test results are not to be
23 included in determining if the conduct of a test
24 required at least six months.

25 “(4)(A) Any reference to section 351 is a reference
26 to section 351 of the Public Health Service Act.

27 “(B) Any reference to section 523, 525, 527, 512,

or 515 is a reference to section 503, 505, 507, 512, or 515 of the Federal Food, Drug, and Cosmetic Act.

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

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

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

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

“(1)(A) In the case of a product which is a drug product, the term means the period described in subparagraph (3) to which the limitation described in paragraph (4) applies.

“(3) The regulatory review period for a drug product is the sum of--

“(1) the period beginning on the date--

“(I) an exemption under subsection (1) of section 505, subsection (d) of section 507, or subsection (j) of section 512, or

“(II) the authority to prepare an experimental drug product under the Virus-Serum-Toxin Act,

became effective for the approved drug product and ending on the date an application was initially

1 submitted for such drug product under section 351,
2 505, 507, or 512 or the Virus-Serum-Toxin Act, and

3 "(11) the period beginning on the date the
4 application was initially submitted for the approved
5 drug product under section 351, subsection (b) of
6 such section 505, section 507, section 512, or the
7 Virus-Serum-Toxin Act and ending on the date such
8 application was approved under such section or Act.

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

13 "(B) The regulatory review period for a food or
14 color additive is the sum of--

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

22 "(11) the period beginning on the date a
23 petition was initially submitted with respect to the
24 product under the Federal Food, Drug, and Cosmetic
25 Act requesting the issuance of a regulation for use
26 of the product, and ending on the date such
27 regulation became effective or, if objections were

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

8 "(3)(A) In the case of a product which is a medical
9 device, the term means the period described in
10 subparagraph (B) to which the limitation described in
11 paragraph (4) applies.

12 "(B) The regulatory review period for a medical
13 device is the sum of--

14 "(1) the period beginning on the date a
15 clinical investigation on humans involving the
16 device was begun and ending on the date an
17 application was initially submitted with respect to
18 the device under section 515, and

19 "(11) the period beginning on the date an
20 application was initially submitted with respect to
21 the device under section 515 and ending on the date
22 such application was approved under such Act or the
23 period beginning on the date a notice of completion
24 of a product development protocol was initially
25 submitted under section 515(f)(5) and ending on the
26 date the protocol was declared completed under
27 section 515(f)(6).

1 “(4) A period determined under any of the preceding
2 paragraphs is subject to the following limitations:

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

8 “(B) If the patent involved was issued before
9 the date of the enactment of this section and--

10 “(1) no request for an exemption described
11 in paragraph (1)(B) was submitted,

12 “(11) no request was submitted for the
13 preparation of an experimental drug product
14 described in paragraph (1)(B),

15 “(111) no major health or environmental
16 effects test described in paragraph (2) was
17 initiated and no petition for a regulation or
18 application for registration described in such
19 paragraph was submitted, or

20 “(1V) no clinical investigation described
21 in paragraph (3) was begun or product
22 development protocol described in such paragraph
23 was submitted,

24 before such date for the approved product the period
25 of extension determined on the basis of the
26 regulatory review period determined under any such
27 paragraph may not exceed five years.

1 “(C) If the patent involved was issued before
2 the date of the enactment of this section and if an
3 action described in subparagraph (B) was taken
4 before the date of the enactment of this section
5 with respect to the approved product and the
6 commercial marketing or use of the product has not
7 been approved before such date, the period of
8 extension determined on the basis of the regulatory
9 review period determined under such paragraph may
10 not exceed two years.

11 “(h) The Commissioner may establish such fees as the
12 Commissioner determines appropriate to cover the costs to
13 the Office of receiving and acting upon applications under
14 this section.”.

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

 “156. Extension of patent term.”.

18 Sec. 282. Section 271 of title 35, United States Code is
19 amended by adding at the end the following:

20 “(e)(1) It shall not be an act of infringement to make,
21 use, or sell a patented invention solely for uses reasonably
22 related to the development and submission of information
23 under a Federal law which regulates the manufacture, use, or
24 sale of drugs.

25 “(2) It shall be an act of infringement to submit an
26 application under section 505(j) of the Federal Food, Drug,

1 and Cosmetic Act for a drug claimed in a patent or the use
2 of which is claimed in a patent, if the purpose of such
3 submission is to obtain approval under such Act to engage in
4 the commercial manufacture, use, or sale of a drug claimed
5 in a patent or the use of which is claimed in a patent
6 before the expiration of such patent.

7 “(3) In any action for patent infringement brought
8 under this section, no injunctive or other relief may be
9 granted which would prohibit the making, using, or selling
10 of a patented invention under paragraph (1).

11 “(4) For an act of infringement described in paragraph
12 (2)--

13 “(A) the court shall order the effective date of
14 any approval of the drug involved in the infringement to
15 be a date which is not earlier than the date of the
16 expiration of the patent which has been infringed,

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

20 “(C) damages or other monetary relief may be
21 awarded against an infringer only if there has been
22 commercial manufacture, use, or sale of an approved
23 drug.

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

1 Sec. 203. Section 282 of title 35, United States Code,
2 is amended by adding at the end the following:

3 "Invalidity of the extension of a patent term or any
4 portion thereof under section 156 of this title because of
5 the material failure--

6 "(1) by the applicant for the extension, or

7 "(2) by the Commissioner,

8 to comply with the requirements of such section shall be a
9 defense in any action involving the infringement of a patent
10 during the period of the extension of its term and shall be
11 pleaded. A due diligence determination under section
12 156(d)(2) is not subject to review in such an action."

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