

Gastrointestinal Drugs Advisory Committee

Food and Drug Administration
Center for Drug Evaluation and Research

Marriott Washington Center, 9751 Washington Blvd., Gaithersburg, MD

NDA 21-200, Zelmac (tegaserod) Novartis Pharmaceuticals Corporation

Agenda for June 26, 2000

- 8:30 Call to Order, Introductions: Stephen Hanauer, M.D., Chair
- Meeting Statement: Thomas H. Perez, M.P.H., Executive Secretary
- Opening Comments: Lilia Talarico, M.D., Director,
Division of Gastrointestinal and Coagulation Drug Products
- 8:45 Novartis Pharmaceuticals Corporation Presentation:
- | | |
|--------------------------------------|---|
| Introduction | Mathias Hukkelhoven, Ph.D.,
Vice President, US Drug Regulatory Affairs, Novartis |
| Irritable Bowel Syndrome | Arnold Wald, M.D.,
University of Pittsburgh Medical Center |
| 5HT ₄ Receptor Activation | Michael Camilleri, M.D.,
Mayo Clinic |
| Efficacy and Safety of Tegaserod | Martin Lefkowitz, M.D.,
Director, Clinical Research, Novartis |
| Review of Data on Ovarian Cysts | Bruce Carr, M.D.,
The University of Texas Southwestern Medical Center |
| Closing Remarks | Sidney Cohen, M.D.,
Temple University School of Medicine |
- 10:15 Break

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10:30 FDA Presentation:

Pharmacology Team Leader Jasti B. Choudry, B.V.Sc., Ph.D.

Statistical Reviewer Sonia Castillo, Ph.D.

Medical Reviewer Raymond Joseph, M.D., F.A.C.P., F.A.C.G.

12:00 Lunch

1:00 Open Public Hearing

2:00 Charge to the Committee, Introduction to Questions:

2:15 Discussion and Questions

3:15 Break

5:30 Adjourn

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NDA 21-200, Zelnac (tegaserod) Novartis Pharmaceuticals Corporation**

**Agenda for June 26, 2000
Continued**

Invited Consultants and Guest Experts

Hammes, Richard J., R.Ph.

Samuel Smith Reproductive

Richard Buyalos Reproductive

Public Comment

<u>Name</u>	<u>Representing</u>	<u>Time</u>
Nancy Norton	Int. Foundation for Functional GI Disorders	5 min.

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NDA 21-107, Lotronex (alosetron) Glaxo Wellcome

Agenda for June 27, 2000

- 8:30 Call to Order, Introductions: Stephen Hanauer, M.D., Chair
- Meeting Statement: Thomas H. Perez, M.P.H., Executive Secretary
- Opening Comments: Florence Houn, M.D., Director, Office of Drug Evaluation III
- 8:45 Glaxo Wellcome Presentation:
- Introduction
 - Lotronex Burden of Illness
 - Review/Update of safety/efficacy
 - Risk Management
 - Update on ongoing activities
 - Risk Management Plan
 - Conclusion
- 10:15 Committee Discussion
- 10:45 Break
- 11:00 FDA Presentation:
- Victor Raczkowski, M.D., Deputy Director, Office of Drug Evaluation III “Benefit-risk Reevaluation of Marketed Drugs”
 - Hugo Gallo-Torres, M.D., Ph.D. Medical Team Leader “Brief Review of Case Reports”
 - Nancy Ostrove, Ph.D., Branch Chief, Division of Drug Marketing, Advertising & Communication “Medication Guides”
 - Evelyn Rodriguez, M.D., M.P.H. Director, Division of Drug Risk Assessment II “How to Evaluate an Intervention”
- 12:15 Committee Discussion

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- 12:30 Lunch
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NDA 21-107, Lotronex (alosetron) Glaxo Wellcome

Agenda for June 27, 2000

Continued

Invited Consultants and Guest Experts

Richard Blum , M.D.,
Hammes, Richard J., R.Ph., University of Wisconsin
Sheila Weiss, M.D., University of Maryland
Barry Kramer, M.D., National Institutes of Health
Arthur Levin, M.P.H., Center for Medical Consumer and Health Care Informantion
Amir Kende, M.D., Armed Forces Institute of Pathology
Mark Welton, M.D., University of California
Jerry Gurwitz, M.D., Meyers Care Institute
Richard Havlik, M.D., National Institutes of Health
Jerry Avorn, M.D., Brigham and Women's Hospital
Neil Powe, M.D.,
Joanne Siegel, M.D.,
Eric Holmboe, M.D.,

Public Comment

<u>Name</u>		<u>Representing</u>	<u>Time</u>
Richard Krause	Physician	Glaxo	up to 5 min.
Sandra Cook	Patient	Glaxo	up to 5 min.
Joyce Donalin	Patient	Glaxo	up to 5 min.
Sandy Conner	Patient	Glaxo	up to 5 min.
Becky Hedspeth	Patient	Glaxo	up to 5 min.
Judy Utter	Patient	Glaxo	up to 5 min.
Nancy Norton	Int. Foundation for Functional GI Disorders		up to 5 min.