

**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**

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*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.*

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**Day 1**

9:30 a.m.	Call to Order and Introduction of Committee	<b>Maria C. Coyle, PharmD, FCCP, BCPS, BCACP, CLS</b> Chairperson, NDAC
9:35 a.m.	Conflict of Interest Statement	<b>Moon Hee V. Choi, PharmD</b> Designated Federal Officer, NDAC
9:40 a.m.	FDA Opening Remarks	<b>Pamela Horn, MD</b> Director Division of Nonprescription Drugs II (DNPD II) Office of Nonprescription Drugs (ONPD) Office of New Drugs (OND), CDER, FDA
9:45 a.m.	<b>APPLICANT PRESENTATIONS</b>	<b>Laboratoire HRA Pharma</b>
	Introduction	<b>Helene Guillard, PharmD</b> Global Rx-To-OTC Switch Director Women's Health HRA Pharma / Perrigo
	Need for Nonprescription Oral Contraception	<b>Carolyn Westhoff, MD, Msc</b> 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	<b>Russell Bradford, MD, MSPH</b> Senior Vice President, Medical Affairs PEGUS Research
	Self-Selection Results	

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**DRAFT AGENDA (cont.)**

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**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.)**

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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.)**

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**Day 2**

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