

HOGAN & HARTSON
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May 21, 2002

BY HAND DELIVERY

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20057

Re: **American Dental Association's Comments
on the Food and Drug Administration's
Proposed Rule on Dental Amalgam Devices**

Docket No. 01N-0067

Dear Sir or Madam:

Hogan & Hartson L.L.P., as regulatory counsel to the American Dental Association ("ADA"), is submitting the attached Comments in full support of the Food and Drug Administration's ("FDA" or "the Agency") proposed rule on the classification of Encapsulated Amalgam Alloy, Dental Mercury, and Amalgam Alloy, and the issuance of Special Controls for these three devices. FDA's proposed rule and notice of availability of its guidance document entitled "Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling; Draft Guidance for Industry and FDA" were published in the Federal Register on February 20, 2002 (67 Fed. Reg. 34 (2002)).

All information included in these Comments was provided by the ADA to Hogan & Hartson L.L.P. for submission to the Agency. The ADA is responsible for the accuracy and completeness of the submission. We trust that the information

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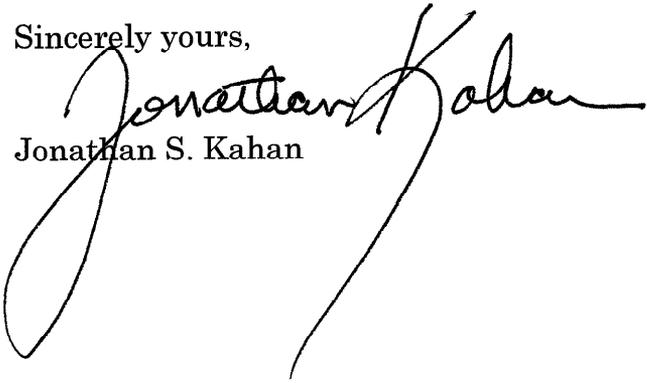
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included in the attached Comments will be sufficient to state ADA's position in full support of the proposed rule and Special Controls for these three dental amalgam devices. If you have any questions regarding these Comments, please contact me at the above number or Ted Wilson at (202) 637-5839.

Sincerely yours,


Jonathan S. Kahan

Attachments

cc: Kathleen Todd, Esq.
Edward C. Wilson, Jr., Esq.
Taylor L. Burke, Esq.

JSK/ank