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(Original Signature of Member)

112TH CONGRESS
1ST SESSION

H. R.

To reauthorize certain provisions of the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act relating to public health preparedness and countermeasure development, and for other purposes.

Mr. ROGERS of Michigan (for himself, Mrs. MYRICK, and Mr. GENE GREEN of Texas) introduced the following bill; which was referred to the Committee on _____

A BILL

To reauthorize certain provisions of the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act relating to public health preparedness and countermeasure development, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Pandemic and All-Hazards Preparedness Reauthoriza-
6 tion Act of 2011”.

1 (b) TABLE OF CONTENTS.—The table of contents for
2 this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Reauthorization of certain provisions relating to public health preparedness.

Sec. 3. Coordination by Assistant Secretary for Preparedness and Response.

Sec. 4. Eliminating duplicative Project Bioshield reports.

Sec. 5. Accelerate countermeasure development by strengthening FDA's role in reviewing products for national security priorities.

3 **SEC. 2. REAUTHORIZATION OF CERTAIN PROVISIONS RE-**
4 **LATING TO PUBLIC HEALTH PREPAREDNESS.**

5 (a) VACCINE TRACKING AND DISTRIBUTION.—Sub-
6 section (e) of section 319A of the Public Health Service
7 Act (42 U.S.C. 247d–1) is amended by striking “such
8 sums for each of fiscal years 2007 through 2011” and
9 inserting “\$30,800,000 for each of fiscal years 2012
10 through 2016”.

11 (b) IMPROVING STATE AND LOCAL PUBLIC HEALTH
12 SECURITY.—Effective on October 1, 2011, section 319C–
13 1 of the Public Health Service Act (42 U.S.C. 247d–3a)
14 is amended—

15 (1) in subsection (f)—

16 (A) in paragraph (2), by inserting “and”
17 at the end;

18 (B) in paragraph (3), by striking “; and”
19 and inserting a period; and

20 (C) by striking paragraph (4);

21 (2) by striking subsection (h); and

22 (3) in subsection (i)—

1 (A) in paragraph (1)—

2 (i) by amending subparagraph (A) to
3 read as follows:

4 “(A) IN GENERAL.—For the purpose of
5 carrying out this section, there is authorized to
6 be appropriated \$632,900,000 for each of fiscal
7 years 2012 through 2016.”; and

8 (ii) by striking subparagraph (B); and

9 (B) in subparagraphs (C) and (D) of para-
10 graph (3), by striking “(1)(A)(i)(I)” each place
11 it appears and inserting “(1)(A)”.

12 (c) PARTNERSHIPS FOR STATE AND REGIONAL HOS-
13 PITAL PREPAREDNESS TO IMPROVE SURGE CAPACITY.—
14 Paragraph (1) of section 319C–2(j) of the Public Health
15 Service Act (42 U.S.C. 247d–3b(j)) is amended to read
16 as follows:

17 “(1) IN GENERAL.—For purposes of carrying
18 out this section, there is authorized to be appro-
19 priated \$378,000,000 for each of fiscal years 2012
20 through 2016.”.

21 (d) CDC PROGRAMS FOR COMBATING PUBLIC
22 HEALTH THREATS.—Section 319D of the Public Health
23 Service Act (42 U.S.C. 247d–4) is amended—

24 (1) by striking subsection (c); and

1 (2) in subsection (g), by striking “such sums as
2 may be necessary in each of fiscal years 2007
3 through 2011” and inserting “\$160,121,000 for
4 each of fiscal years 2012 through 2016”.

5 (e) DENTAL EMERGENCY RESPONDERS: PUBLIC
6 HEALTH AND MEDICAL RESPONSE.—

7 (1) ALL-HAZARDS PUBLIC HEALTH AND MED-
8 ICAL RESPONSE CURRICULA AND TRAINING.—Sec-
9 tion 319F(a)(5)(B) of the Public Health Service Act
10 (42 U.S.C. 247d–6(a)(5)(B)) is amended by striking
11 “public health or medical” and inserting “public
12 health, medical, or dental”.

13 (2) NATIONAL HEALTH SECURITY STRATEGY.—
14 Section 2802(b)(3) of the Public Health Service Act
15 (42 U.S.C. 300hh–1(b)(3)) is amended—

16 (A) in the matter preceding subparagraph
17 (A), by inserting “and which may include den-
18 tal health facilities” after “mental health facili-
19 ties”; and

20 (B) in subparagraph (D), by inserting
21 “(which may include such dental health as-
22 sets)” after “medical assets”.

23 (f) PROCUREMENT OF COUNTERMEASURES.—

24 (1) CONTRACT TERMS.—Clause (ii) of section
25 319F–2(c)(7)(C) of the Public Health Service Act

1 (42 U.S.C. 247d–6b(c)(7)(C)) is amended by adding
2 at the end the following:

3 “(X) GOVERNMENT PURPOSE.—

4 The contract shall provide a clear
5 statement of defined Government pur-
6 pose limited to uses related to a secu-
7 rity countermeasure, as defined in
8 paragraph (1)(B).”.

9 (2) REAUTHORIZATION OF THE SPECIAL RE-
10 SERVE FUND.—Section 319F–2 of the Public Health
11 Service Act (42 U.S.C. 247d–6b) is amended—

12 (A) in subsection (c)—

13 (i) by striking “special reserve fund
14 under paragraph (10)” each place it ap-
15 pears and inserting “special reserve fund
16 as defined in subsection (g)(5)”; and

17 (ii) by striking paragraphs (9) and
18 (10); and

19 (B) by adding at the end the following:

20 “(g) SPECIAL RESERVE FUND.—

21 “(1) AUTHORIZATION OF APPROPRIATIONS.—In
22 addition to amounts appropriated to the special re-
23 serve fund prior to the date of the enactment of this
24 subsection, there is authorized to be appropriated,
25 for the procurement of security countermeasures

1 under subsection (c) and for carrying out section
2 319L (relating to the Biomedical Advanced Research
3 and Development Authority), \$2,800,000,000 for the
4 period of fiscal years 2014 through 2018. Amounts
5 appropriated pursuant to the preceding sentence are
6 authorized to remain available until September 30,
7 2019.

8 “(2) NOTICE OF INSUFFICIENT FUNDS.—Not
9 later than 15 days after any date on which the Sec-
10 retary determines that the amount of funds in the
11 special reserve fund available for procurement is less
12 than \$1,500,000,000, the Secretary shall submit to
13 the relevant committees of Congress a report detail-
14 ing the amount of such funds available for procure-
15 ment and the impact such funding will have—

16 “(A) in meeting the security counter-
17 measure needs identified under this section; and

18 “(B) on the annual Public Health Emer-
19 gency Medical Countermeasure Enterprise Im-
20 plementation Plan under section 319F–5(b).

21 “(3) USE OF SPECIAL RESERVE FUND FOR AD-
22 VANCED RESEARCH AND DEVELOPMENT.—The Sec-
23 retary, acting through the Director of the Bio-
24 medical Advanced Research and Development Au-
25 thority, may utilize not more than 30 percent of the

1 amounts authorized to be appropriated under para-
2 graph (1) to carry out section 319L (related to the
3 Biomedical Advanced Research and Development
4 Authority). Amounts authorized to be appropriated
5 under this subsection to carry out section 319L are
6 in addition to amounts otherwise authorized to be
7 appropriated to carry out such section.

8 “(4) RESTRICTIONS ON USE OF FUNDS.—
9 Amounts in the special reserve fund shall not be
10 used to pay—

11 “(A) costs other than payments made by
12 the Secretary to a vendor for advanced research
13 and development or procurement of a security
14 countermeasure under subsection (c)(7); and

15 “(B) any administrative expenses, includ-
16 ing salaries.

17 “(5) DEFINITION.—In this section, the term
18 ‘special reserve fund’ means the ‘Biodefense Coun-
19 termeasures’ appropriations account, any appropria-
20 tion made available pursuant to section 521(a) of
21 the Homeland Security Act of 2002, and any appro-
22 priation made available pursuant to paragraph (1) of
23 this paragraph.”.

24 (g) BIOMEDICAL ADVANCED RESEARCH AND DEVEL-
25 OPMENT AUTHORITY.—

1 (1) TRANSACTION AUTHORITIES.—Section
2 319L(c)(5) of the Public Health Service Act (42
3 U.S.C. 247d–7e(c)(5)) is amended by adding at the
4 end the following:

5 “(G) GOVERNMENT PURPOSE.—In award-
6 ing contracts, grants, and cooperative agree-
7 ments under this section, the Secretary shall
8 provide a clear statement of defined Govern-
9 ment purpose related to activities included in
10 subsection (a)(6)(B) for a qualified counter-
11 measure or qualified pandemic or epidemic
12 product.”.

13 (2) BIODEFENSE MEDICAL COUNTERMEASURE
14 DEVELOPMENT FUND.—Paragraph (2) of section
15 319L(d) of the Public Health Service Act (42 U.S.C.
16 247d–7e(d)) is amended to read as follows:

17 “(2) FUNDING.—To carry out the purposes of
18 this section, there is authorized to be appropriated
19 to the Fund \$415,000,000 for each of fiscal years
20 2012 through 2016, the amounts to remain available
21 until expended.”.

22 (3) CONTINUED INAPPLICABILITY OF CERTAIN
23 PROVISIONS.—Section 319L(e)(1)(C) of the Public
24 Health Service Act (42 U.S.C. 247d–7e(e)(1)(C)) is

1 amended by striking “7 years” and inserting “10
2 years”.

3 (h) NATIONAL DISASTER MEDICAL SYSTEM.—Sec-
4 tion 2812 of the Public Health Service Act (42 U.S.C.
5 300hh–11) is amended—

6 (1) in subsection (a)(3), by adding at the end
7 the following:

8 “(D) ADMINISTRATION.—The Secretary
9 may determine and pay claims for reimburse-
10 ment for services under subparagraph (A) di-
11 rectly or by contract providing for payment in
12 advance or by way of reimbursement.”; and

13 (2) in subsection (g), by striking “such sums as
14 may be necessary for each of the fiscal years 2007
15 through 2011” and inserting “\$56,000,000 for each
16 of fiscal years 2012 through 2016”.

17 (i) EXTENSION OF LIMITED ANTITRUST EXEMP-
18 TION.—Section 405(b) of the Pandemic and All-Hazard
19 Preparedness Act (42 U.S.C. 247d–6a note) is amended
20 by striking “6-year” and inserting “10-year”.

21 **SEC. 3. COORDINATION BY ASSISTANT SECRETARY FOR**
22 **PREPAREDNESS AND RESPONSE.**

23 (a) IN GENERAL.—Section 2811 of the Public Health
24 Service Act (42 U.S.C. 300hh–10) is amended—

25 (1) in subsection (b)(3)—

1 (A) by inserting “stockpiling, distribution,”
2 before “and procurement”; and

3 (B) by inserting “, security measures (as
4 defined in section 319F-2,” after “qualified
5 countermeasures (as defined in section 319F-
6 1)” ;

7 (2) in subsection (b)(4), by adding at the end
8 the following:

9 “(D) IDENTIFICATION OF INEFFICIEN-
10 CIES.—Identify gaps, duplication, and other in-
11 efficiencies in public health preparedness activi-
12 ties and the actions necessary to overcome these
13 obstacles.

14 “(E) DEVELOPMENT OF COUNTER-
15 MEASURE IMPLEMENTATION PLAN.—Lead the
16 development of a coordinated Countermeasure
17 Implementation Plan under subsection (d).

18 “(F) COUNTERMEASURES BUDGET ANAL-
19 YSIS.—Oversee, in consultation with the Direc-
20 tor of the Office of Management and Budget,
21 the development of a comprehensive, cross-cut-
22 ting 5-year budget analysis with respect to ac-
23 tivities described in paragraph (3)—

24 “(i) to inform prioritization of re-
25 sources; and

1 “(ii) to ensure that challenges are
2 adequately addressed.

3 “(G) GRANT PROGRAMS FOR MEDICAL AND
4 PUBLIC HEALTH PREPAREDNESS CAPABILI-
5 TIES.—Coordinate, in consultation with the
6 Secretary of Homeland Security, grant pro-
7 grams of the Department of Health and
8 Human Services relating to medical and public
9 health preparedness capabilities and the ability
10 of local communities to respond to public health
11 emergencies, including by—

12 “(i) coordinating the program require-
13 ments, timelines, and measurable goals of
14 such grant programs; and

15 “(ii) establishing a system for gath-
16 ering and disseminating best practices
17 among grant recipients.”;

18 (3) by amending subsection (c) to read as fol-
19 lows:

20 “(c) FUNCTIONS.—The Assistant Secretary for Pre-
21 paredness and Response shall—

22 “(1) have authority over and responsibility
23 for—

1 “(A) the National Disaster Medical System
2 (in accordance with section 301 of the Pan-
3 demic and All-Hazards Preparedness Act);

4 “(B) the Hospital Preparedness Coopera-
5 tive Agreement Program pursuant to section
6 319C-2;

7 “(C) the Biomedical Advanced Research
8 and Development Authority under section
9 319L;

10 “(D) the Medical Reserve Corps pursuant
11 to section 2813;

12 “(E) the Emergency System for Advance
13 Registration of Volunteer Health Professionals
14 pursuant to section 319I;

15 “(F) the Strategic National Stockpile;

16 “(G) the Cities Readiness Initiative; and

17 “(2) assume other duties as determined appro-
18 priate by the Secretary.”; and

19 (4) by adding at the end the following:

20 “(d) COUNTERMEASURE IMPLEMENTATION PLAN.—

21 Not later than 6 months after the date of enactment of
22 this subsection, and annually thereafter, the Assistant
23 Secretary for Preparedness and Response shall submit to
24 the Secretary and relevant congressional committees a
25 Countermeasure Implementation Plan that—

1 “(1) describes the chemical, biological, radio-
2 logical, and nuclear threats facing the Nation and
3 the corresponding efforts to develop qualified coun-
4 termeasures (as defined in section 319F–1), secured
5 countermeasures (as defined in section 319F–2), or
6 qualified pandemic or epidemic products (as defined
7 in section 319F–3) for each threat;

8 “(2) evaluates the progress of all activities with
9 respect to such countermeasures or products, includ-
10 ing research, advanced research, development, pro-
11 curement, stockpiling, deployment, and utilization;

12 “(3) identifies and prioritizes near-, mid-, and
13 long-term needs with respect to such counter-
14 measures or products to address chemical, biological,
15 radiological, and nuclear threats;

16 “(4) identifies, with respect to each category of
17 threat, a summary of all advanced development and
18 procurement awards, including the time elapsed
19 from the issuance of the initial solicitation or re-
20 quest for a proposal to the adjudication (such as the
21 award, denial of award, or solicitation termination),
22 and including—

23 “(A) projected timelines for development
24 and procurement of such countermeasures or
25 products;

1 “(B) clearly defined goals, benchmarks,
2 and milestones for each countermeasure or
3 product, including information on the number
4 of doses required, the intended use of the coun-
5 termeasure or product, and the required coun-
6 termeasure or product characteristics; and

7 “(C) projected needs with regard to the re-
8 plenishment of the Strategic National Stockpile;

9 “(5) evaluates progress made in meeting the
10 goals, benchmarks, and milestones identified under
11 paragraph (4);

12 “(6) reports on the amount of funds available
13 for procurement in the special reserve fund as de-
14 fined in section 319F-2(g)(5) and the impact this
15 funding will have on meeting the requirements under
16 section 319F-2; and

17 “(7) incorporates input from Federal, State,
18 local, and tribal stakeholders.”.

19 (b) CONSULTATION IN AUTHORIZING MEDICAL
20 PRODUCTS FOR USE IN EMERGENCIES.—Subsection (c)
21 of section 564 of the Federal Food, Drug, and Cosmetic
22 Act (21 U.S.C. 360bbb-3) is amended by striking “con-
23 sultation with the Director of the National Institutes of
24 Health” and inserting “consultation with the Assistant

1 Secretary for Preparedness and Response, the Director of
2 the National Institutes of Health,”.

3 **SEC. 4. ELIMINATING DUPLICATIVE PROJECT BIOSHIELD**
4 **REPORTS.**

5 Section 5 of the Project Bioshield Act of 2004 (42
6 U.S.C. 247d–6c) is repealed.

7 **SEC. 5. ACCELERATE COUNTERMEASURE DEVELOPMENT**
8 **BY STRENGTHENING FDA’S ROLE IN REVIEW-**
9 **ING PRODUCTS FOR NATIONAL SECURITY**
10 **PRIORITIES.**

11 (a) IN GENERAL.—Section 565 of the Federal Food,
12 Drug, and Cosmetic Act (21 U.S.C. 360bbb–4) is amend-
13 ed to read as follows:

14 **“SEC. 565. COUNTERMEASURE DEVELOPMENT AND RE-**
15 **VIEW.**

16 “(a) COUNTERMEASURES AND PRODUCTS.—The
17 countermeasures and products referred to in this sub-
18 section are—

19 “(1) qualified countermeasures (as defined in
20 section 319F–1 of the Public Health Service Act);

21 “(2) security countermeasures (as defined in
22 section 319F–2 of such Act); and

23 “(3) qualified pandemic or epidemic products
24 (as defined in section 319F–3 of such Act).

25 “(b) IN GENERAL.—

1 “(1) INVOLVEMENT OF FDA PERSONNEL IN
2 INTERAGENCY ACTIVITIES.—The Secretary shall ac-
3 celerate the development, stockpiling, approval, and
4 licensure of countermeasures and products referred
5 to in subsection (a) by expanding the involvement of
6 Food and Drug Administration personnel in inter-
7 agency activities with the Biomedical Advanced Re-
8 search and Development Authority, the Centers for
9 Disease Control and Prevention, the National Insti-
10 tutes of Health, and the Department of Defense.

11 “(2) TECHNICAL ASSISTANCE.—The Secretary
12 shall establish within the Food and Drug Adminis-
13 tration a team of experts on manufacturing and reg-
14 ulatory activities (including compliance with current
15 Good Manufacturing Practice) to provide both off-
16 site and on-site technical assistance to the manufac-
17 turers of countermeasures and products referred to
18 in subsection (a).

19 “(c) AGENCY INTERACTION WITH SECURITY COUN-
20 TERMEASURE SPONSORS.—

21 “(1) COUNTERMEASURE DEVELOPMENT PRO-
22 GRAM.—

23 “(A) IN GENERAL.—For each security
24 countermeasure (as defined in section 319F-2
25 of the Public Health Service Act) that is pro-

1 cured under such section 319F-2, the Secretary
2 shall initiate, in consultation with the security
3 countermeasure sponsor (referred to in this sec-
4 tion as the ‘countermeasure sponsor’), a pro-
5 gram of frequent scientific feedback and inter-
6 actions regarding the process of developing such
7 countermeasure, including—

8 “(i) regular meetings between appro-
9 priate Food and Drug Administration per-
10 sonnel and the countermeasure sponsor
11 during the process of developing the coun-
12 termeasure, to be scheduled within 45 days
13 after attainment of each milestone identi-
14 fied pursuant to subparagraph (B)(iv)(I)
15 in the regulatory management plan for the
16 countermeasure;

17 “(ii) written feedback from the Food
18 and Drug Administration within 30 days
19 after submission of a request for feedback
20 pursuant to subparagraph (B)(iv)(II) in
21 the regulatory management plan for the
22 countermeasure;

23 “(iii) written feedback from the Food
24 and Drug Administration within 30 days
25 after submission by the countermeasure

1 sponsor of a study report that is consid-
2 ered to be complete pursuant to subpara-
3 graph (B)(iv)(III) in the regulatory man-
4 agement plan for the countermeasure;

5 “(iv) at the request of the Director of
6 the Biomedical Advanced Research and
7 Development Authority, participation in
8 meetings of such Authority on the develop-
9 ment of the countermeasure; and

10 “(v) other meetings, including on-site
11 meetings, as appropriate.

12 “(B) REGULATORY MANAGEMENT PLAN.—

13 In carrying out the program under subpara-
14 graph (A), the Secretary shall, in consultation
15 with the countermeasure sponsor, develop a
16 written regulatory management plan for each
17 security countermeasure (as defined in section
18 319F–2 of the Public Health Service Act) that
19 is procured under such section 319F–2. The
20 regulatory management plan shall be completed
21 within 60 days of issuance of a contract for the
22 countermeasure under such section 319F–2 or,
23 for a countermeasure that was procured under
24 such section 319F–2 before the date of the en-
25 actment of the Pandemic and All-Hazards Pre-

1 paredness Reauthorization Act of 2011, within
2 60 days after such date of enactment. The reg-
3 ulatory management plan for a security coun-
4 termeasure shall include—

5 “(i) an assessment of the current reg-
6 ulatory status, an assessment of known
7 scientific gaps, and a proposed pathway to
8 approval or licensure of the counter-
9 measure;

10 “(ii) guidance by the Food and Drug
11 Administration regarding the data required
12 to support delivery of the countermeasure
13 to the Strategic National Stockpile;

14 “(iii) guidance by the Food and Drug
15 Administration regarding data required to
16 support submission of a proposed agree-
17 ment on the design and size of clinical
18 trials for review under section
19 505(b)(5)(B); and

20 “(iv) an agreement between the Food
21 and Drug Administration and the counter-
22 measure sponsor to identify—

23 “(I) developmental milestones
24 that will trigger meetings between the
25 Administration and the sponsor;

1 “(II) the process for requesting
2 and receiving written or oral feedback
3 from the Administration; and

4 “(III) the type study reports that
5 will be considered by the Administra-
6 tion to be complete.

7 “(C) APPLICABILITY TO CERTAIN QUALI-
8 FIED PANDEMIC OR EPIDEMIC PRODUCTS.—The
9 Secretary may, with respect to qualified pan-
10 demic or epidemic products (as defined in sec-
11 tion 319F–3 of the Public Health Service Act)
12 for which a contract for advanced research and
13 development is entered into under section 319L
14 of such Act, choose to apply the provisions of
15 subparagraphs (A) and (B) to the same extent
16 and in the same manner as such provisions
17 apply with respect to security countermeasures.

18 “(d) FINAL GUIDANCE ON DEVELOPMENT OF ANI-
19 MAL MODELS.—Not later than 180 days after the date
20 of the enactment of the Pandemic and All-Hazards Pre-
21 paredness Reauthorization Act of 2011, the Secretary
22 shall provide final guidance to industry regarding the de-
23 velopment of animal models to support approval or licen-
24 sure of countermeasures and products referred to in sub-

1 section (a) when human efficacy studies are not ethical
2 or feasible.

3 “(e) ANNUAL REPORT.—Not later than January 1,
4 2012, and every January 1 thereafter, the Secretary shall
5 submit a report to the Committee on Energy and Com-
6 merce of the House of Representatives and the Committee
7 on Health, Education, Labor, and Pensions of the Senate
8 that, with respect to the preceding fiscal year, includes—

9 “(1) the number of full-time equivalent employ-
10 ees of the Food and Drug Administration who di-
11 rectly support the review of countermeasures and
12 products referred to in subsection (a);

13 “(2) estimates of funds obligated by the Food
14 and Drug Administration for development of such
15 countermeasures and products;

16 “(3) the number of regulatory teams at the
17 Food and Drug Administration specific to such
18 countermeasures and products and, for each such
19 team, the assigned products, classes of products, or
20 technologies;

21 “(4) the length of time between each request by
22 the sponsor of such a countermeasure or product for
23 information and the provision of such information by
24 the Food and Drug Administration;

1 “(5) the number, type, and frequency of official
2 interactions between the Food and Drug Adminis-
3 tration and—

4 “(A) sponsors of a countermeasure or
5 product referred to in subsection (a); or

6 “(B) another agency engaged in develop-
7 ment or management of portfolios for such
8 countermeasures or products, including the
9 Centers for Disease Control and Prevention, the
10 Biomedical Advanced Research and Develop-
11 ment Authority, the National Institutes of
12 Health, and the appropriate agencies of the De-
13 partment of Defense;

14 “(6) any other measure to determine the effi-
15 ciency of the regulatory teams described in para-
16 graph (3); and

17 “(7) the regulatory science priorities which the
18 Food and Drug Administration is addressing and
19 the progress made on these priorities.”.

20 (b) DISCUSSIONS BETWEEN FDA AND SPONSOR ON
21 DESIGN AND SIZE OF ANIMAL AND CLINICAL TRIALS IN-
22 TENDED TO FORM THE PRIMARY BASIS OF AN EFFEC-
23 TIVENESS CLAIM WHEN HUMAN EFFICACY STUDIES ARE
24 NOT ETHICAL OR FEASIBLE.—Subparagraph (B) of sec-

1 tion 505(b)(5) of the Federal Food, Drug, and Cosmetic
2 Act (21 U.S.C. 355(b)(5)) is amended to read as follows:

3 “(B)(i) The Secretary shall meet with a sponsor of
4 an investigation or an applicant for approval for a drug
5 under this subsection or section 351 of the Public Health
6 Service Act if the sponsor or applicant makes a reasonable
7 written request for a meeting for the purpose of reaching
8 agreement on the design and size of—

9 “(I) clinical trials intended to form the primary
10 basis of an effectiveness claim; or

11 “(II) animal and clinical trials intended to form
12 the primary basis of an effectiveness claim when
13 human efficacy studies are not ethical or feasible.

14 “(ii) The sponsor or applicant shall provide informa-
15 tion necessary for discussion and agreement on the design
16 and size of the clinical trials. Minutes of any such meeting
17 shall be prepared by the Secretary and made available to
18 the sponsor or applicant upon request.”.