

STATUTORY CONTEXT OF  
THE DRUG PRICE COMPETITION  
AND PATENT TERM RESTORATION  
ACT OF 1984  
(S. 2926 as revised by H.R. 3605)

	<u>Page</u>
I. New Drug Applications; . . . . .	1
Amendments to §505 of the FDC Act	
II. Interim ANDA Procedures - Miscellaneous . . . . .	20
III. Patent Extensions; . . . . .	21
Amendments to 35 USC	
IV. Infringement and Enforcement . . . . .	30
V. Separability Clause . . . . .	33

S. 2926 - New statutory material in *italics*.  
Deletions in [brackets].

H.R. 3605 - Additions to S. 2926 underlined.  
Deletions from S. 2926 in [[double brackets]].

**I. NEW DRUG APPLICATIONS**  
**Title 21, USC (FDC Act)**

[EFFECTIVE NDA OR ANDA REQUIRED]

Sec. 505. (a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) *or* (j) is effective with respect to such drug.

[CONTENTS OF NDA]

(b) (1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such person shall submit to the Secretary as a part of the application

[(1)] (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use;

[(2)] (B) a full list of the articles used as components of such drug;

[(3)] (C) a full statement of the composition of such drug;

[(4)] (D) a full description of the methods used in, and the facilities and controls used for the manufacture, processing, and packing of such drug;

[(5)] (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; and

[(6)] (F) specimens of the labeling proposed to be used for such drug.

[PATENT INFORMATION REQUIRED IN NDA]

*The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences.*

[PATENT CERTIFICATION FOR "PAPER" NDA]

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

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

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

(ii) that such patent has expired,

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

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

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

[NOTICE REQUIRED FOR "INVALIDITY" CERTIFICATION IN "PAPER" NDA]

(3)(A) An applicant who makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant has given the notice required by subparagraph [(b)] (B) to--

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

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

[Requirement for detailed opinion regarding invalidity]

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

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

[APPROVAL OF NDA: HEARING]

(c) (1) Within one hundred and eighty days after the filing of an application under [this subsection] subsection (b), or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either--

[[1]] (A) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

[[2]] (B) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

[PATENT INFORMATION: EXISTING NDA'S AND NEWLY-ISSUED PATENTS]

(2) If the patent information described in subsection (b) could not be filed with the submission of an application under subsection (b) because the application was filed before the patent information was required under subsection (b) or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If the holder of an approved application could not file patent information under subsection (b) because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after the date of the enactment of this sentence, and if the holder of an approved application could not file patent information under subsection (b) because no patent had been issued when the application was filed or approved, the holder shall file such information under this subsection not later than thirty days after the date the patent involved is issued. Upon the submission of patent information under this subsection the Secretary shall publish it.

[EFFECTIVENESS OF "PAPER" NDA WITH PATENT CERTIFICATION]

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

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

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

[Requirement for infringement action to stay effect]

(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A), the approval shall be made effective immediately unless

an action is brought for infringement of each patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (3)(B) is received. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (3)(B) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that--

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

(ii) if before the expiration of such period the court decides that any such patent has been infringed, the approval may be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, United States Code, or

(iii) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement, the approval shall be made effective on the date of such court decision.

[Requirement for "reasonable cooperation" in expediting infringement action]

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

[MORATORIUM ON "PAPER NDA" FILING/EFFECTIVENESS]

[Ten year effectiveness moratorium for transitional NCE NDA's]

(D)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of another application for a drug for which investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant or which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted effective before the expiration of ten years from the date of the approval of the application previously approved under subsection (b).

[Five year filing moratorium for NCE NDA's]

(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this subsection no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b)[.] except that such an application may be submitted under subsection (b) after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or non-infringement described in clause (iv) of subsection (b)(2)(a). The approval of such an application shall be made effective in accordance with this paragraph except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (C) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

[Three year effectiveness moratorium for OCE NDA's with new clinical tests]

(iii) If an application submitted under subsection (b) for a drug which includes an active ingredient that has been approved in any other application approved under subsection (b) and which contains reports of new clinical investigations (other than bioavailability studies) sponsored by the applicant is approved after the date of enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of three years from the date of the approval of the application under subsection (b).

[Three year effectiveness moratorium for OCE supplemental NDA's]

(iv) If a supplement to an application approved under subsection (b) includes reports of new clinical investigations (other than bioavailability studies) sponsored by the applicant and is approved after the date of enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which such supplement was submitted effective before the expiration of three years from the date of the approval of the supplement under subsection (b).

[Two year effectiveness moratorium for transitional OCE NDA's]

(v) If an application (or supplement to an application submitted under subsection (b) for a drug which includes an active ingredient that has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of two years from the date of enactment of this subsection.

[ORDERS REFUSING NDA]

(d) If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) the application failed to contain the patent information prescribed by subsection (b); or [(6)] (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e), the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

[WITHDRAWAL OF APPROVAL FOR NDA]

(e) The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed,

recommended, or suggested in the labeling thereof; or (4) the patent information prescribed by subsection (c) was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information; or [(4)] (5) that the application contains any untrue statement of a material fact: Provided, That if the Secretary (or in his absence the officer acting Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection [(j)] (k) or to comply with the notice requirements of section 510(j)(2), or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of. Any order under this subsection shall state the findings upon which it is based.

[REINSTATEMENT OF REFUSED, WITHDRAWN, SUSPENDED NDA'S]

(f) Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) refusing, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.

[SERVICE OF ORDERS]

(g) Orders of the Secretary issued under this section shall be served

(1) in person by any officer or employee of the department designated by the Secretary or

(2) by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.



[APPEALS FROM ORDERS REFUSING OR WITHDRAWING NDA'S]

(h) An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment of the court affirming or setting aside any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

[EXEMPTION FOR INVESTIGATIONAL NEW DRUGS]

(i) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon--

(1) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;

(2) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining

a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings; and

(3) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b).

Such regulations shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where they deem it not feasible or, in their professional judgment, contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs.

[AUTHORIZATION FOR ABBREVIATED NDA'S]

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

[CONTENTS OF AN ANDA]

*(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*

*(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredient of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient*

of a listed drug or of a drug which does not meet the requirements of section 201(p), and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

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

(vi) the items specified in clauses (B) through (F) of subsection (b)(i);

[Patent certification required based on NDA patent information]

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

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

(II) that such patent has expired,

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

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

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

[Requirement for additional information prohibited]

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

[NOTICE REQUIRED FOR "INVALIDITY" CERTIFICATION IN ANDA]

(B)(i) An applicant who makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the [[application]] applicant will give the notice required by clause (ii) to--

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

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

(ii) The notice referred to in clause (i) shall state that an application which contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use or sale of such drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

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

[PETITION FOR VARIANCE FROM APPROVED NDA]

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

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

(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

[CONDITIONS MANDATING APPROVAL OF ANDA]

(3) Subject to paragraph (4), the Secretary shall approve an application for a drug unless the Secretary finds--

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

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

(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug,

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

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show--

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

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

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

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

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

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or

therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

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

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e), the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) for grounds described under the first sentence of subsection (e), the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (5), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

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

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

[ACTION ON ANDA MANDATED IN 180 DAYS]

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

[EFFECTIVE DATE OF ANDA APPROVAL]

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

[Immediate Effect: NDA-identified patents expired]

(i) if the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

[Effective on patent expiration]

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

[Effective date after invalidity certification]

(iii) if the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of each patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that--

(I) if before the expiration of such period the court decides that each such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision.

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

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement, the approval shall be made effective on the date of such court decision.

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

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

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

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

whichever is earlier.

[RIGHT TO A HEARING; ANDA APPLICANT]

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

[MORATORIUM ON ANDA FILING/EFFECTIVENESS]

[Ten year effectiveness moratorium for transitional NCE NDA's]

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

[Five year filing moratorium for NCE NDA's]

(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this subsection [. No]] , no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b)[[.] , except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or non-infringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.



[Three year effectiveness moratorium for OCE NDA's]

(iii) If an application submitted under subsection (b) for a drug which includes an active ingredient that has been approved in any other application approved under subsection (b), and which contains reports of new clinical investigations (other than bioavailability studies) sponsored by the applicant, is approved after the date of enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of three years from the date of the approval of the application under subsection (b).

[Three year effectiveness moratorium for OCE supplemental NDA's]

(iv) If a supplement to an application approved under subsection (b) includes reports of new clinical investigations (other than bioavailability studies) sponsored by the applicant and is approved after the date of enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which such supplement was submitted effective before the expiration of three years from the date of the approval of the supplement under subsection (b).

[Two year transitional moratorium for OCE NDA's]

(v) If an application (or supplement to an application) submitted under subsection (b) for a drug which includes an active ingredient that has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of two years from the date of enactment of this subsection.

[WITHDRAWAL OF APPROVED ANDA'S]

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

(A) for the same period as the withdrawal of suspension under subsection (e) or this paragraph, or

(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

[PUBLICATIONS OF APPROVED DRUG LIST AND PATENT INFORMATION]

(6)(A)(i) Within sixty days of the date of the enactment of this subsection, the Secretary shall publish and make available to the public--

[Publication of drug names]

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

[Publication of approval dates]

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

[Publication of bioequivalence data required for ANDA]

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

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

[Publication of patent information]

(iii) When patent information submitted under subsection (b) or (c) respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

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

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

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

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

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

[DEFINITIONS: BIOAVAILABILITY AND BIOEQUIVALENCE]

**(7) For purposes of this subsection:**

**(A) The term "bioavailability" means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.**

**(B) A drug shall be considered to be bioequivalent to a listed drug if--**

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

**(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.**

[REQUIRED RECORDS AND REPORTS]

**[(j)] (k) (1) In the case of any drug for which an approval of an application filed [pursuant to this section] under subsection (b) or (j) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section: Provided, however, That regulations and orders issued under this subsection and under subsection (i) shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.**

**(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.**

[RELEASE OF SAFETY AND EFFICACY DATA]

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

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

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

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

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

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

[LIMITATION OF PATENT INFORMATION TO U.S. PATENTS]

(m) For purposes of this section, the term "patent" means a patent issued by the Patent and Trademark Office of the Department of Commerce.

## II. INTERIM ANDA PROCEDURES - MISCELLANEOUS

### [IMPLEMENTING REGULATIONS WITHIN ONE YEAR]

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

### [ANDA PROCEDURES PRIOR TO REGULATIONS]

*(b) During the period beginning on the date of the enactment of this Act and ending on the date regulations promulgated under subsection (a) take effect, abbreviated new drug applications may be submitted in accordance with the provisions of section 314.2 of title 21 of the Code of Federal Regulations and shall be considered as suitable for any drug which has been approved for safety and effectiveness under section 505(c) of the Federal Food, Drug, and Cosmetic Act before the date of the enactment of this Act. If any such provision is inconsistent with the requirements of section 505(j) of the Federal Food, Drug, and Cosmetic Act, the Secretary shall consider the application under the applicable requirements of such section. The Secretary of Health and Human Services may not approve such an abbreviated new drug application which is filed for a drug which is described in sections 505(c)(3)(D) and 505(j)(4)(D) of the Federal Food, Drug, and Cosmetic Act except in accordance with such section.*

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

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

**III. PATENT EXTENSIONS**  
**TITLE 35, USC**

§154 Contents and term of patent

§155 Patent term extension

[[§155A Patent extension]]

§156 Extension of patent term

[ORDINARY PATENT TERM]

**§154. Contents and term of patent**

Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, for the term of seventeen years, subject to the payment of fees as provided for in this title, of the right to exclude others from making, using, or selling the invention throughout the United States, referring to the specification for the particulars thereof. A copy of the specification and drawings shall be annexed to the patent and be a part thereof.

[ASPARTAME PATENT EXTENSION]

**§155. Patent term extension**

Notwithstanding the provisions of section 154, the term of a patent which encompasses within its scope a composition of matter or a process for using such composition shall be extended if such composition or process has been subjected to a regulatory review by the Federal Food and Drug Administration pursuant to the Federal Food, Drug, and Cosmetic Act leading to the publication of regulation permitting the interstate distribution and sale of such composition or process and for which there has thereafter been a stay of regulation of approval imposed pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act which stay was in effect on January 1, 1981, by a length of time to be measured from the date such stay of regulation of approval was imposed until such proceedings are finally resolved and commercial marketing permitted. The patentee, his heirs, successors or assigns shall notify the Commissioner of Patents and Trademarks within ninety days of the date of enactment of this section or the date the stay of regulation of approval has been removed, whichever is later, of the number of the patent to be extended and the date the stay was imposed and the date commercial marketing was permitted. On receipt of such notice, the Commissioner shall promptly issue to the owner of record of the patent a certificate of extension, under seal, stating the fact and length of the extension and identifying the composition of matter or process for using such composition to which such extension is applicable. Such certificate shall be recorded in the official file of each patent extended and such certificate shall be considered as part of the original patent, and an appropriate notice shall be published in the Official Gazette of the Patent and Trademark Office.

[SULFONYLUREA PATENT EXTENSION]

[[§155A. Patent extension]]

[[*(a) Notwithstanding section 154 of this title, the term of any patent which encompasses within its scope a composition of matter which is a new drug product, if such new drug product is subject to the labeling requirements for oral hypoglycemic drugs of the sulfonylurea class as promulgated by the Food and Drug Administration in its final rule of March 22, 1984 (FR Doc. 84-9640) and was approved by the Food and Drug Administration for marketing after promulgation of such final rule and prior to the date of enactment of this law, shall be extended until April 21, 1992.*]]

[[*(b) The patentee or licensee or authorized representative of any patent described in such subsection (a) shall, within ninety days after the date of enactment of such subsection, notify the Commissioner of Patents and Trademarks of the number of any patent so extended. On receipt of such notice, the Commissioner shall confirm such extension by placing a notice thereof in the official file of such patent and publishing an appropriate notice of such extension in the Official Gazette of the Patent and Trademark Office.*]]

["DRUG" PATENT EXTENSION]

§156. Extension of patent term

[QUALIFYING CONDITIONS FOR PATENT]

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

[Patent has not expired]

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

[No prior extension of patent]

*(2) the term of the patent has never been extended;*

[Extension application made as required]

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

[Product subject to regulatory review]

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

[First commercialization permitted after regulatory review]

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

[Exception for rDNA process patents]

(B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent.

The product referred to in paragraphs (4) and (5) is hereinafter in this section referred to as the "approved product".

[RIGHTS DURING PATENT EXTENSION]

(b) The rights derived from any patent the term of which is extended under this section shall during the period during which the patent is extended--

[Product patent only for approved uses]

(1) in the case of a patent which claims a product be limited to any use approved for the approved product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred;

[Use patent only for patented and approved uses]

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

[Manufacturing patent for claimed process for product]

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

[CALCULATION OF EXTENSION]

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

[Deduction for lack of due diligence]



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

[Deduction of one-half of "investigational" phase]

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

[Limitation to 14 years from date of regulatory approval]

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

[Limitation to one patent per regulatory review]

(4) in no event shall more than one patent be extended for the same regulatory review period for any product;

[REQUIREMENTS FOR EXTENSION APPLICATION]

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

(A) the identity of the approved product and the Federal statute under which regulatory review occurred;

(B) the identity of the patent for which an extension is being sought and the identity of each claim of such patent which claims the approved product or a method of using or manufacturing the approved product;

(C) information to enable the Commissioner to determine under subsections (a) and (b) the eligibility of a patent for extension and the rights that will be derived from the extension and information to enable the Commissioner and the Secretary of Health and Human Services to determine the period of the extension under subsection (g);

(D) a brief description of the activities undertaken by the applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities; and

(E) such patent or other information as the Commissioner may require.

[HHS DETERMINATION OF REGULATORY REVIEW PERIOD]

(2)(A) Within sixty days of the submittal of an application for extension of the term of a patent under paragraph (1), the Commissioner shall notify the Secretary of Health and Human Services if the patent claims any human drug product, a medical device, or a food additive or color additive or a method of using or manufacturing such a product, device, or additive and if the product, device, and additive are subject to the Federal Food, Drug, and Cosmetic Act of the extension application and shall submit to the Secretary a copy of the application. Not later than thirty days after the receipt of an application from the Commissioner, the Secretary shall review the dates contained in the application pursuant to paragraph (1)(C) and determine the applicable regulatory review period, shall notify the Commissioner of the determination, and shall publish in the Federal Register a notice of such determination.

(B)(i) If a petition is submitted to the Secretary under subparagraph (A), not later than one hundred and eighty days after the publication of the determination under subparagraph (A), upon which it may reasonably be determined that the applicant did not act with due diligence during the applicable regulatory review period, the Secretary shall, in accordance with regulations promulgated by the Secretary determine if the applicant acted with due diligence during the applicable regulatory review period. The Secretary shall make such determination not later than ninety days after the receipt of such a petition. The Secretary may not delegate the authority to make the determination prescribed by this subparagraph to an office below the Office of the Commissioner of Food and Drugs.

(ii) The Secretary shall notify the Commissioner of the determination and shall publish in the Federal Register a notice of such determination together with the factual and legal basis for such determination. Any interested person may request, within the sixty-day period beginning on the publication of a determination, the Secretary to hold an informal hearing on the determination. If such a request is made within such period, the Secretary shall hold such hearing not later than thirty days after the date of the request, or at the request of the person making the request, not later than sixty days after such date. The Secretary shall provide notice of the hearing to the owner of the patent involved and to any interested person and provide the owner and any interested person an opportunity to participate in the hearing. Within thirty days after the completion of the hearing, the Secretary shall affirm or revise the determination which was the subject of the hearing and notify the Commissioner of any revision of the determination and shall publish any such revision in the Federal Register.

[DEFINITION OF "DUE DILIGENCE"]

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

[APPLICABILITY OF "DISCLOSURE" REQUIREMENTS]

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

[ISSUANCE OF CERTIFICATE OF EXTENSION]

(e)(1) A determination that a patent is eligible for extension may be made by the Commissioner solely on the basis of the representations contained in the application for the extension. If the Commissioner determines that a patent is eligible for extension under subsection (a) and that the requirements of subsection (d) have been complied with, the Commissioner shall issue to the applicant for the extension of the term of the patent a certificate of extension, under seal, for the period prescribed by subsection (c). Such certificate shall be recorded in the official file of the patent and shall be considered as part of the original patent.

[ONE YEAR INTERIM EXTENSIONS]

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

[DEFINITIONS]

(f) For purposes of this section:

[Product]

(1) The term "product" means:

(A) A human drug product.

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

[Human drug product]

(2) The term "human drug product" means the active ingredient of a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act) including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

[Major health or environmental effects test]

(3) The term "major health or environmental effects test" means a test which is reasonably related to the evaluation of the health or environmental effects of a product, which requires at least six months to conduct, and the data from which is submitted to receive permission for commercial marketing or use. Periods of analysis or evaluation of test results are not to be included in determining if the conduct of a test required at least six months.

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

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

[Informal hearing]

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

[Patent]

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

[Regulatory review period]

(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 human drug product, the term means the period described in subparagraph (B) to which the limitation described in paragraph (4) applies.

(B) The regulatory review period for a human drug product is the sum of--

(i) the period beginning on the date an exemption under subsection (i) of section 505 or under subsection (d) of section 507 became effective for the approved human drug product and ending on the date an application was initially submitted for such drug product under section 351, 505, or 507, and

(ii) the period beginning on the date the application was initially submitted for the approved human drug product under section 351, subsection (b) of section 505, or section 507 and ending on the date such application was approved under such section.

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

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

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

(ii) the period beginning on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and ending

on the date such regulation became effective or, if objections were filed to such regulation, ending on the date such objections were resolved and commercial marketing was permitted or, if commercial marketing was permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings were finally resolved and commercial marketing was permitted.

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

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

(i) the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and

(ii) the period beginning on the date an application was initially submitted with respect to the device under section 515 and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).

[OVERALL LIMITATION ON REGULATORY REVIEW PERIOD]

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

[Five years for patents issued after enactment]

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

[Five years for patents for products which reach the "investigational" phase after enactment]

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

(i) no request for an exemption described in paragraph (1)(B) was submitted,

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

(iii) no clinical investigation described in paragraph (3) was begun or product development protocol described in such paragraph was submitted.

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

[Two years for existing patents for products already  
in "investigational" phase]

*(c) If the patent involved was issued before the date of the enactment of this section and if an action described in subparagraph (b) was taken before the date of the enactment of this section with respect to the approved product and the commercial marketing or use of the product has not been approved before such date, the period of extension determined on the basis of the regulatory review period determined under such paragraph may not exceed two years.*

[AUTHORITY TO ESTABLISH FEES FOR EXTENSION APPLICATIONS]

*(h) The Commissioner may establish such fees as the Commissioner determines appropriate to cover the costs to the Office of receiving and acting upon applications under this section.*

#### IV. INFRINGEMENT AND ENFORCEMENT

##### §271. Infringement of patent

###### [INFRINGEMENT]

(a) Except as otherwise provided in this title, whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent.

###### [INDUCEMENT OF INFRINGEMENT]

(b) Whoever actively induces infringement of a patent shall be liable as an infringer.

###### [CONTRIBUTORY INFRINGEMENT]

(c) Whoever sells a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

###### [EXEMPTION FROM MISUSE]

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: (1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement.

###### [REGULATORY ACTIVITY EXEMPTION FROM INFRINGEMENT]

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

###### [SUBMISSION OF ANDA CONSTITUTES INFRINGEMENT]

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

[INJUNCTIVE RELIEF PROHIBITED FOR "REGULATORY ACTIVITY"]

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

[LIMITATION ON REMEDIES FOR INFRINGEMENT BY MAKING AN ANDA SUBMISSION]

(4) *For an act of infringement described in paragraph (2)--*

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

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

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

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

§282. Presumption of validity; defenses

[PATENT VALIDITY AND DEFENSES]

A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity. The following shall be defenses in any action involving the validity of infringement of a patent and shall be pleaded:

(1) Noninfringement, absence of liability for infringement or unenforceability,

(2) Invalidity of the patent or any claim in suit on any ground specified in part II of this title as a condition for patentability,

(3) Invalidity of the patent or any claim in suit for failure to comply with any requirement of sections 112 or 251 of this title,

(4) Any other fact or act made a defense by this title.

In actions involving the validity or infringement of a patent the party asserting invalidity or noninfringement shall give notice in the pleadings or otherwise in writing to the adverse party at least thirty days before the trial, of the country, number, date, and name of the patentee of any patent, the title, date, and page numbers of any publication to be relied upon as



anticipation of the patent in suit or, except in actions in the United States Court of Claims, as showing the state of the art, and the name and address of any person who may be relied upon as the prior inventor or as having prior knowledge of or as having previously used or offered for sale the invention of the patent in suit. In the absence of such notice proof of the said matters may not be made at the trial except on such terms as the court requires.

[DEFENSES DURING EXTENDED TERM]

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

*(1) by the applicant for the extension, or*

*(2) by the Commissioner,*

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

V. SEPARABILITY CLAUSE

*[[Sec. 301. If any provision of this Act is declared unconstitutional, or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of this Act and the applicability thereof to other persons and circumstances shall not be affected thereby.]]*