

**Food and Drug Administration  
Center for Drug Evaluation and Research**

**Advisory Committee for Reproductive Health Drugs**

**September 30, 2003**

Hilton Hotel, the Ballrooms  
620 Perry Parkway, Gaithersburg, MD

**AGENDA**

8:30	Call to Order and Opening Remarks Introduction of Committee	Linda Giudice, M.D., Ph.D. Chair
	Conflict of Interest Statement	Shalini Jain, PA-C, M.B.A. Executive Secretary, FDA
	Opening Remarks	Daniel Shames, M.D. Director, Division of Reproductive and Urologic Drug Products (DRUDP) FDA

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*Issue: Discussion of NDA 21-322, Luveris® (lutropin alfa for injection), Serono, Inc., a recombinant human luteinizing hormone (r-hLH) drug product, proposed for concomitant administration with recombinant human follicle stimulating hormone (r-hFSH), for the proposed indication of induction of ovulation in infertile women with severe luteinizing hormone and follicle stimulating hormone deficiency.*

8:45	Clinical Presentation of Hypogonadotropic Hypogonadism in Women	James H. Liu, M.D. Professor and Chair Dept. of Reproductive Biology Case Western Reserve University Cleveland, OH
9:30	Genetics of Hypogonadotropic Hypogonadism in Women	Lawrence C. Layman, M.D. Chief, Section of Reproductive Endocrinology, Infertility and Genetics Medical College of Georgia Augusta, GA
10:30	Questions from the Committee	
10:45	Break	

11:00 **SPONSOR PRESENTATIONS**

SERONO, INC

Introduction & Regulatory History

Pamela Williamson Joyce, RAC  
Vice President  
Regulatory Affairs & Quality  
Assurance-United States  
Serono, Inc.

Need for and Role of LH: HH Women  
with Profound Gonadotropin Deficiency

Jerome Strauss, M.D., Ph.D.  
Luigi Mastroianni Jr. Professor  
Director  
Center for Research on Reproduction  
and Women's Health  
University of Pennsylvania

Luveris® Clinical Development Program

Paul Lammers, M.D.  
Chief Medical Officer  
Serono, Inc.

Clinical Perspective and Risk/Benefit  
Assessment

Nanette F. Santoro, M.D.  
Professor and Director  
Division of Reproductive Endocrinology  
Department of Obstetrics &  
Gynecology and Women's Health  
Albert Einstein College of Medicine

Summary and Conclusions

Pamela Williamson Joyce, RAC

12:00 Questions from the Committee

12:15 Lunch

**FDA PRESENTATIONS**

1:00 Luveris®: The FDA perspective

Shelley R. Slaughter, M.D., Ph.D.  
Medical Officer Team Leader  
Division of Reproductive  
And Urologic Drug Products (DRUDP)  
FDA  
Kate Meaker, M.S.  
Statistical Reviewer  
Division of Biometrics II, FDA

1:45 Questions from the Committee

2:15 Open Public Hearing

3:15 Presentation of Questions and Committee discussion

5:00 Adjourn