

## September 2011: Two FDA Advisory Committees Will Discuss The Safety Of Long-Term Use Of Fosamax, Boniva, And Actonel

### **Osteonecrosis Of The Jaw, Or Jawbone Death, And Atypical Femur Fractures, Or Low-Stress Thigh Bone Breaks, Are The Primary Drug-Safety Issues**

(Posted by Tom Lamb at [www.DrugInjuryWatch.com](http://www.DrugInjuryWatch.com) on September 8, 2011; see <http://bit.ly/oEuEY1>)

On September 9, 2011 there will be a joint meeting of the FDA's Reproductive Health Drugs Advisory Committee and the FDA's Drug Safety and Risk Management Advisory Committee.

According to [the FDA's Announcement for this September 2011 meeting](#), these two advisory committees will consider the benefits and risks of long-term use of osteoporosis medications in the bisphosphonate class of drugs, which were identified by the FDA as:

1. FOSAMAX (alendronate sodium) tablets and solution and FOSAMAX PLUS D (alendronate sodium/cholecalciferol) tablets, Merck & Co., Inc.;
2. ACTONEL (risedronate sodium) tablets, ATELVIA (risedronate sodium) delayed release tablets, and ACTONEL WITH CALCIUM (Copackaged) (risedronate sodium with calcium carbonate) tablets, Warner Chilcott, LLC;
3. BONIVA (ibandronate sodium) tablets and injection, Roche Therapeutics, Inc.;
4. RECLAST (zoledronic acid) injection, Novartis Pharmaceuticals Corporation; and,
5. the generic equivalents for these products, if any.

Further, the FDA stated in their Announcement that at this joint meeting the two respective advisory committees would discuss:

... the emergence of the safety concerns of osteonecrosis of the jaw (jawbone death) and atypical femur fractures (unusual broken thigh bone) that may be associated with the long-term use of bisphosphonates.

Prior to this September 9 meeting, the FDA posted online the following meeting materials:

- [Draft Agenda for the September 9, 2011 Joint Meeting of the Reproductive Health Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee \(PDF - 51KB\)](#)
- [Committee Roster for the September 9, 2011 Meeting of the Drug Safety and Risk Management Advisory Committee \(PDF - 32KB\)](#)
- [Committee Roster for the September 9, 2011 Meeting of the Reproductive Health Drugs Advisory Committee \(PDF - 30KB\)](#)
- [Draft Meeting Roster for the September 9, 2011 Joint Meeting of the Reproductive Health Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee \(PDF - 51KB\)](#)
- [Briefing Information for the September 9, 2011 Joint Meeting of the Reproductive Health Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee](#)

Of course, we will report any significant findings that come from this FDA joint meeting regarding the side effects risks associated with long-term use of Fosamax, Boniva, Actonel, and the several other bisphosphonate osteoporosis drugs.

If we hear tomorrow about any live blogging or live tweeting being done from the meeting site in Maryland, we will let you know on Twitter -- [@ThomasJLamb](#)

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Attorney [Tom Lamb](#) represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.  
<http://www.DrugInjuryWatch.com>