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February 14, 2001

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 10-61
5630 Fishers Lane
Rockville MD 20857

CITIZEN'S PETITION

The American Public Health Association, the American Medical Women's Association, the Association of Reproductive Health Professionals, the National Asian Women's Health Organizations, the National Black Women's Health Project, the National Family Planning and Reproductive Health Association, the Planned Parenthood Federation of America, the Reproductive Health Technologies Project and 58 other organizations listed below, by their counsel, the Center for Reproductive Law & Policy, submit this petition pursuant to 21 C.F.R. § 10.30 (1999), to request that the Food and Drug Administration (FDA) switch from prescription to over-the-counter (OTC) status two FDA-approved emergency contraceptive drugs, *Preven*TM and *Plan B*[®], and any new drug eligible for filing an abbreviated new drug application because of its equivalence to *Preven*TM or *Plan B*[®] (hereinafter these drugs will be collectively referred to as EC). Such a switch is authorized under 21 U.S.C. § 353(b)(3) and 21 C.F.R. § 310.200(b) because, as set forth below and in the supporting Declaration of David Grimes, M.D. ("Grimes Dec."), EC is safe and effective for OTC use. Accordingly, the FDA should grant this Petition and exempt EC from prescription dispensing limitations.

ACTION REQUESTED

Petitioners request that the FDA exempt from prescription-dispensing requirements, pursuant to 21 U.S.C. § 353(b)(3) and 21 C.F.R. § 310.200(b), *Preven*TM, *Plan B*[®], and any new drug eligible for filing an abbreviated new drug application because of its equivalence to *Preven*TM or *Plan B*[®].

STATEMENT OF GROUNDS

Under the Food, Drug and Cosmetic Act and FDA regulations, “[a]ny drug limited to prescription use . . . shall be exempted from prescription-dispensing requirements when the Commissioner finds such requirements are not necessary for the protection of the public health by reason of the drug’s toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, and he finds that the drug is safe and effective for use in self-medication as directed in proposed labeling.” 21 C.F.R. § 310.200(b); *see also* 21 U.S.C. § 353(b)(3) (“The Secretary may by regulation remove drugs subject to sections 352(d) and 355 of this title from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health.”). FDA regulations also explicitly authorize the use of a citizen’s petition to seek a switch from prescription to OTC status: “A proposal to exempt a drug from the prescription-dispensing requirements of section 503(b)(1)(C) of the act may be initiated by . . . any interested person . . . fil[ing] a petition . . . pursuant to Part 10 of this chapter . . .” 21 C.F.R. § 310.200(b).

Limiting EC to prescription use is not necessary for the protection of public health. As set forth in greater detail in the accompanying Declaration of Dr. Grimes, EC meets all the criteria for OTC availability. In general, an approved drug is suitable for OTC use when: (1) the drug is safe for self-medication, 21 C.F.R. § 310.200(b)(1999); 21 C.F.R. § 330.10(a)(4)(i) (1999); Tamar Nordenberg, *Now Available Without a Prescription*, FDA Consumer 7, 9 (Nov. 6,

1996); Marian Segal, *Rx to OTC: The Switch is On*, www.fda.gov/bbs/topics/consumer/CN00012c.html (March 1991); R. William Soller, “OTCness”, 32 Drug Information Journal 555, 556-58 (1998); Debra L. Bowen, *Making the Switch to OTC*, III Cosmetics & Toiletries 102 (May 1996); Nancy L. Buc, *The Switch from Prescription to Over the Counter*, in *The Pill: From Prescription to Over the Counter* 237, 238-39 (eds. Samuels & Smith 1994); (2) the drug is effective when self-administered, 21 C.F.R. § 310.200(b)(1999); 21 C.F.R. § 330.10(a)(4)(ii)(1999); Soller, *supra* at 556, 558-59; Bowen, *supra*; Buc, *supra*; Nordenberg, *supra* at 7; (3) the condition to be treated is self-diagnosable, Segal, *supra*; Bowen, *supra*, Buc, *supra*; and (4) the drug’s labeling is tailored to self-administration, 21 C.F.R. § 310.200(b)(1999); 21 C.F.R. § 330.10(a)(4)(v)(1999); Soller, *supra*, at 559-60; Segal, *supra*; Bowen, *supra*; Buc, *supra*; Nordenberg, *supra* at 7-8, 9, 11.

First, EC is safe for self-medication because it is not toxic to the woman (or to the embryo or fetus if a pregnancy had been previously established in the woman); it has a low risk of abuse or overdose; overdose is unlikely to lead to serious consequences; and its side effects are well known and minor. Grimes Dec. ¶¶ 8A, B, C, F. Second, EC is effective when self-administered. Its administration is simple and relies only on assessments as to time elapsed since sexual intercourse that can be independently made by the woman, and any interaction between EC and other drugs would be nonfatal and unlikely to seriously affect EC’s efficacy. Grimes Dec. ¶ 8I. Third, the condition EC treats — contraceptive failure or failure to use contraception during intercourse — is one that is readily diagnosable by a woman, and EC has no contraindications that would pose a danger to the patient. Grimes Dec. ¶ 8D. Fourth, the existing patient labeling for *Preven*TM and *Plan B*[®] is tailored to self-administration in that it is simple, clear, comprehensive and easy to follow. Grimes Dec. ¶ 8H. Finally, switching EC to

OTC status will promote public health because EC is only effective for a short time after unprotected sex, and it works most effectively if used within twenty-four hours of unprotected sex. Because contacting a physician and obtaining and filling a prescription hinder women from obtaining EC in a timely fashion, making EC available OTC will allow more women to use the treatment, and enable more women to prevent unwanted pregnancies, to the benefit of public health. Grimes Dec. ¶¶ 5, 6, 7. Accordingly, both the American Medical Association and the American College of Obstetricians and Gynecologists have publicly supported efforts to move EC to OTC status. *See* Dec. 5, 2000 Statement of American Medical Association, <http://www.ama-assn.org/ama/pub/article/1617-3547.html> (copy attached hereto); December 13, 2001 Statement of the American College of Obstetricians & Gynecologists (filed herewith).

Because limiting EC to prescription dispensing is not necessary for the protection of public health, the FDA should exempt it from that limitation. 21 C.F.R. § 310.200(b) (a drug “shall be exempted from prescription-dispensing requirements when the Commissioner finds such requirements are not necessary for the protection of the public health”).

ENVIRONMENTAL IMPACT

The proposed action is exempt from the requirement of an environmental impact statement under 21 C.F.R. §§ 25.24(a)(8) and (c)(6).

ECONOMIC IMPACT

No information is required at this time.

CERTIFICATION

The Center for Reproductive Law & Policy, counsel for petitioners certifies that, to the best of its knowledge and belief, this petition includes all information and views on which the petition relies. The petitioners know of no data unfavorable to the petition.

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PETITIONERS

Advocates for Youth

The Alaska Emergency Contraceptive Project

American Association of University Women

American Academy of Pediatrics

American College of Nurse-Midwives

Americans for Democratic Action

American Medical Women's Association

The American Nurses Association

American Public Health Association

American Society for Emergency Contraception

American Society for Reproductive Medicine

Arizona Family Planning Council

Association of Reproductive Health Professionals

Beaverhead Family Planning Clinic

Center for Entrepreneurship in International Health and Development, School of Public Health,
University of California, Berkeley

Center for Women's Policy Studies

Choice USA

The Compton Foundation

The Consortium for Emergency Contraception

Family Health Care, Inc.

Family Health International

Family Planning Association of Northern Ohio, Inc.

Family Planning Council

Family Planning Councils of America

Family Planning Council of Iowa

Family Planning Association of Maine

Family Tree Clinic

Fargo Cass Public Health

Health Care of Southeast Massachusetts
Health Quarters
Ipas
Lake County Family Planning
Medical and Health Research Association of New York City, Inc
National Abortion Federation
National Abortion and Reproductive Rights Action League
 California Abortion and Reproductive Rights Action League
 Massachusetts Abortion and Reproductive Rights Action League
 Minnesota Abortion and Reproductive Rights Action League
 New York Abortion and Reproductive Rights Action League
National Asian Women's Health Organization
National Association of Nurse Practitioners in Women's Health
National Black Women's Health Project
National Coalition Against Domestic Violence
National Consumers League
National Family Planning and Reproductive Health Association
The National Organization for Women Legal Defense and Education Fund
The National Organization on Adolescent Pregnancy, Parenting & Prevention
National Partnership for Women and Families
Okanogan Family Planning
Oops- Emergency Contraception Hotline
Pacific Institute for Women's Health
Pathfinder International
Physicians for Reproductive Choice and Health
Planned Parenthood Federation of America and all Planned Parenthood Affiliates Nationwide
 Planned Parenthood of Central Washington
 Planned Parenthood/ Chicago Area
 Planned Parenthood of Connecticut
 Planned Parenthood Heart of Illinois
 Planned Parenthood of Houston and Southeast Texas, Inc

Planned Parenthood Association of Lubbock
Planned Parenthood of Nassau County
Planned Parenthood of the Saint Louis Region
Planned Parenthood of Southern Arizona
Planned Parenthood of Stark County
Planned Parenthood of the Texas Capital Region
Planned Parenthood of Western Washington
The Population Council
Population Services International, U.S. Programs
Pro Choice Resource Center
Program for Appropriate Technology in Health
The Reproductive Health Technologies Project
The Sexuality Information and Education Council of the United States
Texas Family Planning Association
Tri City Health Center
Voters for Choice
Women's Health Center of West Virginia