U.S. Department of Justice

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June 10, 2013

BY ELECTRONIC COURT FILING

Honorable Edward R. Korman
Senior United States District Judge
Eastern District of New York
225 Cadman Plaza East
Brooklyn, NY 11201

Re: *Tummino v. Hamburg*, No. 12-CV-0763 (ERK/VVP)

Dear Judge Korman:

We write to advise the Court that the Food and Drug Administration (FDA) and the Department of Health and Human Services (HHS) have complied with the Court's April 10, 2013, judgment in the above-referenced case by granting the 2001 Citizen Petition and making Plan B One-Step (PBOS) available over-the-counter (OTC) without age or point-of-sale restrictions as described below. It is the government's understanding that this course of action fully complies with the Court's judgment in this action. Once the Court confirms that the government's understanding is correct, the government intends to file with the Circuit Court notice that it is voluntarily withdrawing its appeal in this matter.

Procedurally, FDA today has invited the sponsor of PBOS, Teva Branded Pharmaceutical Products R&D, Inc. (Teva), to promptly submit a supplemental new drug application (SNDA) with proposed labeling that would permit PBOS to be sold without a prescription and without age or point-of-sale restrictions. Upon receipt of this SNDA, FDA will approve it without delay. After FDA receives and approves Teva's supplement, we expect the sponsors of the generic versions of PBOS to submit appropriate amendments to their abbreviated new drug applications. If FDA grants Teva marketing exclusivity, the scope of that exclusivity may affect the labeling that could be approved for generic equivalents of PBOS. Further to comply with the Court's judgment, FDA today has issued a response to the 2001 Citizen Petition granting the petition by taking the steps with respect to PBOS described in this letter. In accordance with this Court's order and as explained below, FDA will not at this time take steps to change the approval status of the two-pill Plan B or its generic equivalents.

As the Court is aware, the Second Circuit stayed this Court's judgment pending appeal to the extent that this Court required FDA to make PBOS available OTC, but denied a stay to the

extent the Court mandated that the two-pill Plan B and its generic equivalents be made available OTC. FDA, however, intends to comply with the Court's order in the manner described in the preceding paragraph because this Court's April 10, 2013, judgment expressly authorized FDA to comply by making PBOS and not Plan B available, if FDA believes that there is a significant difference between Plan B and PBOS. Specifically, while the Court's judgment directed the defendants to "make levonorgestrel-based emergency contraceptives available without a prescription and without point-of-sale or age restrictions within 30 days," it also provided that "FDA may determine whether any new labeling is reasonably necessary" and that "if the 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." ECF No. 87, 04/10/13, at 1-2. FDA continues to believe, for the reasons that the government has previously explained in its briefs to this Court, that 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 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. FDA therefore believes it is appropriate and consistent with this Court's order to comply by making only PBOS (and not the two-pill product) available OTC for younger adolescents.

We appreciate the Court's time and continued attention to this matter.

Respectfully submitted,

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By: /s/ {FILED ELECTRONICALLY}
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