DEPARTMENT OF HEALTH & HUMAN SERVICES

No Prince of Princes o

Public Health Service

Food and Drug Administration Rockville MD 20857

July 24, 2013

FILE COPY

Alan G. Minsk Kelley C. Nduom Arnall Golden Gregory LLP 171 17th Street, N.W. Suite 2100 Atlanta, GA 30363

Dear Mr. Minsk:

Your petition to the Food and Drug Administration requesting to 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that Population Council's Norplant® II Levonorgestrel Implants (Jadelle®) (New Drug Application (NDA) # 020544) was withdrawn from the market for reasons other than safety or effectiveness, was received by this office on 07/24/2013. It was assigned docket number FDA-2013-P-0886/CP1, and it was filed on 07/24/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Karen Kennard

Director

Division of Dockets Management

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FDA/Office of the Executive Secretariat (OES)