

Reproductive Health Drugs Advisory Committee

FDA Technical Center
Gaithersburg MD
19 July 1996

AGENDA

0900-0905 Opening comments. Confirmation of subsequent meeting dates:
20-22 November 1996; 13-14 February 1997; 5-6 June 1997.

NEW DRUG APPLICATION (NDA) FOR THE USE OF MIFEPRISTONE FOR INTERRUPTION OF EARLY PREGNANCY

0905-0915 Opening comments
David A. Kessler, MD
Commissioner of Food and Drugs

0915-1200 Presentations by the Sponsor, The Population Council (PC)

Sandra P. Arnold, BA (Mathematics)
Vice-President, Corporate Affairs (PC)

Ann Robbins, PhD
Scientist, Center for Biomedical Research (PC)

Irvin M. Spitz, MD
Senior Scientist, Center for Biomedical Research (PC)

C. Wayne Bardin, MD
Independent Consultant

Beverly Winikoff, MD, MPH
Program Director
Reproductive Health Programs Division (PC)

Elizabeth Newhall, MD
Medical Director, Downtown Women's Center
Portland, Oregon

1200-1300 Presentations by the FDA Reviewing Division

Introduction
Lisa Rarick, MD
Acting Director, Division of
Reproductive and Urologic Drug Products

Review of pharmacology and toxicology findings
Alexander Jordan, PhD
Pharmacology Team Leader

Review of non-US clinical findings
Ridgely C. Bennett, MD, MPH
Medical Officer

Review of US clinical findings and considerations for use
Lisa Rarick, MD

1300-1400

Lunch

1400-1630

Open Public Hearing

Private citizens or representatives of the following organizations (except for Congressman Coburn's office) contacted the Agency before 5 pm EDT on 12 July to request time to speak:

1. Office of Congressman Tom Coburn
Member, United States House of Representatives
Michael Schwartz
2. Alan Guttmacher Institute
Lisa Kaeser, JD
3. American College of Obstetricians and Gynecologists
Carolyn L. Westoff, MD
4. American Life League, Inc.
Rebecca Lindstedt
5. American Medical Student Association
Paul Jung, MD
6. American Medical Women's Association
Diana Dell, MD
7. American Public Health Association
Allan Rosenfield, MD
8. American Victims of Abortion
Olivia L. Gans
9. Baruch College
Joel Brind, PhD
10. Private citizen
Randy O'Bannon, speaking for Charles Cargille, MD
11. Center for Reproductive Law and Policy
Janet Benshoof, JD
12. Private citizen
Helen M. Donovan, JD
13. Family Research Council
Gracie S. Hsu, MHS
14. Feminist Majority Foundation
Eleanor Smeal
15. Feminist Women's Health Center
Marie Head
16. Jones Institute for Reproductive Medicine
Gary D. Hodgen, PhD
17. Life Issues Institute
Richard D. Glasow, PhD
18. National Abortion and Reproductive Rights League
Marcy J. Wilder, JD
19. National Abortion Federation
Paul Blumenthal, MD

20. National Association of Nurse Practitioners in
Reproductive Health
Susan Wysocki, RNC, NP
21. National Council of Jewish Women
Donna Gary
22. National Organization for Women, Inc.
Janice E. Erickson
23. National Women's Health Network
Cynthia A. Pearson
24. National Women's Health Organization
Susan Hill
25. National Women's Law Center
Ann Kolker
26. Northeast Waterloo Family Practice
M. Louviere, MD
27. Pharmacists for Life, International
Mary Jasinski Caldwell
28. Planned Parenthood Federation of America
Gloria M. Feldt
29. Planned Parenthood of Westchester and Rockland, Inc.
Lynn Borgatta, MD, MPH
30. Reproductive Health Technologies Project
Marie Bass
31. Private citizen
Wendy Simonds, PhD
32. Society of Physicians for
Reproductive Choice and Health
Seymour L. Romney, MD
33. Southwestern Medical Clinic, PC
Donna J. Harrison, MD
34. Women's Legal Defense Fund
Joanne L. Hustead

1630-1645 Break

1645-1845 Discussion and response to questions