NOTICE and RECOMMENDED ACTION

February 23, 2011

VIA United Parcel Service

To: Denture Adhesive Manufacturers

The U.S. Food and Drug Administration (FDA) has received numerous reports of adverse events related to the use of denture adhesives. There are literature and research that suggest that zinc contained in some denture adhesives may be a contributing factor in these adverse events. Although zinc is an essential nutrient, overexposure may result in zinc toxicity. We are notifying all manufacturers of denture adhesives and asking for their assistance in dealing with this public health issue.

Consumers using denture adhesives have reported local and systemic symptoms consistent with zinc toxicity that may be associated with use of the product. Symptoms may include: myeloneuropathy of the extremities and blood dyscrasias.

Consumers most at risk include people using excessive amounts of these products over extended periods of time; people with poor fitting dentures; and people who are unable to read or understand product labeling.

Factors that may contribute to adverse events include:

1) The package labeling may not list zinc as an ingredient.
2) Users may not be aware that overexposure to zinc may lead to zinc toxicity, which may result in adverse health effects.
3) Users may continue to use these products even after experiencing adverse events because they may not associate the adverse events with the use of denture adhesives. This may occur because adverse events may not manifest themselves for months to years while using the product and consumers may assume such events are caused by something other than the denture adhesive.
4) Users may not know how to use the product properly, resulting in an adverse event. For example, users may not be able to understand the instructions for use of the product due to confusing and potentially misleading labeling. Until recently, denture adhesive labels did not give warnings or definitions of overuse.

Action Recommended

If you are a manufacturer of dental adhesive with zinc, we strongly recommend you consider:

1) Performing a risk analysis of your labeling to assess how risks can be mitigated;
2) Conducting a human factors study to assess consumer understanding of labeling and the potential for misuse of your product;
3) Modifying your labeling to include a statement that the product contains zinc if appropriate and define maximum safe usage in easily understood terms, and
4) Replacing zinc with an ingredient that presents less health risks in situations of overuse, and if it is a new formulation, submitting a new 510(k).

The FDA may issue a communication that would be posted on the Agency's web site to notify consumers and the healthcare community of this possible health risk.

Reporting to the FDA

As a manufacturer of denture adhesives, you are responsible for compliance with the requirements of the Medical Device Reporting (MDR) regulation. These requirements include reporting to FDA deaths and serious injuries that your product may have caused or contributed to and establishing and maintaining adverse event files, and submitting summary annual reports.

To ensure that relevant manufacturers receive this information, attached for your signature is an acknowledgement form. Please complete and return the form to acknowledge receipt of this letter and confirm your status as a denture adhesive manufacturer.

Send a copy your communication to: Mr. George Kroehling, Deputy Director, Division of Enforcement A, Office of Compliance, 10903 New Hampshire Avenue, WO66-3516, Silver Spring, Maryland, 20993.

If you have questions relating to this matter, please feel free to call Mr. Kroehling at (301) 796-5770, or log onto our web site at www.fda.gov for general information relating to FDA medical device requirements.

Sincerely yours,

Steven D. Silverman
Director
Office of Compliance
Center for Devices and
Radiological Health

February 23, 2011

Acknowledgements Related to February 23, 2011 NOTICE of Action – Regulatory Compliance

Mr. George Kroehling
Deputy Director
Division of Enforcement A, Office of Compliance
WO66-3516
10903 New Hampshire Avenue
Silver Spring, Maryland, 20993

Dear Mr. Kroehling:

____ I hereby acknowledge the receipt of the September XX, 2010 letter from FDA entitled "NOTICE and RECOMMENDED ACTION".

I hereby acknowledge that (please check those that apply to your firm and product(s)):

____ I am a manufacturer of denture adhesives.

____ I am a manufacturer of denture adhesives containing zinc.

____ I am not a manufacturer of denture adhesives containing zinc.

_____	_____
Signature of Recipient	Signatory's Printed Name
_____	_____
Company Name	Company Address & Phone Number
_____	_____
Signatory's Title	Signatory's Direct Contact Postal and Phone Information