

**Food and Drug Administration's Communication of the Drug Safety Information; Public  
Hearing  
(Docket No. 2005N-0394)**

The American Association of Oral and Maxillofacial Surgeons (AAOMS) submits the following comments to the Center for Drug Evaluation and Research (CDER) of the Food and Drug Administration (FDA) in response to the public hearing that was held on December 7 and 8, 2005. The AAOMS comments specifically address the FDA's MedWatch Alert System. New drug and product alerts and warnings alerts issued by MedWatch are assessed by the AAOMS Advisory Committee on Research Planning and Technology Assessment (ACRPTA). Alerts determined to have an impact on OMS specialty are disseminated to the membership through various AAOMS media. While this system has worked well, the following adjustments to the MedWatch Alert System would facilitate use and dissemination of the alerts by our organization:

**Provider specific information:** The MedWatch alerts should include more detailed information about the providers who are most likely to use drugs/devices mentioned in an alert. Search engines for current and past alerts should allow for searches by type of provider who is likely to use a drug or device, by name of company who makes drug or device, as well as the drug and device name.

**Evidence to support FDA alerts:** Alerts should include as much information as possible (e.g., available data or studies) that demonstrate the risk associated with using a drug or device. This information will allow providers to make informed decisions about using these drugs or devices.

**Provider submitted alerts:** Providers can use the MedWatch On-line Voluntary Submission Form 3500 to submit information about problems they have experienced with drugs or devices. The form appears to be for use on a case by case basis. However, once a condition has been identified it may be useful to track occurrences using a site set up specifically for that condition. For example, on September 4, 2004, the FDA issued an alert about the use of the intravenous bisphosphonates Aredia and Zometa and their apparent relationship to the condition osteonecrosis of the jaws (ONJ). Since this alert was sent out, many Oral and Maxillofacial Surgeons have submitted ONJ cases that they have encountered to the FDA. However, such reporting appears to be sporadic and incomplete. In addition, it does not appear that information submitted to the FDA is readily available to other providers. We recommend that the FDA set up a specific on-line site where providers can report cases of bisphosphonates- related osteonecrosis of the jaws. Information collected at this site should be made available on-line to all providers.

**Information in the popular press:** There have been instances where a public health concern has been publicized in the media prior to the issuance of an FDA alert. We recommend that, especially for high profile cases, the FDA should acknowledge the occurrence of these events and let providers know if an alert will be forthcoming.