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## MEMORANDUM

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**TO:** COMMITTEE MEMBERS/CONSULTANTS  
**FROM:** MICHAEL E. ADJODHA, EXECUTIVE SECRETARY, DENTAL PRODUCTS PANEL  
**SUBJECT:** BACKGROUND INFORMATION FOR THE SEPTEMBER 06-07, 2006, JOINT MEETING ON DENTAL AMALGAM DEVICES  
**DATE:** 11 AUGUST 2006

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Dear Committee Members and Consultants:

Thank you for agreeing to serve at our next meeting, a joint meeting of the Dental Products Panel and the Peripheral and Central Nervous System Drugs Advisory Committee (hereafter, the committee) to be held on September 06-07, 2006.

The subject of this two day meeting is to review and discuss peer-reviewed scientific literature on dental amalgam and its potential mercury toxicity.

The FDA has proposed some questions to guide the committee's discussion.

Please review the enclosed background information package in preparation for the meeting. This package includes:

- A draft agenda for the meeting,
- A draft FDA white paper review of recent scientific studies on dental amalgam
- Correspondence from the public
- The questions for committee consideration
- References (on CD)

**Please review this material.** Note that, although there will be presentations at the meeting to inform your discussion of the science, some preparation in advance of the meeting is required. In particular, the draft questions for committee consideration ask that you evaluate the information and evaluations in the draft FDA White Paper provided with this package. Please let me know if you require copies of any cited references that are not already provided in the package.

Please note that the meeting will begin promptly at **8:00 am** on **Wednesday, September 6, 2006**, and that a **training session** will be held from **2:00 to 5:00 p.m.** at the hotel on

**Tuesday, September 5, 2006**, for new committee members and those who have **never attended a medical device panel meeting**. Please plan your travel accordingly.

FDA has provided you with information for the upcoming meeting of the joint committee. This information is for use by the committee during deliberations at the committee meeting. **You should not discuss this information with members of the press or public, with financial institutions, or with any other person, including other committee members.** If for any reason you are contacted by anyone seeking to obtain or discuss this information, you should refrain from any discussion and advise me immediately. In addition, committee members and consultants who voluntarily, or by way of a homework assignment, submit written analyses, comments, etc., to the agency should be aware that these submission may be **subject to release to the public** by means of the Freedom of Information Act (Ref: CFR 20.80, 20.81, 20.84, 20.103). Thus, such submissions should only contain material that reflects the technical and scientific content of the subject being reviewed.

Due to the general nature of this meeting, **you will not be required to return or destroy any of the material** being sent to you in this package.

Please remember that this package will not be made public until the Friday before the meeting, i.e., **September 01, 2006**. On this day the agenda, roster, and this package will be posted on the internet at <http://www.fda.gov/cdrh/panel>. After the meeting, the transcript and summary minutes will also be posted on this web site.

Please pay particular attention to your personal information listed in the draft agenda. **If there are any changes to your personal information please contact me.** I may be reached at **301-827-5283, ext. 123.**, via fax at **301-480-3002**, or via email at: [michael.adjodha@fda.hhs.gov](mailto:michael.adjodha@fda.hhs.gov). I am in the office weekdays from 7:30 a.m. to 4:00 p.m., Eastern time. Once again, thank you for agreeing to share your expertise with us.

Michael E. Adjodha, Executive Secretary

Dental Products Panel

## **Joint Advisory Committee Meeting on Dental Amalgam Devices**

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## **Section 1: Draft Agenda**

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## **Section 4: Draft Questions for Committee Consideration**

## **Section 5: References**