FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Nonprescription Drugs Advisory Committee (NDAC) and the
Obstetrics, Reproductive, and Urologic Drugs Advisory Committee (ORUDAC)
May 9-10, 2023

DRAFT AGENDA

The committees will discuss a supplemental new drug application (sNDA) 017031/S-041, for OPILL (norgestrel) Tablet, 0.075 mg, submitted by Laboratoire HRA Pharma. OPILL is proposed for nonprescription use as a once daily oral contraceptive to prevent pregnancy.

Day 1

9:30 a.m.	Call to Order and Introduction of Committee	**Maria C. Coyle, PharmD, FCCP, BCPS, BCACP, CLS** Chairperson, NDAC
9:35 a.m.	Conflict of Interest Statement	**Moon Hee V. Choi, PharmD** Designated Federal Officer, NDAC
9:40 a.m.	FDA Opening Remarks	**Pamela Horn, MD** Director Division of Nonprescription Drugs II (DNPD II) Office of Nonprescription Drugs (ONPD) Office of New Drugs (OND), CDER, FDA
9:45 a.m.	**APPLICANT PRESENTATIONS**	**Laboratoire HRA Pharma**
	Introduction	**Helene Guillard, PharmD** Global Rx-To-OTC Switch Director Women's Health HRA Pharma / Perrigo
	Need for Nonprescription Oral Contraception	**Carolyn Westhoff, MD, Msc** Sarah Billinghurst Solomon Professor of Reproductive Health Department of Obstetrics and Gynecology Professor of Population and Family Health and Epidemiology Mailman School of Public Health Columbia University
	Consumer Behavior Studies and ACCESS Study Design Self-Selection Results	**Russell Bradford, MD, MSPH** Senior Vice President, Medical Affairs PEGUS Research

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DRAFT AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	Clinical Interpretation of Potential Risk of POP Use in Breast Cancer Survivors	**Pamela Goodwin, MD, Msc, FRCPC, FASCO** Senior Scientist Lunenfeld-Tanenbaum Research Institute Sinai Health System Professor of Medicine University of Toronto
	ACCESS Actual Use Adherence Results	**Irene Laurora, PharmD** Senior Director, Scientific Affairs Women's Health, HRA Pharma / Perrigo
	Expert Interpretation of ACCESS Adherence Results	**Arthur Stone, PhD** Professor of Psychology, Economics, and Public Policy Director Dornsife Center for Self-Report Science University of Southern California Emeritus Distinguished Professor of Psychiatry & Behavioral Science Stony Brook University School of Medicine
	ACCESS Actual Use Adherence Conclusions	**Irene Laurora, PharmD**
	Clinical Interpretation of ACCESS Results and Considerations Around Effectiveness	**Stephanie Sober, MD, MSHP** Global Lead Medical Affairs Women's Health, HRA Pharma / Perrigo
	Clinical Perspective	**Anna Glasier, MD, Dsc, OBE** Professor at Edinburgh and London Universities
11:45 a.m.	Clarifying Questions	
12:15 p.m.	**LUNCH**	

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DRAFT AGENDA (cont.)

1:00 p.m.	**FDA PRESENTATIONS**	
	Introduction	**Pamela Horn, MD**
	Efficacy and Safety of Prescription Norgestrel Tablet and Implications for the Nonprescription Setting	**Anandi Kotak, MD, MPH** Medical Officer Division of Urology, Obstetrics, and Gynecology Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine, OND, CDER, FDA
	Consumer Behavior Studies (Label Comprehension, Targeted Breast Cancer Self-Selection and Self-Selection in ACCESS)	**Barbara Cohen, MPA** Social Science Analyst DNPD II, ONPD, OND, CDER, FDA
	ACCESS Study Use Phase: Design and Conduct	**Jeena Jacob, MD, PharmD** Medical Officer DNPD II, ONPD, OND, CDER, FDA
	ACCESS Study Use Phase: Use and Adherence Endpoints	**Rongmei Zhang, PhD** Mathematical Statistician Division of Biometrics VII Office of Biostatistics Office of Translational Sciences, CDER, FDA
	ACCESS Study Use Phase: Secondary Endpoints and Safety Findings from Uncontrolled and Postmarketing Data	**Jeena Jacob, MD, PharmD**
	Summary	**Pamela Horn, MD**
3:00 p.m.	Clarifying Questions	
3:30 p.m.	**BREAK**	
3:45 p.m.	**OPEN PUBLIC HEARING**	
5:30 p.m.	**ADJOURNMENT**	

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DRAFT AGENDA (cont.)

Day 2

9:30 a.m.	Call to Order and Introduction of Committee	**Maria C. Coyle, PharmD, FCCP, BCPS, BCACP, CLS**
9:35 a.m.	Conflict of Interest Statement	**Moon Hee V. Choi, PharmD**
9:40 a.m.	Charge to the Committee	**Pamela Horn, MD**
9:50 a.m.	Questions to the Committee/Committee Discussion	
11:30am	**LUNCH**	
12:30pm	Questions to the Committee/Committee Discussion (cont.)	
1:30 p.m.	**ADJOURNMENT**	