OFFICE OF CLINICAL PHARMACOLOGY REVIEW ADDENDUM

NDA 206229	Submission Dates	4/30/14, 5/22/14, 5/30/14, 8/29/14, 9/10/14, 12/16/14, 1/26/15, 2/18/15, 2/19/15
Brand Name	Liletta™	
Generic Name	levonorgestrel-releasing intrauterine system	
Reviewer	Li Li, PhD	
Team Leader	Myong Jin Kim, PharmD	
OCP Division	Division of Clinical Pharmacology 3	
OND Division	Division of Bone, Reproductive and Urologic Products	
Sponsor	Medicines 360 Inc.	
Submission Type	Original	
Formulation; Strengths; Regimen	Intrauterine system containing 52 mg of levonorgestrel with an initial release rate of 18.6 µg/day	
Proposed Indication	Prevention of pregnancy for up to 3 years	

1 Executive Summary

The Clinical Pharmacology review of NDA 206229 (DARRTS, January 30, 2015) stated that NDA 206229 was acceptable provided that an agreement is reached between the sponsor and the Division regarding the language in the package insert labeling. The final agreement on clinical pharmacology sections was reached on Feb 23, 2015 and there are no pending issues from the Office of Clinical Pharmacology. The highlights of the prescribing information and Clinical Pharmacology relevant sections of the final agreed upon package insert labeling are included in Section 2 of this addendum.

1.1 Recommendation

The Division of Clinical Pharmacology-3, Office of Clinical Pharmacology finds the NDA 206229 acceptable.

3 Pages of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

---

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

LI LI
02/24/2015

MYONG JIN KIM
02/24/2015