DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Building #51
Silver Spring, MD 20993

DEC 3 0 2015

Richard Briles Moriarty
Assistant Attorney General
State of Wisconsin
Department of Justice
17 W. Main Street
P.O. Box 7857
Madison, WI 53707-7857

Re: Docket No. FDA-2006-P-0018

Dear Mr. Moriarty:

This letter responds to the State of Wisconsin's citizen petition dated May 22, 2006, regarding Plan B (levonorgestrel) tablets, 0.75 milligrams (mg) (Plan B). In the Petition, you request that FDA "switch" Plan B and equivalent emergency contraception drugs from prescription-only to nonprescription status without age restrictions.[1] You also request that FDA exempt from prescription dispensing requirements "any new drug eligible for filing an abbreviated new drug application because of its equivalence to Plan B" (Petition at 2). For the reasons stated below, your Petition is granted in part and denied in part.

Your Petition requests have been addressed by our December 12, 2011, and June 10, 2013, responses to the requests in a citizen petition dated February 14, 2001, from the Center for Reproductive Rights (CRR Petition).[2] The CRR Petition requested that FDA exempt from prescription dispensing requirements two emergency contraceptive drug products, Preven and Plan B, as well as any generic versions of these products. On June 9, 2006, FDA denied the CRR Petition on the ground that it was not adequately supported by scientific evidence.[3] The June 2006 CRR Petition denial was later vacated by a federal district court in a lawsuit brought by a group of individuals and reproductive health groups seeking FDA approval of nonprescription availability of Plan B for all age groups. *See Tummino v. Torti*, 603 F. Supp. 2d 519 (E.D.N.Y. 2009) (*Tummino I*). The court ordered, among other things, that "[t]he denial of the Citizen Petition is vacated and the matter is remanded to the FDA to reconsider its decisions regarding the Plan B switch to OTC use" (*id.* at 550).

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[1] The Petition was originally assigned docket number 2006P-0223/CP 1. The number was changed to FDA-2006-P-0018 as a result of FDA's transition to its new docketing system (Regulations.gov) in January 2008.

[2] The CRR Petition was originally assigned docket number 2001P-0075/CP1. The number changed to FDA-2001-P-0123 as a result of FDA's transition to its new docketing system (Regulations.gov) in January 2008.

[3] *See* Response to Bonnie Scott Jones and Simon Heller, Docket No. 2001P-0075/CP1 (June 9, 2006), at http://www.regulations.gov/#!documentDetail;D=FDA-2001-P-0123-0029.

Pursuant to the court's order, FDA reconsidered its decisions regarding the "switch to OTC use," taking into account the record before FDA and the relevant developments since the June 2006 denial of the CRR Petition. We issued a response to the Center for Reproductive Rights on December 12, 2011, that further responded to and again denied this petition.[4]

On April 5, 2013, the Federal district court issued an opinion and order upon review of FDA's December 2011 denial of the CRR Petition. See *Tummino v. Hamburg*, 936 F. Supp. 2d 162 (E.D.N.Y. 2013) (*Tummino II*). That ruling directed defendants — Dr. Margaret Hamburg, the Commissioner of FDA, and the Honorable Kathleen Sebelius, Secretary of Health and Human Services — to grant the CRR Petition and to "make levonorgestrel-based emergency contraceptives available without a prescription and without point-of-sale or age restrictions within thirty days," but further provided that "if FDA actually believes that there is any significant difference between the one- and two- pill products, it may limit its over-the-counter approval to the one-pill product" (*id.* at 197).[5]

FDA subsequently granted the CRR Petition in a response dated June 10, 2013.[6] As explained in that response, we believe it is appropriate and consistent with *Tummino II* to comply by making only Plan B One-Step (PBOS), and not Plan B or generic versions of Plan B, available OTC for younger adolescents:

> FDA continues to believe, for the reasons that the government has previously explained in its briefs to the district court, there are significant differences between Plan B and PBOS under FDA's regulations and the Federal Food, Drug, and Cosmetic Act....It is, moreover, the PBOS [supplemental new drug] application that contained actual use data specifically addressing the ability of adolescents, including younger adolescents, to understand and follow the directions for safe and effective use as a nonprescription product; there are fewer data available regarding the actual use of Plan B as a nonprescription product by younger adolescents.[7]

Consistent with our June 10, 2013, response to the CCR petition, we approved PBOS for nonprescription use without age restrictions on June 20, 2013.[8] Plan B and generic versions of Plan B continue to be approved for nonprescription use to women 17 years of age and older and

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[4] A copy of the response is available at http://www.regulations.gov/#!documentDetail;D=FDA-2001-P-0123-0186.

[5] On July 10, 2009, FDA approved Plan B One-Step (PBOS) (levonorgestrel tablet, 1.5 mg, NDA 021998). Plan B uses a two-dose regimen with 0.75 mg of levonorgestrel in each tablet to be taken 12 hours apart, while PBOS is a single dose tablet that contains 1.5 mg of levonorgestrel.

[6] A copy of the response is available at http://www.regulations.gov/#!documentDetail;D=FDA-2001-P-0123-0187.

[7] June 10, 2013 CRR Petition Response at 4.

[8] *See* Supplemental Approval Letter, NDA 021998/S-003 (June 20, 2013), available at http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2013/021998Orig1s003ltr.pdf.

by prescription to women 16 years and younger.

Accordingly, for the reasons described, your Petition is granted in part and denied in part.

Sincerely,

Janet Woodcock
Director
Center for Drug Evaluation and Research