

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

***Joint Meeting of the Nonprescription Drugs Advisory Committee (NDAC) and the
Obstetrics, Reproductive, and Urologic Drugs Advisory Committee (ORUDAC)***

May 9-10, 2023

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 Billingham 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	Russell Bradford, MD, MSPH Senior Vice President, Medical Affairs PEGUS Research
	Self-Selection Results	

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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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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
DNP II, ONPD, OND, CDER, FDA

ACCESS Study Use Phase: Design and
Conduct

Jeena Jacob, MD, PharmD
Medical Officer
DNP 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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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	