

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Joint Meeting of the Advisory Committee for Reproductive Health Drugs and the Drug Safety and Risk Management Advisory Committee

Marriott Inn and Conference Center, University of Maryland University College (UMUC)

3501 University Blvd. East, Adelphi, Maryland

September 9, 2011

DRAFT AGENDA

The committees will discuss the benefits and risks of long- term bisphosphonate use for the treatment and prevention of osteoporosis in light of the emergence of the safety concerns of osteonecrosis of the jaw and atypical femur fractures which may be associated with the long- term use of bisphosphonates. Bisphosphonates for the treatment and prevention of osteoporosis include: FOSAMAX (alendronate sodium) tablets and solution and FOSAMAX PLUS D (alendronate sodium/cholecalciferol) tablets, Merck & Co., Inc., ACTONEL (risedronate sodium) tablets, ATELVIA (risedronate sodium) delayed release tablets and ACTONEL WITH CALCIUM (Copackaged) (risedronate sodium with calcium carbonate) tablets, Warner Chilcott, LLC, BONIVA (ibandronate sodium) tablets and injection, Roche Therapeutics, Inc., RECLAST (zoledronic acid) injection, Novartis Pharmaceuticals Corporation and the generic equivalents for these products, if any.

8:00 a.m.	Call to Order and Opening Remarks Introduction of Committee	Sandra A. Carson, M.D. Acting Chair, Advisory Committee for Reproductive Health Drugs (ACRHD)
	Conflict of Interest Statement	Yvette Waples, Pharm.D. Acting Designated Federal Officer, ACRHD
8:05 a.m.	Opening Remarks	George Benson, M.D. Deputy Director, Division of Reproductive and Urologic Drugs (DRUP)
8:10 a.m.	<u>Speaker Presentation</u> Osteoporosis Treatment: Clinical Decisions Today	Robert A. Adler, M.D. (Speaker) Professor, Division of Endocrinology Virginia Commonwealth University McGuire VA Medical Center
	<u>FDA Presentations</u>	
8:30 a.m.	Bisphosphonates: The Regulatory History	Theresa Kehoe, M.D. Clinical Team Leader, DRUP
8:45 a.m.	Bisphosphonate Long Term Use Risk Benefit Analysis: Safety	Fatmatta Kuyateh, M.D. Lead Medical Officer, Division of Epidemiology (DEPI)
9:10 a.m.	Bisphosphonate Long Term Use Risk Benefit Analysis: Efficacy	Marcea Whitaker, M.D. Medical Officer, DRUP
9:50 a.m.	Clarifying Questions to the Presenters	
10:05 a.m.	BREAK	

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- 10:15 a.m. **Guest Speaker Presentation**
Fracture Risk After Discontinuation
of Bisphosphonates
- Douglas C. Bauer, M.D. (Guest
Speaker)**
Professor, Department of Medicine
University of California, San Francisco
- 10:35 a.m. Clarifying Questions to the Presenters
- Sponsor Presentations**
- 10:50 a.m. **Merck:** Summary of Merck Responses
to FDA Questions (FOSAMAX[®] and
FOSAMAX[®] PLUS D)
- Arthur Santora, II., M.D., Ph.D.**
Executive Director
Clinical Research, Diabetes and
Endocrinology
Merck Research Laboratories
Merck & Co., Inc.
- 11:05 a.m. **Warner Chilcott:** Risedronate Sodium
*Actonel[®], Actonel[®] with Calcium &
Atelvia[®]*
NDA #s 020835, 021823 & 022560
- Matthew W. Lamb, Pharm.D.**
Senior Director, Regulatory Affairs
Warner Chilcott (US), LLC
- Paul D. Miller, M.D.**
Distinguished Clinical Professor of
Medicine
University of Colorado Health Sciences
Center
Medical Director
Colorado Center for Bone Research
- 11:20 a.m. **Hoffmann- La Roche:** BONIVA[®]
(ibandronate sodium)
- Joseph Kohles, Ph.D.**
International Medical Leader for Boniva,
Hoffmann-La Roche, Inc.
- 11:35 a.m. **Novartis:** Reclast[®] (zoledronic acid)
Injection: Presentation to the Joint
Meeting of the Advisory Committee for
Reproductive Health Drugs and Drug
Safety and Risk Management Advisory
Committee
- Christina Bucci-Rechtweg, M.D.**
Global Program Medical Director
Novartis Pharmaceuticals Corporation
- 11:50 a.m. Clarifying Questions to the Presenters

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DRAFT AGENDA (cont.)

12:00 p.m. **LUNCH**

1:00 p.m. Open Public Hearing

2:00 p.m. Bisphosphonate Long Term Use Risk **Theresa Kehoe, M.D.**
Benefit Analysis Wrap Up Clinical Team Leader, DRUP

2:15 p.m. Clarifying Questions to the Presenters

2:30 p.m. Questions to the ACRHD & DSaRM
and ACRHD & DSaRM Discussion

4:30 p.m. **ADJOURNMENT**