tigational new drug protocol submission to the FDA and the reviewing IRB. Training and health risk communication shall include at a minimum:

(1) The basis for any determination by the President that informed consent is not or may not be feasible;

(2) The means for tracking use and adverse effects of the investigational drug;

(3) The benefits and risks of using the investigational drug; and

(4) A statement that the investigational drug is not approved (or not approved for the intended use).

(d) The DoD shall keep operational commanders informed of the overall requirements of successful protocol execution and their role, with the support of medical personnel, in ensuring successful execution of the protocol.

SEC. 6. *Scope*. (a) This order applies to the consideration and Presidential approval of a waiver of informed consent under 10 U.S.C. 1107 and does not apply to other FDA regulations.

(b) This order is intended only to improve the internal management of the Federal Government. Nothing contained in this order shall create any right or benefit, substantive or procedural, enforceable by any party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

WILLIAM J. CLINTON.

§ 1107a. Emergency use products

(a) WAIVER BY THE PRESIDENT.—(1) In the case of the administration of a product authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act to members of the armed forces, the condition described in section 564(e)(1)(A)(ii)(III) of such Act and required under paragraph (1)(A) or (2)(A) of such section 564(e), designed to ensure that individuals are informed of an option to accept or refuse administration of a product, may be waived only by the President only if the President determines, in writing, that complying with such requirement is not in the interests of national security.

(2) The waiver authority provided in paragraph (1) shall not be construed to apply to any case other than a case in which an individual is required to be informed of an option to accept or refuse administration of a particular product by reason of a determination by the Secretary of Health and Human Services that emergency use of such product is authorized under section 564 of the Federal Food, Drug, and Cosmetic Act.

(b) PROVISION OF INFORMATION.—If the President, under subsection (a), waives the condition described in section 564(e)(1)(A)(ii)(III) of the Federal Food, Drug, and Cosmetic Act, and if the Secretary of Defense, in consultation with the Secretary of Health and Human Services, makes a determination that it is not feasible based on time limitations for the information described in section 564(e)(1)(A)(ii)(I) or (II) of such Act and required under paragraph (1)(A) or (2)(A) of such section 564(e), to be provided to a member of the armed forces prior to the administration of the product, such information shall be provided to such member of the armed forces (or next-of-kin in the case of the death of a member) to whom the product was administered as soon as possible, but not later than 30 days, after such administration. The authority provided for in this subsection may not be delegated. Information concerning the administration of the product shall be recorded in the medical record of the member.

(c) APPLICABILITY OF OTHER PROVISIONS.—In the case of an authorization by the Secretary of Health and Human Services under section 564(a)(1) of the Federal Food, Drug, and Cosmetic Act based on a determination by the Secretary of Defense under section 564(b)(1)(B) of such Act, subsections (a) through (f) of section 1107 shall not apply to the use of a product that is the subject of such authorization, within the scope of such authorization and while such authorization is effective.

(Added Pub. L. 108–136, div. A, title XVI, § 1603(b)(1), Nov. 24, 2003, 117 Stat. 1689; amended Pub. L. 108–375, div. A, title VII, § 726(b), Oct. 28, 2004, 118 Stat. 1992; Pub. L. 109–364, div. A, title X, § 1071(a)(5), (g)(7), Oct. 17, 2006, 120 Stat. 2398, 2402.)

REFERENCES IN TEXT

Section 564 of the Federal Food, Drug, and Cosmetic Act, referred to in text, is classified to section 360bbb–3 of Title 21, Food and Drugs.

AMENDMENTS

2006—Subsec. (a). Pub. L. 109–364, § 1071(g)(7), made technical correction to directory language of Pub. L. 108–375, § 726(b)(1). See 2004 Amendment note below.

Pub. L. 109–364, § 1071(a)(5), redesignated subpars. (A) and (B) as pars. (1) and (2), respectively, and, in par. (2), substituted ''paragraph (1)'' for ''subparagraph (A)''.

2004—Subsec. (a). Pub. L. 108–375, § 726(b)(1), as amended by Pub. L. 109–364, § 1071(g)(7), inserted ''(A)'' after ''PRESIDENT.—''.

Subsec. (a)(A). Pub. L. 108–375, § 726(b)(2), struck out ''is not feasible, is contrary to the best interests of the members affected, or'' after ''such requirement''.

Subsec. (a)(B). Pub. L. 108–375, § 726(b)(3), added subpar. (B).

EFFECTIVE DATE OF 2006 AMENDMENT

Pub. L. 109–364, div. A, title X, § 1071(g), Oct. 17, 2006, 120 Stat. 2402, provided that the amendment made by section 1071(g)(7) is effective as of Oct. 28, 2004, and as if included in Pub. L. 108–375 as enacted.

TERMINATION DATE

Pub. L. 108–136, div. A, title XVI, § 1603(d), Nov. 24, 2003, 117 Stat. 1690, which provided that section 1603 of Pub. L. 108–136 (enacting this section and section 360bbb–3 of Title 21, Food and Drugs, and amending section 331 of Title 21) would not be in effect (and the law was to read as if that section had never been enacted) as of the date on which, following enactment of the Project Bioshield Act of 2003, the President submits to Congress a notification that the Project Bioshield Act of 2003 provides an effective emergency use authority with respect to members of the Armed Forces, was repealed by Pub. L. 108–276, § 4(b), July 21, 2004, 118 Stat. 859. [The Project Bioshield Act of 2003 was not enacted.]

§ 1108. Health care coverage through Federal Employees Health Benefits program: demonstration project

(a) FEHBP OPTION DEMONSTRATION.—The Secretary of Defense, after consulting with the other administering Secretaries, shall enter into an agreement with the Office of Personnel Management to conduct a demonstration project (in this section referred to as the ''demonstration project'') under which eligible beneficiaries described in subsection (b) and residing within one of the areas covered by the demonstration project may enroll in health benefits plans offered through the Federal Employees Health