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request (which shall include a timeframe for negotiations for an agreement) for pediatric studies concerning a drug identified in the list described in subsection (a)(1)(A) (except clause (iv)) to all holders of an approved application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act. Such a written request shall be made in a manner equivalent to the manner in which a written request is made under subsection (a) or (b) of section 505A of the Federal Food, Drug, and Cosmetic Act, including with respect to information provided on the pediatric studies to be conducted pursuant to the request.	pediatric studies of a specific pediatric indication identified under subsection (a). Such a proposed pediatric study request shall be made in a manner equivalent to a written request made under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act, including with respect to the information provided on the pediatric studies to be conducted pursuant to the request. The Director of the National Institutes of Health may submit a proposed pediatric study request for a drug for which— `(A)(i) there is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act; or  `(ii) there is a submitted application that could be approved under the criteria of such section; and `(B) there is no patent protection or market exclusivity protection for at least one form of the drug under the Federal Food, Drug, and Cosmetic Act; and  `(C) additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population. `(2) 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 request based on the proposed pediatric study request for the indication or indications submitted pursuant to paragraph (1) (which shall include a timeframe for negotiations for an agreement) for pediatric studies concerning a drug identified under subsection (a) to all holders of an approved application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act. Such a written request shall be made in a manner equivalent to the manner in which a written request is made under subsection (b) or (c) of section 505A of such Act, including with respect to information provided on the pediatric studies to be conducted pursuant to the request and using appropriate formulations for each age group for which the study is requested.	
(2) REQUESTS FOR CONTRACT PROPOSALS.—If the Commissioner of Food and Drugs does not receive a response to a written request issued under paragraph (1) within 30 days of the date on which a request was issued, or if a referral described in subsection (a)(1)(A)(iv) is made, the Secretary, acting through the Director of the National Institutes of Health	`(3) REQUESTS FOR PROPOSALS—If the Commissioner of Food and Drugs does not receive a response to a written request issued under paragraph (2) not later than 30 days after the date on which a request was issued, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs, shall publish a request	

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and in consultation with the Commissioner of Food and Drugs, shall publish a request for contract proposals to conduct the pediatric studies described in the written request.	for proposals to conduct the pediatric studies described in the written request in accordance with subsection (b).	
(3) DISQUALIFICATION.—A holder that receives a first right of refusal shall not be entitled to respond to a request for contract proposals under paragraph (2).	`(4) DISQUALIFICATION—A holder that receives a first right of refusal shall not be entitled to respond to a request for proposals under paragraph (3).	
(4) GUIDANCE.—Not later than 270 days after the date of enactment of this section, the Commissioner of Food and Drugs shall promulgate guidance to establish the process for the submission of responses to written requests under paragraph (1).		
(5) CONTRACTS.—A contract under this section may be awarded only if a proposal for the contract is submitted to the Secretary in such form and manner, and containing such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.	`(5) CONTRACTS, GRANTS, OR OTHER FUNDING MECHANISMS—A contract, grant, or other funding may be awarded under this section only if a proposal is submitted to the Secretary in such form and manner, and containing such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.	
(6) REPORTING OF STUDIES.—	`(6) REPORTING OF STUDIES—	
(A) IN GENERAL.—On completion of a pediatric study in accordance with a contract awarded under this section, a report concerning the study shall be submitted to the Director of the National Institutes of Health and the Commissioner of Food and Drugs. The report shall include all data generated in connection with the study.	`(A) IN GENERAL—On completion of a pediatric study in accordance with an award under this section, a report concerning the study shall be submitted to the Director of the National Institutes of Health and the Commissioner of Food and Drugs. The report shall include all data generated in connection with the study, including a written request if issued.	
(B) AVAILABILITY OF REPORTS.—Each report submitted under subparagraph (A) shall be considered to be in the public domain (subject to section 505A(d)(4)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(d)(4)(D)) and shall be assigned a docket number by the Commissioner of Food and Drugs. An interested person may submit written comments concerning such pediatric studies to the Commissioner of Food and Drugs, and the written comments shall become part of the docket file with respect to each of the drugs.	`(B) AVAILABILITY OF REPORTS—Each report submitted under subparagraph (A) shall be considered to be in the public domain (subject to section 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act) and shall be assigned a docket number by the Commissioner of Food and Drugs. An interested person may submit written comments concerning such pediatric studies to the Commissioner of Food and Drugs, and the written comments shall become part of the docket file with respect to each of the drugs.	
(C) ACTION BY COMMISSIONER.—The Commissioner of Food and Drugs shall take appropriate action in response to the reports submitted under subparagraph (A) in accordance with paragraph (7).	`(C) ACTION BY COMMISSIONER—The Commissioner of Food and Drugs shall take appropriate action in response to the reports submitted under subparagraph (A) in accordance with paragraph (7).	
(7) REQUESTS FOR LABELING CHANGE.—During the 180-day period after the date on which a report is submitted under paragraph (6)(A), the Commissioner	`(7) REQUESTS FOR LABELING CHANGE—During the 180-day period after the date on which a report is submitted under paragraph (6)(A), the Commissioner	

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of Food and Drugs shall—	of Food and Drugs shall—	
(A) review the report and such other data as are available concerning the safe and effective use in the pediatric population of the drug studied;	`(A) review the report and such other data as are available concerning the safe and effective use in the pediatric population of the drug studied;	
(B) negotiate with the holders of approved applications for the drug studied for any labeling changes that the Commissioner of Food and Drugs determines to be appropriate and requests the holders to make; and	`(B) negotiate with the holders of approved applications for the drug studied for any labeling changes that the Commissioner of Food and Drugs determines to be appropriate and requests the holders to make; and	
(C)(i) place in the public docket file a copy of the report and of any requested labeling changes; and	`(C)(i) place in the public docket file a copy of the report and of any requested labeling changes; and	
(ii) publish in the Federal Register a summary of the report and a copy of any requested labeling changes.	`(ii) publish in the Federal Register and through a posting on the Web site of the Food and Drug Administration a summary of the report and a copy of any requested labeling changes.	
(8) DISPUTE RESOLUTION.—	`(8) DISPUTE RESOLUTION—	
(A) REFERRAL TO PEDIATRIC ADVISORY SUBCOMMITTEE OF THE ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE.—If, not later than the end of the 180-day period specified in paragraph (7), the holder of an approved application for the drug involved does not agree to any labeling change requested by the Commissioner of Food and Drugs under that paragraph, the Commissioner of Food and Drugs shall refer the request to the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee.	`(A) REFERRAL TO PEDIATRIC ADVISORY COMMITTEE—If, not later than the end of the 180-day period specified in paragraph (7), the holder of an approved application for the drug involved does not agree to any labeling change requested by the Commissioner of Food and Drugs under that paragraph, the Commissioner of Food and Drugs shall refer the request 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), the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee shall—	`(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE—Not later than 90 days after receiving a referral under subparagraph (A), the Pediatric Advisory Committee shall–	
(i) review the available information on the safe and effective use of the drug in the pediatric population, including study reports submitted under this section; and	`(i) review the available information on the safe and effective use of the drug in the pediatric population, including study reports submitted under this section; and	
(ii) make a recommendation to the Commissioner of Food and Drugs as to appropriate labeling changes, if any.	`(ii) make a recommendation to the Commissioner of Food and Drugs as to appropriate labeling changes, if any.	
(9) FDA DETERMINATION.—Not later than 30 days after receiving a recommendation from the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee under paragraph (8)(B)(ii) with respect to a drug, the Commissioner of Food and Drugs shall consider the	`(9) FDA DETERMINATION—Not later than 30 days after receiving a recommendation from the Pediatric Advisory Committee under paragraph (8)(B)(ii) with respect to a drug, the Commissioner of Food and Drugs shall consider the recommendation and, if appropriate, make a request to the holders	

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recommendation and, if appropriate, make a request to the holders of approved applications for the drug to make any labeling change that the Commissioner of Food and Drugs determines to be appropriate.	of approved applications for the drug to make any labeling change that the Commissioner of Food and Drugs determines to be appropriate.	
(10) FAILURE TO AGREE.—If a holder of an approved application for a drug, within 30 days after receiving a request to make a labeling change under paragraph (9), does not agree to make a requested labeling change, the Commissioner may deem the drug to be misbranded under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).	`(10) FAILURE TO AGREE—If a holder of an approved application for a drug, within 30 days after receiving a request to make a labeling change under paragraph (9), does not agree to make a requested labeling change, the Commissioner of Food and Drugs may deem the drug to be misbranded under the Federal Food, Drug, and Cosmetic Act.	
(11) NO EFFECT ON AUTHORITY.—Nothing in this subsection limits the authority of the United States to bring an enforcement action under the Federal Food, Drug, and Cosmetic Act when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Subcommittee of the Anti-Infective Drugs 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.	`(11) NO EFFECT ON AUTHORITY—Nothing in this subsection limits the authority of the United States to bring an enforcement action under the Federal Food, Drug, and Cosmetic 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.	
(12) RECOMMENDATION FOR FORMULATION CHANGES.—If a pediatric study completed under public contract indicates that a formulation change is necessary and the Secretary agrees, the Secretary shall send a nonbinding letter of recommendation regarding that change to each holder of an approved application.		
	`(d) DISSEMINATION OF PEDIATRIC INFORMATION—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, shall study the feasibility of establishing a compilation of information on pediatric drug use and report the findings to Congress.	
(d) AUTHORIZATION OF APPROPRIATIONS.—	`(e) AUTHORIZATION OF APPROPRIATIONS—	**Authorization** Retains $200,000,000 authorization for pediatric research fund.
(1) IN GENERAL.—There are authorized to be appropriated to carry out this section—	`(1) IN GENERAL—There are authorized to be appropriated to carry out this section—	
(A) $200,000,000 for fiscal year 2002; and	`(A) $200,000,000 for fiscal year 2008; and	
(B) such sums as are necessary for each of the five succeeding fiscal years.	`(B) such sums as are necessary for each of the four succeeding fiscal years.	
(2) AVAILABILITY.—Any amount appropriated under paragraph (1) shall remain available to carry out this section until expended.	`(2) AVAILABILITY—Any amount appropriated under paragraph (1) shall remain available to carry out this section until expended.'.	

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[The following language is from PL107-109.] **SEC. 13. FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH.** Section 499 of the Public Health Service Act (42 U.S.C. 290b) is amended— (1) in subsection (b), by inserting "(including collection of funds for pediatric pharmacologic research)" after "mission"; (2) in subsection (c)(1)— (A) by redesignating subparagraph (C) as subparagraph (D); and (B) by inserting after subparagraph (B) the following: "(C) A program to collect funds for pediatric pharmacologic research and studies listed by the Secretary pursuant to section 409I(a)(1)(A) of this Act and referred under section 505A(d)(4)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(d)(4)(C))."; (3) in subsection (d)— (A) in paragraph (1)— (i) in subparagraph (B)— (I) in clause (ii), by striking "and" at the end; (II) in clause (iii), by striking the period and inserting "; and"; and (III) by adding at the end the following: "(iv) the Commissioner of Food and Drugs."; and (ii) by striking subparagraph (C) and inserting the following: "(C) The ex officio members of the Board under subparagraph (B) shall appoint to the Board individuals from among a list of candidates to be provided by the National Academy of Science. Such appointed members shall include— "(i) representatives of the general biomedical field; "(ii) representatives of experts in pediatric medicine and research; "(iii) representatives of the general biobehavioral field, which may include experts in biomedical ethics; and	(c) FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH— Section 499(c)(1)(C) of the Public Health Service Act (42 U.S.C. 290b(c)(1)(C)) is amended by striking `and studies listed by the Secretary pursuant to section 409I(a)(1)(A) of this Act and referred under section 505A(d)(4)(C) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(a)(d)(4)(C)' and inserting `and studies for which the Secretary issues a certification in the affirmative under section 505A(n)(1)(A) of the Federal Food, Drug, and Cosmetic Act'.	

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"(iv) representatives of the general public, which may include representatives of affected industries."; and (B) in paragraph (2), by realigning the margin of subparagraph (B) to align with subparagraph (A); (4) in subsection (k)(9)— (5) by redesignating subsections (f) through (m) as subsections (e) through (l), respectively; (6) in subsection (h)(11) (as so redesignated), by striking "solicit" and inserting "solicit,"; and (7) in paragraphs (1) and (2) of subsection (j) (as so redesignated), by striking "(including those developed under subsection (d)(2)(B)(i)(II))" each place it appears. **SEC. 14. PEDIATRIC PHARMACOLOGY ADVISORY COMMITTEE.** (a) IN GENERAL—The Secretary of Health and Human Services shall, under section 222 of the Public Health Service Act (42 U.S.C. 217a), convene and consult an advisory committee on pediatric pharmacology (referred to in this section as the "advisory committee"). (b) PURPOSE— (1) IN GENERAL—The advisory committee shall advise and make recommendations to the Secretary, through the Commissioner of Food and Drugs and in consultation with the Director of the National Institutes of Health, on matters relating to pediatric pharmacology. (2) MATTERS INCLUDED—The matters referred to in paragraph (1) include— (A) pediatric research conducted under sections 351, 409I, and 499 of the Public Health Service Act and sections 501, 502, 505, and 505A of the Federal Food, Drug, and Cosmetic Act; (B) identification of research priorities related to pediatric pharmacology and the need for additional treatments of specific pediatric diseases or conditions; and (C) the ethics, design, and analysis of clinical trials related to pediatric pharmacology. (c) COMPOSITION—The advisory committee shall include representatives of	(d) CONTINUATION OF OPERATION OF COMMITTEE—Section 14 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended by adding at the end the following new subsection:	

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pediatric health organizations, pediatric researchers, relevant patient and patient-family organizations, and other experts selected by the Secretary.		
	`(d) CONTINUATION OF OPERATION OF COMMITTEE—Notwithstanding section 14 of the Federal Advisory Committee Act, the advisory committee shall continue to operate during the five-year period beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007.'.	**Extension of Pediatric Advisory Committee** Extends advisory committee through October 1, 2012.
SEC. 15. PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC DRUGS ADVISORY COMMITTEE. (a) CLARIFICATION OF AUTHORITIES—	(e) PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC DRUGS ADVISORY COMMITTEE—Section 15 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended—	
(1) IN GENERAL—The Pediatric Subcommittee of the Oncologic Drugs Advisory Committee (referred to in this section as the "Subcommittee"), in carrying out the mission of reviewing and evaluating the data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of pediatric cancers, shall—	(1) in subsection (a)— (A) in paragraph (1)—	
(A) evaluate and, to the extent practicable, prioritize new and emerging therapeutic alternatives available to treat pediatric cancer;		
(B) provide recommendations and guidance to help ensure that children with cancer have timely access to the most promising new cancer therapies; and	(i) in subparagraph (B), by striking `and' after the semicolon;	
(C) advise on ways to improve consistency in the availability of new therapeutic agents.	(ii) in subparagraph (C), by striking the period at the end and inserting `; and'; and (iii) by adding at the end the following new subparagraph:	
	`(D) provide recommendations to the internal review committee created under section 505B(f) of the Federal Food, Drug, and Cosmetic Act regarding the implementation of amendments to sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act with respect to the treatment of pediatric cancers.'; and	**Subcommittee Recommendations** Provides for recommendations from the Pediatric Subcommittee of the Oncologic Drugs Advisory Committee on the implementation of BPCA and PREA amendments.
(2) MEMBERSHIP— (A) IN GENERAL—The Secretary shall appoint not more than 11 voting members to the Pediatric Subcommittee from the membership of the Pediatric Pharmacology Advisory Committee and the Oncologic Drugs Advisory Committee. (B) REQUEST FOR PARTICIPATION—The		

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Subcommittee shall request participation of the following members in the scientific and ethical consideration of topics of pediatric cancer, as necessary: (i) At least two pediatric oncology specialists from the National Cancer Institute. (ii) At least four pediatric oncology specialists from— (I) the Children's Oncology Group; (II) other pediatric experts with an established history of conducting clinical trials in children; or (III) consortia sponsored by the National Cancer Institute, such as the Pediatric Brain Tumor Consortium, the New Approaches to Neuroblastoma Therapy or other pediatric oncology consortia. (iii) At least two representatives of the pediatric cancer patient and patient-family community. (iv) One representative of the nursing community. (v) At least one statistician. (vi) At least one representative of the pharmaceutical industry. (b) PRE-CLINICAL MODELS TO EVALUATE PROMISING PEDIATRIC CANCER THERAPIES—Section 413 of the Public Health Service Act (42 U.S.C. 285a-2) is amended by adding at the end the following: "(c) PRE-CLINICAL MODELS TO EVALUATE PROMISING PEDIATRIC CANCER THERAPIES— "(1) EXPANSION AND COORDINATION OF ACTIVITIES—The Director of the National Cancer Institute shall expand, intensify, and coordinate the activities of the Institute with respect to research on the development of preclinical models to evaluate which therapies are likely to be effective for treating pediatric cancer. "(2) COORDINATION WITH OTHER INSTITUTES—The Director of the Institute shall coordinate the activities under paragraph (1) with similar activities conducted by other national research institutes and agencies of the National Institutes of Health to the extent that those Institutes and agencies have responsibilities that are related to pediatric cancer.".		

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(c) CLARIFICATION OF AVAILABILITY OF INVESTIGATIONAL NEW DRUGS FOR PEDIATRIC STUDY AND USE— (1) AMENDMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT- Section 505(i)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(1)) is amended— (A) in subparagraph (B), by striking "and" at the end; (B) in subparagraph (C), by striking the period at the end and inserting "; and"; and (C) by adding at the end the following: "(D) the submission to the Secretary by the manufacturer or the sponsor of the investigation of a new drug of a statement of intent regarding whether the manufacturer or sponsor has plans for assessing pediatric safety and efficacy.". (2) AMENDMENT OF THE PUBLIC HEALTH SERVICE ACT- Section 402(j)(3)(A) of the Public Health Service Act (42 U.S.C. 282(j)(3)(A)) is amended in the first sentence— (A) by striking "trial sites, and" and inserting "trial sites,"; and (B) by striking "in the trial," and inserting "in the trial, and a description of whether, and through what procedure, the manufacturer or sponsor of the investigation of a new drug will respond to requests for protocol exception, with appropriate safeguards, for single-patient and expanded protocol use of the new drug, particularly in children,". (d) REPORT—Not later than January 31, 2003, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs and in consultation with the Director of the National Institutes of Health, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on patient access to new therapeutic agents for pediatric cancer, including access to single patient use of new therapeutic agents.	(B) by adding at the end the following new paragraph: '(3) CONTINUATION OF OPERATION OF SUBCOMMITTEE—Notwithstanding section 14 of the Federal Advisory Committee Act, the Subcommittee shall continue to operate during the five-year period beginning on the	**Extension of Subcommittee** Extends the Pediatric Subcommittee of the Oncologic Drugs Advisory Committee through October 1, 2012.

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	date of the enactment of the Best Pharmaceuticals for Children Act of 2007.'; and (2) in subsection (d), by striking `2003' and inserting `2009'. **SEC. 503. TRAINING OF PEDIATRIC PHARMACOLOGISTS.** (a) INVESTMENT IN TOMORROW'S PEDIATRIC RESEARCHERS—Section 452G(2) of the Public Health Service Act (42 U.S.C. 285g-10(2)) is amended by adding before the period at the end the following: `, including pediatric pharmacological research'.  (b) PEDIATRIC RESEARCH LOAN REPAYMENT PROGRAM—Section 487F(a)(1) of the Public Health Service Act (42 U.S.C. 288-6(a)(1)) is amended by inserting `including pediatric pharmacological research,' after `pediatric research,'.	**Pediatric Pharmacologists** Includes pediatric pharmacologists in existing NIH career development and loan repayment programs.

Pediatric Research Equity Act: Improvements to Existing Law

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	SEC. 401. SHORT TITLE. This title may be cited as the `Pediatric Research Equity Act of 2007'. **SEC. 402. REAUTHORIZATION OF PEDIATRIC RESEARCH EQUITY ACT.** (a) In General- Section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amended to read as follows:	
SEC. 505B. [21 U.S.C. 355c] RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PRODUCTS.	**`SEC. 505B. RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PRODUCTS.**	
(a) NEW DRUGS AND BIOLOGICAL PRODUCTS—	`(a) NEW DRUGS AND BIOLOGICAL PRODUCTS—	
(1) IN GENERAL—A person that submits an application (or supplement to an application)—	`(1) IN GENERAL- A person that submits, on or after the date of the enactment of the Pediatric Research Equity Act of 2007, an application (or supplement to an application)–	
(A) under section 505 for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration; or	`(A) under section 505 for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration, or	
(B) under section 351 of the Public Health Service Act (42 U.S.C. 262) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration; shall submit with the application the assessments described in paragraph (2).	`(B) under section 351 of the Public Health Service Act (42 U.S.C. 262) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration, shall submit with the application the assessments described in paragraph (2).	
(2) ASSESSMENTS—	`(2) ASSESSMENTS—	
(A) IN GENERAL—The assessments referred to in paragraph (1) shall contain data, gathered using appropriate formulations for each age group for which the assessment is required, that are adequate—	`(A) IN GENERAL—The assessments referred to in paragraph (1) shall contain data, gathered using appropriate formulations for each age group for which the assessment is required, that are adequate—	
(i) to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations; and	`(i) to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations; and	
(ii) to support dosing and administration for each pediatric subpopulation for which the drug or the biological product is safe and effective.	`(ii) to support dosing and administration for each pediatric subpopulation for which the drug or the biological product is safe and effective.	
(B) SIMILAR COURSE OF DISEASE OR SIMILAR EFFECT OF DRUG OR BIOLOGICAL PRODUCT—	`(B) SIMILAR COURSE OF DISEASE OR SIMILAR EFFECT OF DRUG OR BIOLOGICAL PRODUCT—	
(i) IN GENERAL—If the course of the disease and the effects of the drug are	`(i) IN GENERAL—If the course of the disease and the effects of the drug are	

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sufficiently similar in adults and pediatric patients, the Secretary may conclude that pediatric effectiveness can be extrapolated from adequate and well-controlled studies in adults, usually supplemented with other information obtained in pediatric patients, such as pharmacokinetic studies.	sufficiently similar in adults and pediatric patients, the Secretary may conclude that pediatric effectiveness can be extrapolated from adequate and well-controlled studies in adults, usually supplemented with other information obtained in pediatric patients, such as pharmacokinetic studies.	
(ii) EXTRAPOLATION BETWEEN AGE GROUPS—A study may not be needed in each pediatric age group if data from 1 age group can be extrapolated to another age group.	`(ii) EXTRAPOLATION BETWEEN AGE GROUPS—A study may not be needed in each pediatric age group if data from one age group can be extrapolated to another age group.	
	`(iii) INFORMATION ON EXTRAPOLATION- A brief documentation of the scientific data supporting the conclusion under clauses (i) and (ii) shall be included in any pertinent reviews for the application under section 505 of this Act or section 351 of the Public Health Service Act (42 U.S.C. 262).	
(3) DEFERRAL—On the initiative of the Secretary or at the request of the applicant, the Secretary may defer submission of some or all assessments required under paragraph (1) until a specified date after approval of the drug or issuance of the license for a biological product if—	`(3) DEFERRAL—	
	`(A) IN GENERAL—On the initiative of the Secretary or at the request of the applicant, the Secretary may defer submission of some or all assessments required under paragraph (1) until a specified date after approval of the drug or issuance of the license for a biological product if—	
(A) the Secretary finds that—	`(i) the Secretary finds that—	
(i) the drug or biological product is ready for approval for use in adults before pediatric studies are complete;	`(I) the drug or biological product is ready for approval for use in adults before pediatric studies are complete;	
(ii) pediatric studies should be delayed until additional safety or effectiveness data have been collected; or	`(II) pediatric studies should be delayed until additional safety or effectiveness data have been collected; or	
(iii) there is another appropriate reason for deferral; and	`(III) there is another appropriate reason for deferral; and	
(B) the applicant submits to the Secretary—	`(ii) the applicant submits to the Secretary--	
(i) certification of the grounds for deferring the assessments;	`(I) certification of the grounds for deferring the assessments;	
(ii) a description of the planned or ongoing studies; and	`(II) a description of the planned or ongoing studies;	
(iii) evidence that the studies are being conducted or will be conducted with due diligence and at the earliest possible time.	`(III) evidence that the studies are being conducted or will be conducted with due diligence and at the earliest possible time; and	
	`(IV) a timeline for the completion of such studies.	
	`(B) ANNUAL REVIEW—	**Annual Deferral Review** Requires an annual review from an applicant who has received a deferral.
	`(i) IN GENERAL—On an annual basis following the approval of a deferral under	

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	subparagraph (A), the applicant shall submit to the Secretary the following information: `(I) Information detailing the progress made in conducting pediatric studies.  `(II) If no progress has been made in conducting such studies, evidence and documentation that such studies will be conducted with due diligence and at the earliest possible time. `(ii) PUBLIC AVAILABILITY—The information submitted through the annual review under clause (i) shall promptly be made available to the public in an easily accessible manner, including through the Web site of the Food and Drug Administration.	**Public Annual Deferral Reviews** Requires annual deferral reviews to be made public.
(4) WAIVERS— (A) FULL WAIVER—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection if the applicant certifies and the Secretary finds that— (i) necessary studies are impossible or highly impracticable (because, for example, the number of patients is so small or the patients are geographically dispersed); (ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups; or (iii) the drug or biological product— (I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and (II) is not likely to be used in a substantial number of pediatric patients. (B) PARTIAL WAIVER—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that— (i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);	`(4) WAIVERS—  `(A) FULL WAIVER—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection if the applicant certifies and the Secretary finds that-- `(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients is so small or the patients are geographically dispersed);  `(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups; or `(iii) the drug or biological product--  `(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and `(II) is not likely to be used in a substantial number of pediatric patients.  `(B) PARTIAL WAIVER—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that— `(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);	

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(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;	`(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;	
(iii) the drug or biological product—	`(iii) the drug or biological product--	
(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and	`(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and	
(II) is not likely to be used by a substantial number of pediatric patients in that age group; or	`(II) is not likely to be used by a substantial number of pediatric patients in that age group; or	
(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed	`(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.	
(C) PEDIATRIC FORMULATION NOT POSSIBLE—If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation.	`(C) PEDIATRIC FORMULATION NOT POSSIBLE—If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation. An applicant seeking either a full or partial waiver shall submit to the Secretary documentation detailing why a pediatric formulation cannot be developed and, if the waiver is granted, the applicant's submission shall promptly be made available to the public in an easily accessible manner, including through posting on the Web site of the Food and Drug Administration.	**Pediatric Formulations** Requires manufacturers that have tried but been unable to produce a pediatric formulation to submit to FDA the reasons why the formulation cannot be developed.
(D) LABELING REQUIREMENT—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.	`(D) LABELING REQUIREMENT—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.	
(b) MARKETED DRUGS AND BIOLOGICAL PRODUCTS—	`(b) MARKETED DRUGS AND BIOLOGICAL PRODUCTS—	
(1) IN GENERAL—After providing notice in the form of a letter and an opportunity for written response and a meeting, which may include an advisory committee meeting, the Secretary may (by order in the form of a letter) require the holder of an approved application for a drug under section 505 or the holder of a license for a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262) to submit by a specified date the assessments described in subsection (a)(2) if the Secretary finds that—	`(1) IN GENERAL—After providing notice in the form of a letter (that, for a drug approved under section 505, references a declined written request under section 505A for a labeled indication which written request is not referred under section 505A(n)(1)(A) to the Foundation of the National Institutes of Health for the pediatric studies), the Secretary may (by order in the form of a letter) require the sponsor or holder of an approved application for a drug under section 505 or the holder of a license for a biological product under section 351 of the Public Health Service Act to submit by a specified date the assessments described in subsection (a)(2), if the Secretary finds that—	
(A)(i) the drug or biological product is used	`(A)(i) the drug or biological product is used	

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for a substantial number of pediatric patients for the labeled indications; and	for a substantial number of pediatric patients for the labeled indications; and	
(ii) the absence of adequate labeling could pose significant risks to pediatric patients; or	`(ii) adequate pediatric labeling could confer a benefit on pediatric patients;	**Post-Market Standard** Changes the criteria for applying PREA to already marketed drugs. New language allows FDA to use a "benefit" standard as opposed to a "risk" standard.
(B)(i) there is reason to believe that the drug or biological product would represent a meaningful therapeutic benefit over existing therapies for pediatric patients for 1 or more of the claimed indications; and	`(B) there is reason to believe that the drug or biological product would represent a meaningful therapeutic benefit over existing therapies for pediatric patients for 1 or more of the claimed indications; or	
(ii) the absence of adequate labeling could pose significant risks to pediatric patients.	`(C) the absence of adequate pediatric labeling could pose a risk to pediatric patients.	
(2) WAIVERS—	`(2) WAIVERS—	
(A) FULL WAIVER—At the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments under this subsection if the applicant certifies and the Secretary finds that—	`(A) FULL WAIVER—At the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments under this subsection if the applicant certifies and the Secretary finds that—	
(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed); or	`(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed); or	
(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups.	`(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups.	
(B) PARTIAL WAIVER—At the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that—	`(B) PARTIAL WAIVER—At the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that—	
(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);	`(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);	
(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;	`(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;	
(iii)(I) the drug or biological product—	`(iii)(I) the drug or biological product–	
(aa) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and	`(aa) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and	
(bb) is not likely to be used in a substantial number of pediatric patients in that age group; and	`(bb) is not likely to be used in a substantial number of pediatric patients in that age group; and	
(II) the absence of adequate labeling could	`(II) the absence of adequate labeling could	

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not pose significant risks to pediatric patients; or (iv) the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.	not pose significant risks to pediatric patients; or `(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.	
(C) PEDIATRIC FORMULATION NOT POSSIBLE—If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation.	`(C) PEDIATRIC FORMULATION NOT POSSIBLE—If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation. An applicant seeking either a full or partial waiver shall submit to the Secretary documentation detailing why a pediatric formulation cannot be developed and, if the waiver is granted, the applicant's submission shall promptly be made available to the public in an easily accessible manner, including through posting on the Web site of the Food and Drug Administration.	**Pediatric Formulations** Requires a manufacturer that has tried but been unable to produce a pediatric formulation to submit to FDA the reasons why the formulation cannot be developed.
(D) LABELING REQUIREMENT—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.	`(D) LABELING REQUIREMENT—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.  `(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.	
(3) RELATIONSHIP TO OTHER PEDIATRIC PROVISIONS— (A) NO ASSESSMENT WITHOUT WRITTEN REQUEST—No assessment may be required under paragraph (1) for a drug subject to an approved application under section 505 unless— (i) the Secretary has issued a written request for a related pediatric study under section 505A(c) of this Act or section 409I of the Public Health Service Act (42 U.S.C. 284m); (ii)(I) if the request was made under section 505A(c)— (aa) the recipient of the written request does not agree to the request; or (bb) the Secretary does not receive a response as specified under section 505A(d)(4)(A); or (II) if the request was made under section 409I of the Public Health Service Act (42 U.S.C. 284m)—		**"Exhaustion" Process** Eliminates much of the "exhaustion" process FDA must now go through before it can mandate a study of a drug already on the market under PREA.

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(aa) the recipient of the written request does not agree to the request; or (bb) the Secretary does not receive a response as specified under section 409I(c)(2) of that Act; and (iii)(I) the Secretary certifies under subparagraph (B) that there are insufficient funds under sections 409I and 499 of the Public Health Service Act (42 U.S.C. 284m, 290b) to conduct the study; or (II) the Secretary publishes in the Federal Register a certification that certifies that— (aa) no contract or grant has been awarded under section 409I or 499 of the Public Health Service Act (42 U.S.C. 284m, 290b); and (bb) not less than 270 days have passed since the date of a certification under subparagraph (B) that there are sufficient funds to conduct the study. (B) NO AGREEMENT TO REQUEST—Not later than 60 days after determining that no holder will agree to the written request (including a determination that the Secretary has not received a response specified under section 505A(d) of this Act or section 409I of the Public Health Service Act (42 U.S.C. 284m), the Secretary shall certify whether the Secretary has sufficient funds to conduct the study under section 409I or 499 of the Public Health Service Act (42 U.S.C. 284m, 290b), taking into account the prioritization under section 409I.		
(c) MEANINGFUL THERAPEUTIC BENEFIT—For the purposes of paragraph (4)(A)(iii)(I) and (4)(B)(iii)(I) of subsection (a) and paragraphs (1)(B)(i) and (2)(B)(iii)(I)(aa) of subsection (b), a drug or biological product shall be considered to represent a meaningful therapeutic benefit over existing therapies if the Secretary estimates that—	`(c) MEANINGFUL THERAPEUTIC BENEFIT—For the purposes of paragraph (4)(A)(iii)(I) and (4)(B)(iii)(I) of subsection (a) and paragraphs (1)(B) and (2)(B)(iii)(I)(aa) of subsection (b), a drug or biological product shall be considered to represent a meaningful therapeutic benefit over existing therapies if the Secretary determines that—	
(1) if approved, the drug or biological product would represent a significant improvement in the treatment, diagnosis, or prevention of a disease, compared with marketed products adequately labeled for that use in the relevant pediatric population; or	`(1) if approved, the drug or biological product could represent an improvement in the treatment, diagnosis, or prevention of a disease, compared with marketed products adequately labeled for that use in the relevant pediatric population; or	
(2) the drug or biological product is in a class of products or for an indication for which there is a need for additional options.	`(2) the drug or biological product is in a class of products or for an indication for which there is a need for additional options.	
(d) SUBMISSION OF ASSESSMENTS—If a person fails to submit an assessment described in subsection (a)(2), or a request	`(d) SUBMISSION OF ASSESSMENTS—If a person fails to submit an assessment described in subsection (a)(2), or a request	

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for approval of a pediatric formulation described in subsection (a) or (b), in accordance with applicable provisions of subsections (a) and (b)—	for approval of a pediatric formulation described in subsection (a) or (b), in accordance with applicable provisions of subsections (a) and (b)—	
(1) the drug or biological product that is the subject of the assessment or request may be considered misbranded solely because of that failure and subject to relevant enforcement action (except that the drug or biological product shall not be subject to action under section 303); but	`(1) the drug or biological product that is the subject of the assessment or request may be considered misbranded solely because of that failure and subject to relevant enforcement action (except that the drug or biological product shall not be subject to action under section 303); but	
(2) the failure to submit the assessment or request shall not be the basis for a proceeding—	`(2) the failure to submit the assessment or request shall not be the basis for a proceeding–	
(A) to withdraw approval for a drug under section 505(e); or	`(A) to withdraw approval for a drug under section 505(e); or	
(B) to revoke the license for a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262).	`(B) to revoke the license for a biological product under section 351 of the Public Health Service Act.	
(e) MEETINGS—Before and during the investigational process for a new drug or biological product, the Secretary shall meet at appropriate times with the sponsor of the new drug or biological product to discuss—	`(e) MEETINGS—Before and during the investigational process for a new drug or biological product, the Secretary shall meet at appropriate times with the sponsor of the new drug or biological product to discuss–	
(1) information that the sponsor submits on plans and timelines for pediatric studies; or	`(1) information that the sponsor submits on plans and timelines for pediatric studies; or	
(2) any planned request by the sponsor for waiver or deferral of pediatric studies.	`(2) any planned request by the sponsor for waiver or deferral of pediatric studies.	
	`(f) REVIEW OF PEDIATRIC PLANS, ASSESSMENTS, DEFERRALS, AND WAIVERS—	**Internal Review** Requires internal committee to review study plans and assessments, as well as deferrals and waivers.
	`(1) REVIEW—Beginning not later than 30 days after the date of the enactment of the Pediatric Research Equity Act of 2007, the Secretary shall utilize the internal committee established under section 505C to provide consultation to reviewing divisions on all pediatric plans and assessments prior to approval of an application or supplement for which a pediatric assessment is required under this section and all deferral and waiver requests granted pursuant to this section.	
	`(2) 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.	
	`(3) DOCUMENTATION OF COMMITTEE ACTION—For each drug or biological product, the committee referred to in paragraph (1) shall document, for each activity described in paragraph (4) or (5), which members of the committee	

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	participated in such activity. `(4) REVIEW OF PEDIATRIC PLANS, ASSESSMENTS, DEFERRALS, AND WAIVERS—Consultation on pediatric plans and assessments by the committee referred to in paragraph (1) pursuant to this section shall occur prior to approval of an application or supplement for which a pediatric assessment is required under this section. The committee shall review all requests for deferrals and waivers from the requirement to submit a pediatric assessment granted under this section and shall provide recommendations as needed to reviewing divisions, including with respect to whether such a supplement, when submitted, shall be considered for priority review. `(5) RETROSPECTIVE REVIEW OF PEDIATRIC ASSESSMENTS, DEFERRALS, AND WAIVERS—Not later than 1 year after the date of the enactment of the Pediatric Research Equity Act of 2007, the committee referred to in paragraph (1) shall conduct a retrospective review and analysis of a representative sample of assessments submitted and deferrals and waivers approved under this section since the enactment of the Pediatric Research Equity Act of 2003. Such review shall include an analysis of the quality and consistency of pediatric information in pediatric assessments and the appropriateness of waivers and deferrals granted. Based on such review, the Secretary shall issue recommendations to the review divisions for improvements and initiate guidance to industry related to the scope of pediatric studies required under this section. `(6) TRACKING OF ASSESSMENTS 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—  `(A) the number of assessments conducted under this section; `(B) the specific drugs and biological products and their uses assessed under this section;  `(C) the types of assessments conducted under this section, including trial design, the number of pediatric patients studied, and the number of centers and countries involved;	**Tracking** Requires FDA to track the number and type of studies completed, as well as labeling changes and other data resulting from PREA.

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	`(D) the total number of deferrals requested and granted under this section and, if granted, the reasons for such deferrals, the timeline for completion, and the number completed and pending by the specified date, as outlined in subsection (a)(3);  `(E) the number of waivers requested and granted under this section and, if granted, the reasons for the waivers; `(F) the number of pediatric formulations developed and the number of pediatric formulations not developed and the reasons any such formulation was not developed;  `(G) the labeling changes made as a result of assessments conducted under this section; `(H) an annual summary of labeling changes made as a result of assessments conducted under this section for distribution pursuant to subsection (h)(2);  `(I) an annual summary of information submitted pursuant to subsection (a)(3)(B); and `(J) the number of times the committee referred to in paragraph (1) made a recommendation to the Secretary under paragraph (4) regarding priority review, the number of times the Secretary followed or did not follow such a recommendation, and, if not followed, the reasons why such a recommendation was not followed. `(g) LABELING CHANGES—  `(1) DISPUTE RESOLUTION— `(A) REQUEST FOR LABELING CHANGE AND FAILURE TO AGREE—If, on or after the date of the enactment of the Pediatric Research Equity Act of 2007, the Commissioner determines that a 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 or supplement, not later than 180 days after the date of the submission of the application or supplement— `(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 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.	**Dispute Resolution** The dispute resolution provision previously only applied to BPCA. The BPCA dispute resolution process was modified and applied to PREA. The modified language reduces the overall time period for dispute resolution over labeling and removes the provision requiring labeling to be the only remaining open issue before referral for resolution.