DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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February 11, 2013

J. Michael Nicholas, Ph.D.
Teva Women's Health, Inc.
41 Moores Road
P.O Box 4011
Frazer, PA 19355

Dear Dr. Nicholas:

Your petition to the Food and Drug Administration on behalf of Teva Pharmaceutical Industries Ltd., requesting that FDA refrain from approving any Abbreviated New Drug Application referencing ParaGard® T 380A (intrauterine copper contraceptive) until certain conditions are met, was received by this office on 2/11/2013. It was assigned docket number FDA-2013-P-0163/CP1, and it was filed on 2/11/2013. 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,

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)