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July 17, 2013

Via Certified Mail

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, Maryland 20852

CITIZEN PETITION

The undersigned (the "Petitioner") submits this petition, in quadruplicate, under section 505 of the Federal Food, Drug, and Cosmetic Act (the "FDC Act"), 21 U.S.C. § 355, and 21 C.F.R. §§ 10.20, 10.25, 10.30, and 314.161, to request the Commissioner of Food and Drugs to determine that the drug, Norplant® II Levonorgestrel Implants (Jadelle®) (New Drug Application (NDA) # 020544) was voluntarily withdrawn from the market for reasons other than safety or effectiveness.

A. Action Requested

The Petitioner requests that the Commissioner of Food and Drugs (hereinafter referred to as "FDA") make a determination that Population Council's Norplant® II Levonorgestrel Implants (Jadelle®) (New Drug Application (NDA) # 020544) was withdrawn from the market for reasons other than safety or effectiveness and, therefore, an NDA may be submitted and approved under section 505(b)(2) of the FDC Act, using Norplant® II (Jadelle®) as a Reference Listed Drug (RLD).

B. Statement of Grounds

The Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as "the Orange Book", contains all FDA–approved drug products. Although FDA approved Norplant® II Levonorgestrel Implants (Jadelle®) (New Drug Application (NDA) # 020544), the Orange Book currently lists the drug in the Discontinued Drug Product List section. See Attachment A.

Before FDA can approve an application that references a discontinued drug, FDA must determine whether a discontinued drug was withdrawn for reasons of safety or effectiveness. See 21 C.F.R. § 314.161. If FDA determines that the drug was not withdrawn for safety or

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effectiveness reasons, FDA must publish a notice in the Federal Register about its conclusion. See 21 C.F.R. § 314.161(e).

The Petitioner has no information to suggest the market withdrawal of Population Council's Norplant® II Levonorgestrel Implants (Jadelle®) was for safety or effectiveness reasons. Therefore, the Petitioner requests that FDA determine the withdrawal was made for reasons other than safety or effectiveness and, therefore, an NDA may be submitted and approved under section 505(b)(2) of the FDC Act , using Norplant® II (Jadelle®) as an RLD.

C. Environmental Impact

As provided in 21 C.F.R. § 25.31, neither an environmental assessment nor an environmental impact statement is required.

D. Economic Impact

As provided in 21 C.F.R. § 10.30(b), economic impact information will be provided if requested by FDA.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioner which are unfavorable to the Petition.

Respectfully submitted,

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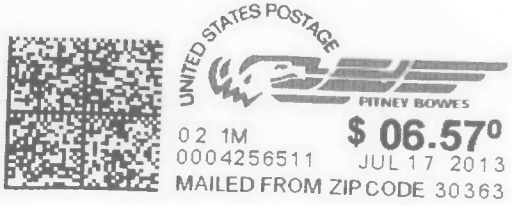

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