(1)(A)「(j)(4)(D)(ii)」をすべて削除し「(j)(5)(D)(ii)」を挿入する。

(B)「(J)(4)(D)」をすべて削除し「(j)(5)(D)」を挿入する。

(C)「505(j)(4)(D)」をすべて削除し「505(j)(5)(D)」を挿入する。

(2)サブセクション(a)、(g)、(h)、(i)、(j)、(k)、(l)、(m)、(n)および(o)をサブセクション(b)、(a)、(g)、(h)、(n)、(m)、(i)、(j)、(k)および(l)にそれぞれ変更する。

(3)上記のサブセクションをアルファベット順になるよう移動する。

(4)サブセクション(d)のパラグラフ(1)、(2)および(3)、サブセクション(e)ならびにサブセクション(m)（パラグラフ(2)により変更）において、「サブセクション(a)または(c)」を削除し「サブセクション(b)または(c)」を挿入する。ならびに

(5)サブセクション(g)（パラグラフ(2)により変更）において、「サブセクション(a)または(b)」を削除し「サブセクション(b)または(c)」を挿入する。

下院議長

アメリカ合衆国副大統領兼上院議長

S. 650

One Hundred Eighth Congress of the United States of America

AT THE FIRST SESSION

Begun and held at the City of Washington on Tuesday, the seventh day of January, two thousand and three

An Act

To amend the Federal Food, Drug, and Cosmetic Act to authorize the Food and Drug Administration to require certain research into drugs used in pediatric patients.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Pediatric Research Equity Act of 2003".

SEC. 2. RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PRODUCTS.

(a) IN GENERAL.—Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505A the following:

"SEC. 505B. RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PRODUCTS.

"(a) NEW DRUGS AND BIOLOGICAL PRODUCTS.—

"(1) IN GENERAL.—A person that submits 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

"(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.—

"(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

"(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.—

"(i) IN GENERAL.—If the course of the disease and the effects of the drug are 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 one age group can be extrapolated to another age group.

"(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—

"(A) the Secretary finds that—

"(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

"(iii) there is another appropriate reason for deferral; and

"(B) the applicant submits to the Secretary—

"(i) certification of the grounds for deferring the assessments;

"(ii) a description of the planned or ongoing studies; and

"(iii) evidence that the studies are being conducted or will be conducted with due diligence and at the earliest possible time.

"(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);

"(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—

"(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

"(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.

"(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.—

"(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—

"(A)(i) the drug or biological product is used 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

"(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 one or more of the claimed indications; and

"(ii) the absence of adequate labeling could pose significant risks to pediatric patients.

"(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—

"(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.

"(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);

"(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—

"(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

"(II) the absence of adequate labeling could 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.

"(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) 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)—

"(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—

"(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

"(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 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

"(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

"(B) to revoke the license for a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262).

"(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

"(2) any planned request by the sponsor for waiver or deferral of pediatric studies.

"(f) SCOPE OF AUTHORITY.—Nothing in this section provides to the Secretary any authority to require a pediatric assessment of any drug or biological product, or any assessment regarding other populations or uses of a drug or biological product, other than the pediatric assessments described in this section.

"(g) ORPHAN DRUGS.—Unless the Secretary requires otherwise by regulation, this section does not apply to any drug for an indication for which orphan designation has been granted under section 526.

"(h) INTEGRATION WITH OTHER PEDIATRIC STUDIES.—The authority under this section shall remain in effect so long as an application subject to this section may be accepted for filing by the Secretary on or before the date specified in section 505A(n).".

(b) CONFORMING AMENDMENTS.—(1) Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)) is amended in the second sentence—

(A) by striking "and (F)" and inserting "(F)"; and

(B) by striking the period at the end and inserting ", and (G) any assessments required under section 505B.".

(2) Section 505A(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(h)) is amended—

(A) in the subsection heading, by striking "REGULATIONS" and inserting "PEDIATRIC RESEARCH REQUIREMENTS"; and

(B) by striking "pursuant to regulations promulgated by the Secretary" and inserting "by a provision of law (including a regulation) other than this section".

(3) Section 351(a)(2) of the Public Health Service Act (42 U.S.C. 262(a)(2)) is amended—

(A) by redesignating subparagraph (B) as subparagraph (C); and

(B) by inserting after subparagraph (A) the following:

"(B) PEDIATRIC STUDIES.—A person that submits an application for a license under this paragraph shall submit to the Secretary as part of the application any assessments required under section 505B of the Federal Food, Drug, and Cosmetic Act.".

SEC. 3. TECHNICAL AND CONFORMING AMENDMENTS.

(a) ABBREVIATED NEW DRUG APPLICATION.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended in subparagraphs (A) and (B) of subsection (b)(2) and subparagraphs (A) and (B) of subsection (c)(2) by striking "505(j)(4)(B)" and inserting "505(j)(5)(B)".

(b) PEDIATRIC ADVISORY COMMITTEE.—(1) Section 505A(i)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(i)(2)) is amended by striking "Advisory Subcommittee of the Anti-Infective Drugs" each place it appears.

(2) Section 14 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note; Public Law 107–109) is amended—

(A) in the section heading, by striking "PHARMACOLOGY";

(B) in subsection (a), by striking "(42 U.S.C. 217a)," and inserting (42 U.S.C. 217a) or other appropriate authority,";

(C) in subsection (b)—

(i) in paragraph (1), by striking "and in consultation with the Director of the National Institutes of Health"; and

(ii) in paragraph (2), by striking "and 505A" and inserting "505A, and 505B"; and

(D) by striking "pharmacology" each place it appears and inserting "therapeutics".

(3) Section 15(a)(2)(A) of the Best Pharmaceuticals for Children Act (115 Stat. 1419) is amended by striking "Pharmacology".

(4) Section 16(1)(C) of the Best Pharmaceuticals for Children Act (21 U.S.C. 355a note; Public Law 107–109) is amended by striking "Advisory Subcommittee of the Anti-Infective Drugs".

(5) Section 17(b)(1) of the Best Pharmaceuticals for Children Act (21 U.S.C. 355b(b)(1)) is amended in the second sentence by striking "Advisory Subcommittee of the Anti-Infective Drugs".

(6) Paragraphs (8), (9), and (11) of section 409I(c) of the Public Health Service Act (42 U.S.C. 284m(c)) are amended by striking "Advisory Subcommittee of the Anti-Infective Drugs" each place it appears.

SEC. 4. EFFECTIVE DATE.

(a) IN GENERAL.—Subject to subsection (b), this Act and the amendments made by this Act take effect on the date of enactment of this Act.

(b) APPLICABILITY TO NEW DRUGS AND BIOLOGICAL PRODUCTS.—

(1) IN GENERAL.—Subsection (a) of section 505B of the Federal Food, Drug, and Cosmetic Act (as added by section 2) shall apply to an application described in paragraph (1) of that subsection submitted to the Secretary of Health and Human Services on or after April 1, 1999.

(2) WAIVERS AND DEFERRALS.—

(A) WAIVER OR DEFERRAL GRANTED.—If, with respect to an application submitted to the Secretary of Health and Human Services between April 1, 1999, and the date of enactment of this Act, a waiver or deferral of pediatric assessments was granted under regulations of the Secretary then in effect, the waiver or deferral shall be a waiver or deferral under subsection (a) of section 505B of the Federal Food, Drug, and Cosmetic Act, except that any date specified in such a deferral shall be extended by the number of days that is equal to the number of days between October 17, 2002, and the date of enactment of this Act.

(B) WAIVER AND DEFERRAL NOT GRANTED.—If, with respect to an application submitted to the Secretary of Health and Human Services between April 1, 1999, and the date of enactment of this Act, neither a waiver nor deferral of pediatric assessments was granted under regulations of the Secretary then in effect, the person that submitted the application shall be required to submit assessments under subsection (a)(2) of section 505B of the Federal Food, Drug, and Cosmetic Act on the date that is the later of—

(i) the date that is 1 year after the date of enactment of this Act; or

(ii) such date as the Secretary may specify under subsection (a)(3) of that section;

unless the Secretary grants a waiver under subsection (a)(4) of that section.

(c) NO LIMITATION OF AUTHORITY.—Neither the lack of guidance or regulations to implement this Act or the amendments made by this Act nor the pendency of the process for issuing guidance or regulations shall limit the authority of the Secretary of Health and Human Services under, or defer any requirement under, this Act or those amendments.

Speaker of the House of Representatives.

Vice President of the United States and
President of the Senate.

制定法 650

アメリカ合衆国第 108 連邦議会

第 1 会期

2003 年 1 月 7 日（火）ワシントン市において開始・開催

小児患者に用いる医薬品に関する一定の試験を命じる権限を FDA(Food & Drug Administration:食品･医薬品管理局)に与えるため FD&C Act(Federal Food, Drug & Cosmetic Act:連邦食品・医薬品・化粧品法)を改正する法律

アメリカ合衆国連邦議会上院および下院により制定。

セクション 1　略称

この法律は、PREA(Pediatric Research Equity Act of 2003:「2003 年小児研究公正法」)としてこれを引用することができる。

セクション 2　医薬品および生物学的製剤の小児使用に関する試験

(a)**総則**－FD&C Act チャプターV のサブチャプターA（21 U.S.C. 351 以下）は、セクション 505A の後に以下を挿入してこれを改正する。

「セクション 505B　医薬品および生物学的製剤の小児使用に関する試験

"(a)**新医薬品および生物学的製剤**

"(1)**総則**－

"(A)新有効成分、新効能、新剤型、新投与法、新投与経路についてセクション 505 に基づき、または

"(B)新有効成分、新効能、新剤型、新投与法、新投与経路について公衆衛生法セクション 351（42 U.S.C. 262）に基づき、

申請書を提出する者は、パラグラフ(2)に記載する評価を申請書に添えて提出する。

"(2)**評価**

"(A)**総則**－パラグラフ(1)に言及する評価には、以下を目的として、評価を要する年齢層ごとに適切な製剤を用いて収集した十分なデータが必要である。

"(i)関連するすべての小児集団における申請効能について、当該医薬品
または生物学的製剤の安全性および有効性を評価する。ならびに

"(ii)当該医薬品または生物学的製剤が安全かつ有効である各小児集団に対する投与方法を裏付ける。

"(B)**疾患経過の類似性または医薬品もしくは生物学的製剤の効果類似性**

"(i)**総則**－疾患の経過および医薬品の効果が成人と小児患者とにおいて十分に類似するときは、DHHS 長官は、小児の効果が、通常、薬物動態試験など小児患者で得られる他の情報の補足により、成人における適切かつ十分な対照比較による臨床試験 (adequate and well-controlled studies) から外挿できると結論することができる。

"(ii)**年齢層間の外挿**－1 つの年齢層データから別の年齢層について外挿できるときは、試験は小児年齢層ごとに必要ではない。

"(3)**延期（Deferral）**－DHHS 長官の発議で、または申請者の要請により、DHHS 長官は、次の場合には、

医薬品の承認後または生物学的製剤のライセンス発行後の特定の日まで、パラグラフ(1)に基づき必要な評価の一部または全部の提出を延期することができる。

"(A)DHHS 長官が次のいずれかを認める場合。

"(i)当該医薬品または生物学的製剤が小児試験の完了前に成人の適応が承認可能な場合、

"(ii)追加の安全性または有効性のデータが収集されるまで小児試験を延期すべきである場合、または

"(iii)その他の適切な延期理由がある場合。

"(B)申請者が DHHS 長官に次に掲げるものを提出する場合。

"(i)評価を延期する根拠の証明、

"(ii)計画中、もしくは実施中の試験の説明、および

"(iii)試験実施中、あるいは試験が実施予定であり、これらが相当の注意をもってできるだけ早期に実施される証拠。

"(4)**免除 (Waiver)**

"(A)**完全免除 (Full waiver)** —DHHS 長官の発議で、または申請者の要請により、DHHS 長官は、次に掲げるいずれかの事項を申請者が証明し、かつ DHHS 長官が認めるときは、適宜、本サブセクションに基づき医薬品または生物学的製剤に関する評価を提出する要件の完全免除を与える。

"(i)必要な試験が不可能または非常に実施困難であること (たとえば、患者数が少ない、あるいは患者が地理的に分散しているため)、

"(ii)当該医薬品または生物学的製剤がすべての小児年齢層において無効あるいは安全ではないことを強く示唆する証拠があること、または

"(iii)当該医薬品または生物学的製剤が次に該当すること。

"(I)小児患者の既存治療法を上回る治療上の有益性を示さない、および

"(II)相当数の小児患者に使用される可能性がない。

"(B)**一部免除 (Partial waiver)**—DHHS 長官の発議で、または申請者の要請により、DHHS 長官は、次のいずれかの事項を申請者が証明しかつ DHHS 長官が認めるときは、適宜、特定の小児年齢層に関して本サブセクションに基づき医薬品または生物製剤に関する評価を提出する要件の一部免除を与える。

"(i)必要な試験が、不可能または非常に実施困難であること (たとえば当該年齢層の患者数が少ないため、あるいは当該年齢層の患者が地理的に分散しているため)、

"(ii)当該医薬品または生物学的製剤が当該年齢層において無効である、あるいは安全でないことを強く示唆する証拠があること、

"(iii)当該医薬品または生物学的製剤が以下に該当すること、

"(I)当該年齢層の小児患者の既存治療法を上回る治療上の有益性を示さない、および

"(II)相当数の当該年齢層の小児患者に使用される可能性がない、または

"(iv)当該年齢層に必要な小児用製剤を製造する正当な試みが失敗したことを申請者が証明できること。

"(C)**製造不可能な小児用製剤**—小児製剤の開発が不可能であるという根拠により免除が与えられるときは、当該免除は、当該製剤を要する小児グループのみを対象とする。

"(D)**製品情報要件**—DHHS 長官が、医薬品または生物学的製剤が小児集団において無効ないし安全で

はないと推定する証拠があるため、完全免除または一部免除となる場合は、その旨を当該医薬品または生物学的製剤の製品情報に含める。

"(b)**既承認医薬品および生物学的製剤**

"(1)**総則**－DHHS 長官は、書簡による通知ならびに書面回答および会議（諮問委員会の会議を含む）の機会を与えた後、次の事項を認めるときは、セクション 505 に基づく医薬品の承認保持者または公衆衛生法セクション 351（42 U.S.C. 262）に基づく生物学的製剤の販売承認保持者に対して、サブセクション(a)(2)に記載する評価を指定の日までに提出することを（書簡形式により）命じることができる。

"(A)(i)当該医薬品または生物学的製剤が製品情報に記載された適応症に関して相当数の小児患者に使用されていること、および

"(ii)適切な製品情報を欠くと小児患者に重大な危険を生じる可能性があること、または

"(B)(i)当該医薬品または生物学的製剤が製品情報に記載された適応症の 1 つ以上について、既存治療法を上回る治療上の有益性を示すであろうと信じる理由があること、および

"(ii)適切な製品情報を欠くと小児患者に重大な危険を生じる可能性があること。

"(2)**免除**（Waiver）

"(A)**完全免除**（Full waiver）－申請者の要請により、DHHS 長官は、次の事項を申請者が証明しかつ DHHS 長官が認めるときは、場合に応じて、本サブセクションに基づき評価を提出する要件の完全免除を与える。

"(i)必要な試験が不可能または非常に実施困難であること（たとえば当該年齢層の患者数が少ないため、あるいは当該年齢層の患者が地理的に分散しているため）。または

"(ii)当該医薬品または生物学的製剤がすべての小児年齢層において無効である、あるいは安全でないことを強く示唆する証拠があること。

"(B)**一部免除**（Partial waiver）－申請者の要請により、DHHS 長官は、次のいずれかの事項を申請者が証明しかつ DHHS 長官が認めるときは、場合に応じて、特定の小児年齢層に関して本サブセクションに基づき、医薬品又は生物学的製剤に関する評価を提出する要件の一部免除を与える。

"(i)必要な試験が不可能または非常に実施困難であること（たとえば当該年齢層の患者数が少ない、あるいは当該年齢層の患者が地理的に分散しているため）、

"(ii)当該医薬品または生物学的製剤が当該年齢層において無効である、あるいは安全でないことを強く示唆する証拠があること、

"(iii)(I)当該医薬品または生物学的製剤が

"(aa)当該年齢層の小児患者の既存治療法を上回る治療上の有益性を示さないこと、および

"(bb)相当な数の当該年齢層の小児患者に使用される可能性がないこと、および

"(II)適切な製品情報を欠いても小児患者に重大な危険が生じる可能性がないこと、または

"(iv)当該年齢層に必要な小児製剤を製造する正当な試みが失敗したことを申請者が証明できること。

"(C)**製造不可能な小児用製剤**－小児用製剤の開発が不可能であるという根拠で免除が与えられるときは、当該免除は、当該製剤を要する小児集団のみを対象とする。

"(D)**製品情報要件**－DHHS 長官が、医薬品または生物学的製剤が小児集団において無効ないし安全でないと推定される証拠があるために、完全免除または一部免除を与えるときは、その旨を当該医薬品または生物学的製剤の製品情報に記載する。

"(3)他の関連小児規定との関係

"(A)要請書が無い場合の評価の不要－次の場合を除いて、セクション 505 に基づいて承認された医薬品については、パラグラフ(1)に基づく評価は命じられない。

"(i)DHHS 長官がこの法律のセクション 505A(c)または公衆衛生法セクション 409I (42 U.S.C. 284m) に基づき、関係する小児試験についての要請書を発行した場合。

"(ii)(I)要請がセクション 505A(c)に基づき行われたとき、

"(aa)要請書の受取人が当該要請に同意しない場合、または

"(bb)DHHS 長官がセクション 505A(d)(4)(A)に記載する回答を受領しない場合。

"(II)要請が公衆衛生法セクション 409I (42 U.S.C. 284m) に基づき行われたとき、

"(aa)要請書の受取人が当該要請に同意しない場合、または

"(bb)DHHS 長官が、同法セクション 409I(c)(2)に基づいて規定される回答を受領しない場合、および

"(iii)(I)DHHS 長官がサブパラグラフ (B) に基づき公衆衛生法セクション 409I および 499 (42 U.S.C. 284m, 290b) に基づく資金が試験実施に不十分であることを証明する場合、または

"(II)DHHS 長官が FR(Federal Register:連邦広報)に、次の事項に関する証明を公表する場合。

"(aa)公衆衛生法セクション 409I または 499 (42 U.S.C. 284m, 290b) に基づく契約または補助金が与えられないこと、および

"(bb)試験実施に十分な資金があるというサブパラグラフ(B)に基づく証明の日から少なくとも 270 日が経過していること。

"(B)要請の不同意－保持者が要請書に同意しないであろうという決定（この法律のセクション 505A(d) または公衆衛生法セクション 409I (42 U.S.C. 284m) に記載する回答を DHHS 長官が受領していないという決定を含む）から少なくとも 60 日以内に、DHHS 長官は、セクション 409I に基づく優先順位の決定を考慮して、DHHS 長官が公衆衛生法セクション 409I または 499 に基づく試験を行うのに十分な資金を持つか否かを証明する。

"(c)治療上の有益性 (meaningful therapeutic benefit)－サブセクション(a)の(4)(A)(iii)(I)ならびに(4)(B)(iii)(I) およびサブセクション(b)の(1)(B)(i)ならびに(2)(B)(iii)(I)(aa)の目的において、医薬品または生物製剤は、DHHS 長官が次のいずれかを推定できるときは、既存治療法を上回る治療上の有益性を示すものとみなされる。

"(1)承認される場合、当該医薬品もしくは生物学的製剤が、関連する小児集団での使用に関し適切な製品情報を有している市販製剤と比較して、病気の治療、診断もしくは予防に著しい改善をもたらす、または

"(2)当該医薬品または生物学的製剤に関して、製剤の選択枝の追加の必要がある部類の製品であること、もしくはその必要がある適応症のものであること。

"(d)評価の提出－サブセクション(a)および(b)の該当規定に従って、サブセクション(a)(2)に記載する評価またはサブセクション(a)もしくは(b)に記載する小児用製剤の承認申請書が提出されない場合は、

"(1)当該評価または申請書の対象である医薬品または生物学的製剤は、不提出のみを理由としてこれを「不当表示 (misbranded)」であるとみなすことができ、かつこれを関連法規制の対象とすることができる（当該医薬品または生物学的製剤がセクション 303 に基づく規制の対象としてはならない場合を除く）。ただし

"(2)評価または申請書の不提出は、次の措置の根拠としてはならない。

"(A)セクション 505(e)に基づく医薬品承認の取り消し、または

"(B)公衆衛生法セクション 351（42 U.S.C. 262）に基づく生物学的製剤の承認の取り消し。

"(e)**会議**－新医薬品または生物学的製剤の開発前および開発中に、DHHS 長官は、次の事項を論議するため、当該新医薬品または生物学的製剤のスポンサーと適切な時期に会議を行う。

"(1)スポンサーが小児試験の計画および予定に関して提出する情報、または

"(2)スポンサーによる小児試験の免除もしくは延期の要請予定。

"(f)**権限の範囲**－本セクションに記載した内容は、本セクションで要求する小児の評価以外に、医薬品もしくは生物学的製剤の小児評価または小児以外の他の集団もしくは使用に関する評価を命じる権限を DHHS 長官に与えるものではない。」。

"(g)**オーファンドラッグ**－DHHS 長官が規則によって別途に要求するときを除いて、本セクションは、セクション 526 に基づき希少疾病用薬の名称が与えられた効能については、どの医薬品にも適用されない。

"(h)**他の小児試験との統合**－本セクションに基づく権限は、本セクションに服する申請の提出をセクション 505A(n)に記載する日以前に DHHS 長官が受領できる限り、効力を保つ。

(b)**適合改正**－(1) FD&C Act セクション 505(b)(1)（21 U.S.C. 355(b)(1)）は、第 2 段を次の通り改正する。

(A)「および(F)」を削除し「(F)」を挿入する。および

(B)末尾の終止符を削除し「、および(G)セクション 505B に基づき必要な評価」を挿入する。

(2) FD&C Act セクション 505A(h)（21 U.S.C. 355a(h)）は、次の通りこれを改正する。

(A)同サブセクションの見出しにおいて、「規則」を削除し「小児試験要件」を挿入する、および

(B)「DHHS 長官により公布された規制に従い」を削除し「本セクション以外の法（規則を含む）の規定により」を挿入する。

(3)公衆衛生法セクション 351(a)(2)（42 U.S.C. 262(a)(2)）は、次の通りこれを改正する。

(A)サブパラグラフ(B)をサブパラグラフ(C)に変更する、および

(B)サブパラグラフ(A)の後に次を挿入する。

「(B)小児試験－本パラグラフに基づき販売承認申請を提出する者は、申請書の一部として、FD&C Act セクション 505B に基づき必要な評価を DHHS 長官に提出する。」

セクション 3　技術的改正および適合改正

(a)**簡略化新医薬品申請**（abbreviated new drug application: ANDA）－FD&C Act セクション 505A（21 U.S.C. 355a）は、サブセクション(b)(2)のサブパラグラフ(A)および(B)ならびにサブセクション(c)(2)のサブパラグラフ(A)および(B)において「505(j)(4)(B)」を削除し「505(j)(5)(B)」を挿入してこれを改正する。

(b)**小児諮問委員会**（Pediatric Advisory Committee）－(1) FD&C Act セクション 505A(i)(2)(21 U.S.C. 355a(i)(2)) は、「抗感染症薬諮問小委員会 (Advisory Subcommittee of the Anti-Infective Drugs)」をすべて削除してこれを改正する。

(2)BPCA(Best Pharmaceuticals for Children Act「小児優良医薬品法」)セクション 14（42 U.S.C. 284m 注、一般法律 107-109）は、次の通りこれを改正する。

(A)同セクションの見出しにおいて**「薬理学（pharmacology）」**を削除する。

(B)サブセクション(a)で「(42 U.S.C. 217a)、」を削除し「(42 U.S.C. 217a) または他の適切な権限、」を挿入する。

(C)サブセクション(b)で、

(i)パラグラフ(1)で「および NIH(National Institute of Health:国立衛生研究所)所長との協議により」を削除

し、および

(ii)パラグラフ(2)で「およびセクション 505A」を削除し「セクション 505A、およびセクション 505B」を挿入する、および

(D)「薬理学」をすべて削除し「治療学 (therapeutics)」を挿入する。

(3) BPCA セクション 15(a)(2)(A)（115 Stat. 1419）は、「薬理学」を削除してこれを改正する。

(4) BPCA セクション 16(1)(C)（21 U.S.C. 355a 注、一般法律 107-109）は、「抗感染症薬諮問小委員会」を削除してこれを改正する。

(5) BPCA セクション 17(b)(1)（21 U.S.C. 355b(b)(1)）は、第 2 段で「抗感染症薬諮問小委員会」を削除してこれを改正する。

(6) 公衆衛生法セクション 409I(c)のパラグラフ(8)、(9)および(11)（42 U.S.C. 284m(c)）は、「抗感染症薬諮問小委員会」をすべて削除してこれを改正する。

セクション 4　施行期日

(a)**総則**－サブセクション(b)に従って、この法律およびこの法律により行われる改正は、この法律の制定の日に効力を発する。

(b)**新医薬品および生物学的製剤への適用**

(1)**総則**－FD&C Act セクション 505B のサブセクション(a)（セクション 2 により追加）は、1999 年 4 月 1 日以降に DHHS 長官に提出される同サブセクションのパラグラフ(1)に記載する申請にこれを適用する。

(2)**免除および延期**

(A)**免除または延期の付与**－1999 年 4 月 1 日とこの法律の制定の日との間 DHHS 長官に提出された申請に関して、小児評価の免除または延期が与えられる場合は、当該免除または延期は、FD&C Act セクション 505B のサブセクション(a)に基づく免除または延期である。ただし、前記の延期に記載する日付は、2002 年 10 月 17 日とこの法律の制定の日との間の日数に等しい日数だけ延長される。

(B)**付与されない免除および延期**－1999 年 4 月 1 日とこの法律の制定の日との間に DHHS 長官に提出された申請に関して、その時点で有効な DHHS 長官の規則に基づき免除も延期も与えられなかったときは、当該申請を提出した者は、次のうち遅い方の日に FD&C Act セクション 505B のサブセクション(a)(2)に基づく評価の提出を命じられる。

(i)この法律の制定の日の 1 年後である日、または

(ii)同セクションのサブセクション(a)(3)に基づき DHHS 長官が指定する日。

ただし、DHHS 長官が同セクションのサブセクション(a)(4)に基づき免除を与えるときはこの限りでない。

(c)**権限の無制限**－この法律またはこの法律によって行われた改正を実施するガイダンスまたは規則の欠如も、指導または規則の発布過程の未完了も、この法律または前記の改正に基づく DHHS 長官の権限を制限するものではなく、またこの法律または前記の改正に基づく要件を猶予するものではない。

下院議長

アメリカ合衆国副大統領兼上院議長

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	

Existing Law	2007 Reauthorization	Improvements
	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

Existing Law	2007 Reauthorization	Improvements
	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).