REGULATION (EC) No 1902/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 20 December 2006

amending Regulation 1901/2006 on medicinal products for paediatric use

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee,

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty [1],

Whereas:

(1) The measures necessary for the implementation of Regulation (EC) No 1901/2006 [2] should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [3].

(2) In particular, the Commission should be empowered to define further the grounds for granting a deferral for the initiation or completion of some or all of the measures in the paediatric investigation plan and to specify the maximum amounts as well as the conditions and methods for collection of the financial penalties for infringement of the provisions of Regulation (EC) No 1901/2006 or the implementing measures adopted pursuant to it. Since these measures are of general scope and are designed to supplement Regulation (EC) No 1901/2006 by the addition of new non-essential elements, these measures should be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(3) It is necessary to amend Regulation (EC) No 1901/2006 accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1901/2006 is hereby amended as follows:

1) in Article 20, paragraph 2 shall be replaced by the following:

'2. On the basis of the experience acquired as a result of the operation of this Article, the Commission may adopt provisions, in accordance with the regulatory procedure with scrutiny referred to in Article 51(2), amending or supplementing non-essential elements of this Regulation to define further the grounds for granting a deferral.';

2) in Article 49, paragraph 3 shall be replaced by the following:

'3. At the Agency's request, the Commission may impose financial penalties for infringement of the provisions of this Regulation or the implementing measures adopted pursuant to it in relation to medicinal products authorised through the procedure laid down in Regulation (EC) No 726/2004. Measures amending or supplementing non-essential elements of this Regulation concerning the maximum amounts as well as the conditions and methods for collection of those penalties shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 51(2).';

3) in Article 51, paragraph 2 shall be replaced by the following:

'2. Where reference is made to this paragraph, Article 5a (1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.'.

Article 2

This Regulation shall enter into force on the thirtieth day following that of its publication in the *Official Journal of the European Union*.

[1] Opinion of the European Parliament of 14 December 2006 (not yet published in the Official Journal) and Council Decision of 19 December 2006.

[2] See page 1 of this Official Journal

[3] OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

This Regulation is binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 December 2006

For the European Parliament	*For the Council*
The President	*The President*
J. BORRELL FONTELLES	J. KORKEAOJA

資料２．米国における小児治験推進のための法令
(英文のみ)

1. 変更点一覧

2. 旧版の BPCA 及び PREA

Best Pharmaceuticals for Children Act
Pediatric Research Equity Act

2007 REAUTHORIZATION
Improvements to Existing Law

110th Congress: H.R. 3580

Best Pharmaceuticals for Children Act: Improvements to Existing Law		
Existing Law	**2007 Reauthorization**	**Improvements**
	SEC. 501. SHORT TITLE. This title may be cited as the `Best Pharmaceuticals for Children Act of 2007'. **SEC. 502. REAUTHORIZATION OF BEST PHARMACEUTICALS FOR CHILDREN ACT.** (a) Pediatric Studies of Drugs- (1) IN GENERAL- Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended to read as follows:	
SEC. 505A. [21 U.S.C. 355a] PEDIATRIC STUDIES OF DRUGS. (a) DEFINITIONS.—As used in this section, the term "pediatric studies" or "studies" means at least one clinical investigation (that, at the Secretary's discretion, may include pharmacokinetic studies) in pediatric age groups (including neonates in appropriate cases) in which a drug is anticipated to be used.	**`SEC. 505A. PEDIATRIC STUDIES OF DRUGS.**  `(a) DEFINITIONS.—As used in this section, the term `pediatric studies' or `studies' means at least one clinical investigation (that, at the Secretary's discretion, may include pharmacokinetic studies) in pediatric age groups (including neonates in appropriate cases) in which a drug is anticipated to be used, and, at the discretion of the Secretary, may include preclinical studies.	**Preclinical Studies** Allows FDA to ask for preclinical studies as part of a written request.
(b) MARKET EXCLUSIVITY FOR NEW DRUGS.—If, prior to approval of an application that is submitted under section 505(b)(1), the Secretary determines that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), and such studies are completed within any such timeframe and the reports thereof submitted in accordance with subsection (d)(2) or accepted in accordance with subsection (d)(3)—	`(b) MARKET EXCLUSIVITY FOR NEW DRUGS.—  `(1) IN GENERAL—Except as provided in paragraph (2), if, prior to approval of an application that is submitted under section 505(b)(1), the Secretary determines that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), the applicant agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with	

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	subsection (d)(3)—	
(1)(A)(i) the period referred to in subsection (c)(3)(D)(ii) of section 505, and in subsection (j)(5)(F)(ii)of such section, is deemed to be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and (j)(5)(F)(ii) of such section to four years, to forty-eight months, and to seven and one-half years are deemed to be four and one-half years, fifty-four months, and eight years, respectively; or	`(A)(i)(I) the period referred to in subsection (c)(3)(E)(ii) of section 505, and in subsection (j)(5)(F)(ii) of such section, is deemed to be five years and six months rather than five years, and the references in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of such section to four years, to forty-eight months, and to seven and one-half years are deemed to be four and one-half years, fifty-four months, and eight years, respectively; or	
(ii) the period referred to in clauses (iii) and (iv) of subsection (c)(3)(D) of such section, and in clauses (iii) and (iv) of subsection (j)(5)(F) of such section, is deemed to be three years and six months rather than three years; and	`(II) the period referred to in clauses (iii) and (iv) of subsection (c)(3)(E) of such section, and in clauses (iii) and (iv) of subsection (j)(5)(F) of such section, is deemed to be three years and six months rather than three years; and	
(B) if the drug is designated under section 526 for a rare disease or condition, the period referred to in section 527(a) is deemed to be seven years and six months rather than seven years; and	`(ii) if the drug is designated under section 526 for a rare disease or condition, the period referred to in section 527(a) is deemed to be seven years and six months rather than seven years; and	
(2)(A) if the drug is the subject of—	`(B)(i) if the drug is the subject of—	
(i) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or	`(I) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or	
(ii) a listed patent for which a certification has been submitted under subsections (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,	`(II) a listed patent for which a certification has been submitted under subsections (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,	
the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or	the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or	
(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions).	`(ii) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions).	
	`(2) EXCEPTION—The Secretary shall not extend the period referred to in paragraph (1)(A) or (1)(B) if the determination made	**Market Predictability** Requires that pediatric studies under BPCA be submitted and exclusivity

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	under subsection (d)(3) is made later than 9 months prior to the expiration of such period.	awarded nine months before expiration of patent.
(c) MARKET EXCLUSIVITY FOR ALREADY-MARKETED DRUGS.—If the Secretary determines that information relating to the use of an approved drug in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under section 505(b)(1) for pediatric studies (which shall include a timeframe for completing such studies) , the holder agrees to the request, the studies are completed within any such timeframe, and the reports thereof are submitted in accordance with subsection (d)(2) or accepted in accordance with subsection (d)(3)—	`(c) MARKET EXCLUSIVITY FOR ALREADY-MARKETED DRUGS.—  `(1) IN GENERAL- Except as provided in paragraph (2), if the Secretary determines that information relating to the use of an approved drug in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under section 505(b)(1) for pediatric studies (which shall include a timeframe for completing such studies), the holder agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with subsection (d)(3)—	
(1)(A)(i) the period referred to in subsection (c)(3)(D)(ii) of section 505, and in subsection (j)(5)(F)(ii) of such section, is deemed to be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and (j)(5)(F)(ii) of such section to four years, to forty-eight months, and to seven and one-half years are deemed to be four and one-half years, fifty-four months, and eight years, respectively; or	`(A)(i)(I) the period referred to in subsection (c)(3)(E)(ii) of section 505, and in subsection (j)(5)(F)(ii) of such section, is deemed to be five years and six months rather than five years, and the references in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of such section to four years, to forty-eight months, and to seven and one-half years are deemed to be four and one-half years, fifty-four months, and eight years, respectively; or	
(ii) the period referred to in clauses (iii) and (iv) of subsection (c)(3)(D) of such section, and in clauses (iii) and (iv) of subsection (j)(5)(F) of such section, is deemed to be three years and six months rather than three years; and	`(II) the period referred to in clauses (iii) and (iv) of subsection (c)(3)(D) of such section, and in clauses (iii) and (iv) of subsection (j)(5)(F) of such section, is deemed to be three years and six months rather than three years; and	
(B) if the drug is designated under section 526 for a rare disease or condition, the period referred to in section 527(a) is deemed to be seven years and six months rather than seven years; and	`(ii) if the drug is designated under section 526 for a rare disease or condition, the period referred to in section 527(a) is deemed to be seven years and six months rather than seven years; and	
(2)(A) if the drug is the subject of—	`(B)(i) if the drug is the subject of—	
(i) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or	`(I) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or	
(ii) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,	`(II) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,	
the period during which an application may not be approved under section 505(c)(3) or	the period during which an application may not be approved under section 505(c)(3) or	

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section 505(j)(5)(B)(ii) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or (B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions).	section 505(j)(5)(B)(ii) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or `(ii) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions). `(2) EXCEPTION- The Secretary shall not extend the period referred to in paragraph (1)(A) or (1)(B) if the determination made under subsection (d)(3) is made later than 9 months prior to the expiration of such period.	**Market Predictability** Requires that pediatric studies under BPCA be submitted and exclusivity awarded nine months before expiration of patent.
(d) CONDUCT OF PEDIATRIC STUDIES.—(1) AGREEMENT FOR STUDIES.—The Secretary may, pursuant to a written request from the Secretary under subsection (b) or (c), after consultation with— (A) the sponsor of an application for an investigational new drug under section 505(i); (B) the sponsor of an application for a new drug under section 505(b)(1); or (C) the holder of an approved application for a drug under section 505(b)(1), agree with the sponsor or holder for the conduct of pediatric studies for such drug. Such agreement shall be in writing and shall include a timeframe for such studies.	`(d) CONDUCT OF PEDIATRIC STUDIES.—  `(1) REQUEST FOR STUDIES— `(A) IN GENERAL—The Secretary may, after consultation with the sponsor of an application for an investigational new drug under section 505(i), the sponsor of an application for a new drug under section 505(b)(1), or the holder of an approved application for a drug under section 505(b)(1), issue to the sponsor or holder a written request for the conduct of pediatric studies for such drug. In issuing such request, the Secretary shall take into account adequate representation of children of ethnic and racial minorities. Such request to conduct pediatric studies shall be in writing and shall include a timeframe for such studies and a request to the sponsor or holder to propose pediatric labeling resulting from such studies. `(B) SINGLE WRITTEN REQUEST—A single written request—  `(i) may relate to more than one use of a drug; and `(ii) may include uses that are both approved and unapproved.	**Multiple Drug Uses and On- and Off-Label Written Requests** Allows FDA to issue one study request for more than one use of a drug, and allows FDA to issue one study request to capture both on- and off-label uses.
(2) WRITTEN PROTOCOLS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and the Secretary agree upon written protocols for the studies, the studies requirement of subsection (b) or (c) is satisfied upon the completion of the studies	`(2) WRITTEN REQUEST FOR PEDIATRIC STUDIES—  `(A) REQUEST AND RESPONSE— `(i) IN GENERAL—If the Secretary makes a	

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and submission of the reports thereof in accordance with the original written request and the written agreement referred to in paragraph (1). In reaching an agreement regarding written protocols, the Secretary shall take into account adequate representation of children of ethnic and racial minorities. Not later than 60 days after the submission of the report of the studies, the Secretary shall determine if such studies were or were not conducted in accordance with the original written request and the written agreement and reported in accordance with the requirements of the Secretary for filing and so notify the sponsor or holder.	written request for pediatric studies (including neonates, as appropriate) under subsection (b) or (c), the applicant or holder, not later than 180 days after receiving the written request, shall respond to the Secretary as to the intention of the applicant or holder to act on the request by— `(I) indicating when the pediatric studies will be initiated, if the applicant or holder agrees to the request; or  `(II) indicating that the applicant or holder does not agree to the request and stating the reasons for declining the request.	
	`(ii) DISAGREE WITH REQUEST—If, on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the applicant or holder does not agree to the request on the grounds that it is not possible to develop the appropriate pediatric formulation, the applicant or holder shall submit to the Secretary the reasons such pediatric formulation cannot be developed.	**Pediatric Formulations** Requires a manufacturer who declines a written request on the basis that it was unable to produce a pediatric formulation to submit to FDA the reasons why the formulation cannot be developed.
	`(B) ADVERSE EVENT REPORTS—An applicant or holder that, on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, agrees to the request for such studies shall provide the Secretary, at the same time as the submission of the reports of such studies, with all postmarket adverse event reports regarding the drug that is the subject of such studies and are available prior to submission of such reports.	**Adverse Events** Requires manufacturers to submit all post-market adverse events as part of the exclusivity application or supplement.
(3) OTHER METHODS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and the Secretary have not agreed in writing on the protocols for the studies, the studies requirement of subsection (b) or (c) is satisfied when such studies have been completed and the reports accepted by the Secretary. Not later than 90 days after the submission of the reports of the studies, the Secretary shall accept or reject such reports and so notify the sponsor or holder. The Secretary's only responsibility in accepting or rejecting the reports shall be to determine, within the 90 days, whether the studies fairly respond to the written request, have been conducted in accordance with commonly accepted scientific principles and protocols, and have been reported in accordance with the requirements of the Secretary for filing.	`(3) MEETING THE STUDIES REQUIREMENT—Not later than 180 days after the submission of the reports of the studies, the Secretary shall accept or reject such reports and so notify the sponsor or holder. The Secretary's only responsibility in accepting or rejecting the reports shall be to determine, within the 180-day period, whether the studies fairly respond to the written request, have been conducted in accordance with commonly accepted scientific principles and protocols, and have been reported in accordance with the requirements of the Secretary for filing.	**Time to Review Submitted Studies** Lengthens the period of time FDA has to review submitted studies from 90 to 180 days.
(4) WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS FOR DRUGS THAT HAVE MARKET EXCLUSIVITY— (A) REQUEST AND RESPONSE—If the Secretary makes a written request for		**"Exhaustion" Process** Eliminates "exhaustion" provision in favor of expedited 30-day review before referral to PREA. See subsection (n).

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pediatric studies (including neonates, as appropriate) under subsection (c) to the holder of an application approved under section 505(b)(1), the holder, not later than 180 days after receiving the written request, shall respond to the Secretary as to the intention of the holder to act on the request by— (i) indicating when the pediatric studies will be initiated, if the holder agrees to the request; or (ii) indicating that the holder does not agree to the request. (B) NO AGREEMENT TO REQUEST— (i) REFERRAL—If the holder does not agree to a written request within the time period specified in subparagraph (A), and if the Secretary determines that there is a continuing need for information relating to the use of the drug in the pediatric population (including neonates, as appropriate), the Secretary shall refer the drug to the Foundation for the National Institutes of Health established under section 499 of the Public Health Service Act (42 U.S.C. 290b) (referred to in this paragraph as the `Foundation') for the conduct of the pediatric studies described in the written request. (ii) PUBLIC NOTICE—The Secretary shall give public notice of the name of the drug, the name of the manufacturer, and the indications to be studied made in a referral under clause (i). (C) LACK OF FUNDS—On referral of a drug under subparagraph (B)(i), the Foundation shall issue a proposal to award a grant to conduct the requested studies unless the Foundation certifies to the Secretary, within a timeframe that the Secretary determines is appropriate through guidance, that the Foundation does not have funds available under section 499(j)(9)(B)(i) to conduct the requested studies. If the Foundation so certifies, the Secretary shall refer the drug for inclusion on the list established under section 409I of the Public Health Service Act for the conduct of the studies. (D) EFFECT OF SUBSECTION—Nothing in this subsection (including with respect to referrals from the Secretary to the Foundation) alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code. (E) NO REQUIREMENT TO REFER—Nothing in this subsection shall be construed to require that every declined	`(4) EFFECT OF SUBSECTION—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.	

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written request shall be referred to the Foundation. (F) WRITTEN REQUESTS UNDER SUBSECTION (b)—For drugs under subsection (b) for which written requests have not been accepted, if the Secretary determines that there is a continuing need for information relating to the use of the drug in the pediatric population (including neonates, as appropriate), the Secretary shall issue a written request under subsection (c) after the date of approval of the drug. (e) DELAY OF EFFECTIVE DATE FOR CERTAIN APPLICATION.—If the Secretary determines that the acceptance or approval of an application under section 505(b)(2) or 505(j) for a new drug may occur after submission of reports of pediatric studies under this section, which were submitted prior to the expiration of the patent (including any patent extension) or the applicable period under clauses (ii) through (iv) of section 505(c)(3)(D) or clauses (ii) through (iv) of section 505(j)(5)(F), but before the Secretary has determined whether the requirements of subsection (d) have been satisfied, the Secretary shall delay the acceptance or approval under section 505(b)(2) or 505(j) until the determination under subsection (d) is made, but any such delay shall not exceed 90 days. In the event that requirements of this section are satisfied, the applicable six month period under subsection (b) or (c) shall be deemed to have been running during the period of delay.		
(f) NOTICE OF DETERMINATIONS ON STUDIES REQUIREMENT.—The Secretary shall publish a notice of any determination that the requirements of subsection (d) have been met and that submissions and approvals under subsection (b)(2) or (j) of section 505 for a drug will be subject to the provisions of this section.	`(e) NOTICE OF DETERMINATIONS ON STUDIES REQUIREMENT.—  `(1) IN GENERAL—The Secretary shall publish a notice of any determination, made on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, that the requirements of subsection (d) have been met and that submissions and approvals under subsection (b)(2) or (j) of section 505 for a drug will be subject to the provisions of this section. Such notice shall be published not later than 30 days after the date of the Secretary's determination regarding market exclusivity and shall include a copy of the written request made under subsection (b) or (c). `(2) IDENTIFICATION OF CERTAIN DRUGS—The Secretary shall publish a notice identifying any drug for which, on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, a pediatric formulation was developed, studied, and found to be safe and effective	**Written Requests Public** Requires FDA to make study requests public after the drug has been granted exclusivity. **Pediatric Formulations Not Marketed** Requires prominent public disclosure when a manufacturer creates a pediatric formulation and refuses to market it.

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	in the pediatric population (or specified subpopulation) if the pediatric formulation for such drug is not introduced onto the market within one year after the date that the Secretary publishes the notice described in paragraph (1). Such notice identifying such drug shall be published not later than 30 days after the date of the expiration of such one year period.	
	`(f) INTERNAL REVIEW OF WRITTEN REQUESTS AND PEDIATRIC STUDIES—	**Internal Review of Written Requests** Requires new internal committee to review written requests prior to issue.
	`(1) INTERNAL REVIEW—The Secretary shall utilize the internal review committee established under section 505C to review all written requests issued on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, in accordance with paragraph (2).	
	`(2) REVIEW OF WRITTEN REQUESTS—The committee referred to in paragraph (1) shall review all written requests issued pursuant to this section prior to being issued.	
	`(3) REVIEW OF PEDIATRIC STUDIES—The committee referred to in paragraph (1) may review studies conducted pursuant to this section to make a recommendation to the Secretary whether to accept or reject such reports under subsection (d)(3).	**Internal Review of Studies** Provides committee authority to review studies submitted in response to a written request, as needed.
	`(4) ACTIVITY BY COMMITTEE- The committee referred to in paragraph (1) may operate using appropriate members of such committee and need not convene all members of the committee.	
	`(5) DOCUMENTATION OF COMMITTEE ACTION—For each drug, the committee referred to in paragraph (1) shall document, for each activity described in paragraph (2) or (3), which members of the committee participated in such activity.	
	`(6) TRACKING PEDIATRIC STUDIES AND LABELING CHANGES—The Secretary, in consultation with the committee referred to in paragraph (1), shall track and make available to the public, in an easily accessible manner, including through posting on the Web site of the Food and Drug Administration—	**Tracking** Requires FDA to track the number and type of studies completed, as well as labeling changes and other data resulting from BPCA.
	`(A) the number of studies conducted under this section and under section 409I of the Public Health Service Act;	
	`(B) the specific drugs and drug uses, including labeled and off-labeled indications, studied under such sections;	
	`(C) the types of studies conducted under	

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	such sections, including trial design, the number of pediatric patients studied, and the number of centers and countries involved; `(D) the number of pediatric formulations developed and the number of pediatric formulations not developed and the reasons such formulations were not developed;  `(E) the labeling changes made as a result of studies conducted under such sections; `(F) an annual summary of labeling changes made as a result of studies conducted under such sections for distribution pursuant to subsection (k)(2); and  `(G) information regarding reports submitted on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007.	
(g) LIMITATIONS.—A drug to which the six-month period under subsection (b) or (c) has already been applied—	`(g) LIMITATIONS.—Notwithstanding subsection (c)(2), a drug to which the six-month period under subsection (b) or (c) has already been applied—	
(1) may receive an additional six-month period under subsection (c)(1)(A)(ii) for a supplemental application if all other requirements under this section are satisfied, except that such a drug may not receive any additional such period under subsection (c)(2); and	`(1) may receive an additional six-month period under subsection (c)(1)(A)(i)(II) for a supplemental application if all other requirements under this section are satisfied, except that such drug may not receive any additional such period under subsection (c)(1)(B); and	
(2) may not receive any additional such period under subsection (c)(1)(B).	`(2) may not receive any additional such period under subsection (c)(1)(A)(ii).	
(h) RELATIONSHIP TO PEDIATRIC RESEARCH REQUIREMENTS.—Notwithstanding any other provision of law, if any pediatric study is required by a provision of law (including a regulation) other than this section and such study meets the completeness, timeliness, and other requirements of this section, such study shall be deemed to satisfy the requirement for market exclusivity pursuant to this section.	`(h) RELATIONSHIP TO PEDIATRIC RESEARCH REQUIREMENTS.—Notwithstanding any other provision of law, if any pediatric study is required by a provision of law (including a regulation) other than this section and such study meets the completeness, timeliness, and other requirements of this section, such study shall be deemed to satisfy the requirement for market exclusivity pursuant to this section.	
(i) LABELING SUPPLEMENTS—	`(i) LABELING CHANGES—	
(1) PRIORITY STATUS FOR PEDIATRIC SUPPLEMENTS—Any supplement to an application under section 505 proposing a labeling change pursuant to a report on a pediatric study under this section—	`(1) PRIORITY STATUS FOR PEDIATRIC APPLICATIONS AND SUPPLEMENTS—Any application or supplement to an application under section 505 proposing a labeling change as a result of any pediatric study conducted pursuant to this section—	
(A) shall be considered to be a priority supplement; and	`(A) shall be considered to be a priority application or supplement; and	
(B) shall be subject to the performance goals established by the Commissioner for	`(B) shall be subject to the performance goals established by the Commissioner for	

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priority drugs.	priority drugs.	
(2) DISPUTE RESOLUTION—	`(2) DISPUTE RESOLUTION—	**Dispute Resolution** Reduces overall time period for resolving disputes over labeling and removes the current dispute resolution provision requiring labeling to be the only remaining open issue before referral for resolution. Applies the dispute resolution process to all drugs issued study requests, not just those granted exclusivity.
(A) REQUEST FOR LABELING CHANGE AND FAILURE TO AGREE—If the Commissioner determines that an application with respect to which a pediatric study is conducted under this section is approvable and that the only open issue for final action on the application is the reaching of an agreement between the sponsor of the application and the Commissioner on appropriate changes to the labeling for the drug that is the subject of the application, not later than 180 days after the date of submission of the application—	`(A) REQUEST FOR LABELING CHANGE AND FAILURE TO AGREE—If, on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Commissioner determines that the sponsor and the Commissioner have been unable to reach agreement on appropriate changes to the labeling for the drug that is the subject of the application, not later than 180 days after the date of submission of the application—	
(i) the Commissioner shall request that the sponsor of the application make any labeling change that the Commissioner determines to be appropriate; and	`(i) the Commissioner shall request that the sponsor of the application make any labeling change that the Commissioner determines to be appropriate; and	
(ii) if the sponsor of the application does not agree to make a labeling change requested by the Commissioner, the Commissioner shall refer the matter to the Pediatric Advisory Committee.	`(ii) if the sponsor of the application does not agree within 30 days after the Commissioner's request to make a labeling change requested by the Commissioner, the Commissioner shall refer the matter to the Pediatric Advisory Committee.	
(B) ACTION BY THE PEDIATRIC ADVISORY SUBCOMMITTEE OF THE ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE—Not later than 90 days after receiving a referral under subparagraph (A)(ii), the Pediatric Advisory Committee shall—	`(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE—Not later than 90 days after receiving a referral under subparagraph (A)(ii), the Pediatric Advisory Committee shall—	
(i) review the pediatric study reports; and	`(i) review the pediatric study reports; and	
(ii) make a recommendation to the Commissioner concerning appropriate labeling changes, if any.	`(ii) make a recommendation to the Commissioner concerning appropriate labeling changes, if any.	
(C) CONSIDERATION OF RECOMMENDATIONS—The Commissioner shall consider the recommendations of the Pediatric Advisory Committee and, if appropriate, not later than 30 days after receiving the recommendation, make a request to the sponsor of the application to make any labeling change that the Commissioner determines to be appropriate.	`(C) CONSIDERATION OF RECOMMENDATIONS—The Commissioner shall consider the recommendations of the Pediatric Advisory Committee and, if appropriate, not later than 30 days after receiving the recommendation, make a request to the sponsor of the application to make any labeling change that the Commissioner determines to be appropriate.	
(D) MISBRANDING—If the sponsor of the application, within 30 days after receiving a request under subparagraph (C), does not agree to make a labeling change requested by the Commissioner, the Commissioner may deem the drug that is the subject of the application to be misbranded.	`(D) MISBRANDING—If the sponsor of the application, within 30 days after receiving a request under subparagraph (C), does not agree to make a labeling change requested by the Commissioner, the Commissioner may deem the drug that is the subject of the application to be misbranded.	
(E) NO EFFECT ON AUTHORITY—Nothing in this subsection limits the authority of the	`(E) NO EFFECT ON AUTHORITY—Nothing in this subsection limits the	

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United States to bring an enforcement action under this Act when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.	authority of the United States to bring an enforcement action under this Act when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.	
	`(j) OTHER LABELING CHANGES—If, on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary determines that a pediatric study conducted under this section does or does not demonstrate that the drug that is the subject of the study is safe and effective, including whether such study results are inconclusive, in pediatric populations or subpopulations, the Secretary shall order the labeling of such product to include information about the results of the study and a statement of the Secretary's determination.	**Labeling Authority** Gives FDA explicit authority to indicate on a label when a product has been studied in children.
(j) DISSEMINATION OF PEDIATRIC INFORMATION—	`(k) DISSEMINATION OF PEDIATRIC INFORMATION—	
(1) IN GENERAL- Not later than 180 days after the date of submission of a report on a pediatric study under this section, the Commissioner shall make available to the public a summary of the medical and clinical pharmacology reviews of pediatric studies conducted for the supplement, including by publication in the Federal Register.	`(1) IN GENERAL—Not later than 210 days after the date of submission of a report on a pediatric study under this section, the Secretary shall make available to the public the medical, statistical, and clinical pharmacology reviews of pediatric studies conducted under subsection (b) or (c).	**Reviews Made Public** Requires Secretary to make publicly available the actual medical, statistical, and clinical pharmacology reviews, not summaries.
	`(2) DISSEMINATION OF INFORMATION REGARDING LABELING CHANGES—Beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary shall include as a requirement of a written request that the sponsors of the studies that result in labeling changes that are reflected in the annual summary developed pursuant to subsection (f)(3)(F) distribute, at least annually (or more frequently if the Secretary determines that it would be beneficial to the public health), such information to physicians and other health care providers.	**Dissemination Requirements** Requires sponsors who have been granted exclusivity to provide physicians and other health care providers with any new pediatric labeling information.
(2) EFFECT OF SUBSECTION—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.'.	`(3) EFFECT OF SUBSECTION—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.	
[The following section on adverse event reporting is from PL107-109. It was never codified.]		
SEC. 17. ADVERSE-EVENT REPORTING.	`(l) ADVERSE EVENT REPORTING—	**Adverse Event Reporting** Continues the requirement that all adverse events be reviewed by the Pediatric Advisory Committee for one
(b) DRUGS WITH PEDIATRIC MARKET EXCLUSIVITY—	`(1) REPORTING IN YEAR ONE—Beginning on the date of the enactment of	

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(1) IN GENERAL—During the one year beginning on the date on which a drug receives a period of market exclusivity under 505A of the Federal Food, Drug, and Cosmetic Act, any report of an adverse event regarding the drug that the Secretary of Health and Human Services receives shall be referred to the Office of Pediatric Therapeutics established under section 6 of this Act. In considering the report, the Director of such Office shall provide for the review of the report by the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee, including obtaining any recommendations of such subcommittee regarding whether the Secretary should take action under the Federal Food, Drug, and Cosmetic Act in response to the report.	the Best Pharmaceuticals for Children Act of 2007, during the one-year period beginning on the date a labeling change is approved pursuant to subsection (i), the Secretary shall ensure that all adverse event reports that have been received for such drug (regardless of when such report was received) are referred to the Office of Pediatric Therapeutics established under section 6 of the Best Pharmaceuticals for Children Act (Public Law 107-109). In considering the reports, the Director of such Office shall provide for the review of the reports by the Pediatric Advisory Committee, including obtaining any recommendations of such Committee regarding whether the Secretary should take action under this Act in response to such reports.	year following the awarding of exclusivity. Provides for additional reporting after year one, as needed.
(2) RULE OF CONSTRUCTION—Paragraph (1) may not be construed as restricting the authority of the Secretary of Health and Human Services to continue carrying out the activities described in such paragraph regarding a drug after the one-year period described in such paragraph regarding the drug has expired.	`(2) REPORTING IN SUBSEQUENT YEARS—Following the one-year period described in paragraph (1), the Secretary shall, as appropriate, refer to the Office of Pediatric Therapeutics all pediatric adverse event reports for a drug for which a pediatric study was conducted under this section. In considering such reports, the Director of such Office may provide for the review of such reports by the Pediatric Advisory Committee, including obtaining any recommendation of such Committee regarding whether the Secretary should take action in response to such reports. `(3) EFFECT—The requirements of this subsection shall supplement, not supplant, other review of such adverse event reports by the Secretary.	
(k) CLARIFICATION OF INTERACTION OF MARKET EXCLUSIVITY UNDER THIS SECTION AND MARKET EXCLUSIVITY AWARDED TO AN APPLICANT FOR APPROVAL OF A DRUG UNDER SECTION 505(j)—If a 180-day period under section 505(j)(5)(B)(iv) overlaps with a 6-month exclusivity period under this section, so that the applicant for approval of a drug under section 505(j) entitled to the 180-day period under that section loses a portion of the 180-day period to which the applicant is entitled for the drug, the 180-day period shall be extended from— (1) the date on which the 180-day period would have expired by the number of days of the overlap, if the 180-day period would, but for the application of this subsection, expire after the 6-month exclusivity period; or (2) the date on which the 6-month exclusivity period expires, by the number of days of the overlap if the 180-day period	`(m) CLARIFICATION OF INTERACTION OF MARKET EXCLUSIVITY UNDER THIS SECTION AND MARKET EXCLUSIVITY AWARDED TO AN APPLICANT FOR APPROVAL OF A DRUG UNDER SECTION 505(j)—If a 180-day period under section 505(j)(5)(B)(iv) overlaps with a 6-month exclusivity period under this section, so that the applicant for approval of a drug under section 505(j) entitled to the 180-day period under that section loses a portion of the 180-day period to which the applicant is entitled for the drug, the 180-day period shall be extended from— `(1) the date on which the 180-day period would have expired by the number of days of the overlap, if the 180-day period would, but for the application of this subsection, expire after the 6-month exclusivity period; or  `(2) the date on which the 6-month exclusivity period expires, by the number of days of the overlap if the 180-day period	

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would, but for the application of this subsection, expire during the six-month exclusivity period.	would, but for the application of this subsection, expire during the six-month exclusivity period.	
	`(n) REFERRAL IF PEDIATRIC STUDIES NOT COMPLETED—	**Referral to PREA** If study is declined by the manufacturer, requires FDA to determine whether the drug should be studied under PREA. If applicable, FDA will report why it did not use PREA.
	`(1) IN GENERAL- Beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, if pediatric studies of a drug have not been completed under subsection (d) and if the Secretary, through the committee established under section 505C, determines that there is a continuing need for information relating to the use of the drug in the pediatric population (including neonates, as appropriate), the Secretary shall carry out the following:	
	`(A) For a drug for which a listed patent has not expired, make a determination regarding whether an assessment shall be required to be submitted under section 505B(b). Prior to making such a determination, the Secretary may not take more than 30 days to certify whether the Foundation for the National Institutes of Health has sufficient funding at the time of such certification to initiate and fund all of the studies in the written request in their entirety within the timeframes specified within the written request. Only if the Secretary makes such certification in the affirmative, the Secretary shall refer all pediatric studies in the written request to the Foundation for the National Institutes of Health for the conduct of such studies, and such Foundation shall fund such studies. If no certification has been made at the end of the 30-day period, or if the Secretary certifies that funds are not sufficient to initiate and fund all the studies in their entirety, the Secretary shall consider whether assessments shall be required under section 505B(b) for such drug.	**Shorter Period Before Referral** Allows only 30 days to determine if private donations are available to completely fund all studies in a declined written request before referral to PREA.
	`(B) For a drug that has no listed patents or has 1 or more listed patents that have expired, the Secretary shall refer the drug for inclusion on the list established under section 409I of the Public Health Service Act for the conduct of studies.	
	`(2) PUBLIC NOTICE—The Secretary shall give the public notice of a decision under paragraph (1)(A) not to require an assessment under section 505B and the basis for such decision.	
	`(3) EFFECT OF SUBSECTION—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.	
(l) PROMPT APPROVAL OF DRUGS UNDER SECTION 505(j) WHEN	`(o) PROMPT APPROVAL OF DRUGS UNDER SECTION 505(J) WHEN	

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PEDIATRIC INFORMATION IS ADDED TO LABELING—	PEDIATRIC INFORMATION IS ADDED TO LABELING—	
(1) GENERAL RULE—A drug for which an application has been submitted or approved under section 505(j) shall not be considered ineligible for approval under that section or misbranded under section 502 on the basis that the labeling of the drug omits a pediatric indication or any other aspect of labeling pertaining to pediatric use when the omitted indication or other aspect is protected by patent or by exclusivity under clause (iii) or (iv) of section 505(j)(5)(F).	`(1) GENERAL RULE—A drug for which an application has been submitted or approved under section 505(j) shall not be considered ineligible for approval under that section or misbranded under section 502 on the basis that the labeling of the drug omits a pediatric indication or any other aspect of labeling pertaining to pediatric use when the omitted indication or other aspect is protected by patent or by exclusivity under clause (iii) or (iv) of section 505(j)(5)(F).	
(2) LABELING—Notwithstanding clauses (iii) and (iv) of section 505(j)(5)(F), the Secretary may require that the labeling of a drug approved under section 505(j) that omits a pediatric indication or other aspect of labeling as described in paragraph (1) include—	`(2) LABELING—Notwithstanding clauses (iii) and (iv) of section 505(j)(5)(F), the Secretary may require that the labeling of a drug approved under section 505(j) that omits a pediatric indication or other aspect of labeling as described in paragraph (1) include—	
(A) a statement that, because of marketing exclusivity for a manufacturer—	`(A) a statement that, because of marketing exclusivity for a manufacturer—	
(i) the drug is not labeled for pediatric use; or	`(i) the drug is not labeled for pediatric use; or	
(ii) in the case of a drug for which there is an additional pediatric use not referred to in paragraph (1), the drug is not labeled for the pediatric use under paragraph (1); and	`(ii) in the case of a drug for which there is an additional pediatric use not referred to in paragraph (1), the drug is not labeled for the pediatric use under paragraph (1); and	
(B) a statement of any appropriate pediatric contraindications, warnings, or precautions that the Secretary considers necessary.	`(B) a statement of any appropriate pediatric contraindications, warnings, or precautions that the Secretary considers necessary.	
(3) PRESERVATION OF PEDIATRIC EXCLUSIVITY AND OTHER PROVISIONS—This subsection does not affect—	`(3) PRESERVATION OF PEDIATRIC EXCLUSIVITY AND OTHER PROVISIONS—This subsection does not affect—	
(A) the availability or scope of exclusivity under this section;	`(A) the availability or scope of exclusivity under this section;	
(B) the availability or scope of exclusivity under section 505 for pediatric formulations;	`(B) the availability or scope of exclusivity under section 505 for pediatric formulations;	
(C) the question of the eligibility for approval of any application under section 505(j) that omits any other conditions of approval entitled to exclusivity under clause (iii) or (iv) of section 505(j)(5)(F); or	`(C) the question of the eligibility for approval of any application under section 505(j) that omits any other conditions of approval entitled to exclusivity under clause (iii) or (iv) of section 505(j)(5)(F); or	
(D) except as expressly provided in paragraphs (1) and (2), the operation of section 505.	`(D) except as expressly provided in paragraphs (1) and (2), the operation of section 505.	
(m) REPORT.—The Secretary shall conduct a study and report to Congress not later than January 1, 2001, based on the experience under the program established under this section. The study and report shall examine all relevant issues,		

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including— (1) the effectiveness of the program in improving information about important pediatric uses for approved drugs; (2) the adequacy of the incentive provided under this section; (3) the economic impact of the program on taxpayers and consumers, including the impact of the lack of lower cost generic drugs on patients, including on lower income patients; and (4) any suggestions for modification that the Secretary determines to be appropriate.		
	`(p) INSTITUTE OF MEDICINE STUDY—Not later than 3 years after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary shall enter into a contract with the Institute of Medicine to conduct a study and report to Congress regarding the written requests made and the studies conducted pursuant to this section. The Institute of Medicine may devise an appropriate mechanism to review a representative sample of requests made and studies conducted pursuant to this section in order to conduct such study. Such study shall-- `(1) review such representative written requests issued by the Secretary since 1997 under subsections (b) and (c);  `(2) review and assess such representative pediatric studies conducted under subsections (b) and (c) since 1997 and labeling changes made as a result of such studies; `(3) review the use of extrapolation for pediatric subpopulations, the use of alternative endpoints for pediatric populations, neonatal assessment tools, and ethical issues in pediatric clinical trials;  `(4) review and assess the pediatric studies of biological products as required under subsections (a) and (b) of section 505B; and `(5) make recommendations regarding appropriate incentives for encouraging pediatric studies of biologics.	**IOM Study** Asks the Institute of Medicine to review past written requests issued by FDA and make recommendations to FDA for future requests.
(n) SUNSET—A drug may not receive any 6-month period under subsection (b) or (c) unless— (1) on or before October 1, 2007 , the Secretary makes a written request for pediatric studies of the drug;	`(q) SUNSET—A drug may not receive any 6-month period under subsection (b) or (c) unless—  `(1) on or before October 1, 2012, the Secretary makes a written request for pediatric studies of the drug;	**Extension** Extends BPCA until October 1, 2012.

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(2) on or before October 1, 2007 , an application for the drug is accepted for filing under section 505(b); and (3) all requirements of this section are met.	`(2) on or before October 1, 2012, an application for the drug is accepted for filing under section 505(b); and  `(3) all requirements of this section are met.'. (2) APPLICABILITY— (A) IN GENERAL—The amendment made by this subsection shall apply to written requests under section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) issued on or after the date of the enactment of this Act. (B) CERTAIN WRITTEN REQUESTS—A written request issued under section 505A of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date of the enactment of this Act, which has been accepted and for which no determination under subsection (d)(2) of such section has been made before such date of enactment, shall be subject to such section 505A, except that such written requests shall be subject to subsections (d)(2)(A)(ii), (e)(1) and (2), (f), (i)(2)(A), (j), (k)(1), (l)(1), and (n) of section 505A of the Federal Food, Drug, and Cosmetic Act, as in effect on or after the date of the enactment of this Act. (b) PROGRAM FOR PEDIATRIC STUDIES OF DRUGS— Section 409I of the Public Health Service Act (42 U.S.C. 284m) is amended to read as follows:	
SEC. 409I. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS. (a) LIST OF DRUGS FOR WHICH PEDIATRIC STUDIES ARE NEEDED.— (1) IN GENERAL.—Not later than one year after the date of enactment of this section, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs and experts in pediatric research, shall develop, prioritize, and publish an annual list of approved drugs for which— (A)(i) there is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)); (ii) there is a submitted application that could be approved under the criteria of section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)); (iii) there is no patent protection or market exclusivity protection under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); or	**`SEC. 409I. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.**  `(a) LIST OF PRIORITY ISSUES IN PEDIATRIC THERAPEUTICS— `(1) IN GENERAL—Not later than one year after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs and experts in pediatric research, shall develop and publish a priority list of needs in pediatric therapeutics, including drugs or indications that require study. The list shall be revised every three years.	**Needs in Pediatric Therapeutics** Provides expanded authority for NIH to examine needs in pediatric therapeutics, including drugs.

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(iv) there is a referral for inclusion on the list under section 505A(d)(4)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(d)(4)(C)); and (B) in the case of a drug referred to in clause (i), (ii), or (iii) of subparagraph (A), additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population.		
(2) CONSIDERATION OF AVAILABLE INFORMATION.—In developing and prioritizing the list under paragraph (1), the Secretary shall consider for each drug on the list—	`(2) CONSIDERATION OF AVAILABLE INFORMATION- In developing and prioritizing the list under paragraph (1), the Secretary shall consider—	
(A) the availability of information concerning the safe and effective use of the drug in the pediatric population; (B) whether additional information is needed;	`(A) therapeutic gaps in pediatrics that may include developmental pharmacology, pharmacogenetic determinants of drug response, metabolism of drugs and biologics in children, and pediatric clinical trials;	
(C) whether new pediatric studies concerning the drug may produce health benefits in the pediatric population; and (D) whether reformulation of the drug is necessary.	`(B) particular pediatric diseases, disorders or conditions where more complete knowledge and testing of therapeutics, including drugs and biologics, may be beneficial in pediatric populations; and  `(C) the adequacy of necessary infrastructure to conduct pediatric pharmacological research, including research networks and trained pediatric investigators.	
(b) CONTRACTS FOR PEDIATRIC STUDIES.—The Secretary shall award contracts to entities that have the expertise to conduct pediatric clinical trials (including qualified universities, hospitals, laboratories, contract research organizations, federally funded programs such as pediatric pharmacology research units, other public or private institutions, or individuals) to enable the entities to conduct pediatric studies concerning one or more drugs identified in the list described in subsection (a).	`(b) PEDIATRIC STUDIES AND RESEARCH—The Secretary, acting through the National Institutes of Health, shall award funds to entities that have the expertise to conduct pediatric clinical trials or other research (including qualified universities, hospitals, laboratories, contract research organizations, practice groups, federally funded programs such as pediatric pharmacology research units, other public or private institutions, or individuals) to enable the entities to conduct the drug studies or other research on the issues described in subsection (a). The Secretary may use contracts, grants, or other appropriate funding mechanisms to award funds under this subsection.	
(c) PROCESS FOR CONTRACTS AND LABELING CHANGES.—	`(c) PROCESS FOR PROPOSED PEDIATRIC STUDY REQUESTS AND LABELING CHANGES—	
(1) WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS FOR DRUGS LACKING EXCLUSIVITY.—The Commissioner of Food and Drugs, in consultation with the Director of the National Institutes of Health, may issue a written	`(1) SUBMISSION OF PROPOSED PEDIATRIC STUDY REQUEST—The Director of the National Institutes of Health shall, as appropriate, submit proposed pediatric study requests for consideration by the Commissioner of Food and Drugs for	**Studies for Drug Labeling** Streamlines process by which NIH studies drugs for labeling.