

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 8 2007

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Edward Shellard, DMD
President
Kerr Corporation
1717 West Collins Avenue
Orange, California 92867

Re: FDA Docket No. 2006P-0365

Dear Dr. Shellard:

This responds to your citizen petition dated August 25, 2006, and filed by the Food and Drug Administration (FDA or the agency) on September 5, 2006. Your petition alleges several violations under the Federal Food, Drug, and Cosmetic Act by a number of dental device manufacturers and distributors, and requests that the agency "initiate enforcement action to prevent" continued violations. We appreciate the kind of information provided by you because it is often very helpful to us in identifying problems with marketed products and possible violations of the laws we enforce. We will evaluate the information in your petition and determine what action is appropriate.

While FDA does not provide information to the public regarding open investigations or other enforcement actions, information can be obtained through a Freedom of information Act (FOIA) request once an action is closed. You may submit written requests for information under the FOIA to the following address:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, Maryland 20857

2006P-0365

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If you have any questions regarding this response, please contact Ms. Domini Cassis by telephone at 240-276-2342, or by e-mail at domini.cassis@fda.hhs.gov.

Sincerely,

A handwritten signature in cursive script that reads "Linda S. Kahan".

Linda S. Kahan
Deputy Director
Center for Devices
and Radiological Health