

**Food and Drug Administration and Federal Government Officials
Explore Oversight of the Dental Laboratory Industry –
NADL Responds with Best Practice Guidelines and Recommendations**

October 2007

With the recent concern over import safety, NADL is taking a proactive stance in order to best represent the dental laboratory industry and protect patients in the United States. As a member of the dental laboratory community, you may have read some recent articles, e-mails or Internet posts about NADL's recent interaction with federal government officials, namely the Food and Drug Administration and the Presidential Interagency Working Group on Import Safety, www.importsafety.gov.

In June 2007, different officials with the Food and Drug Administration contacted NADL over their growing concern of the safety of imported dental restorations. Because FDA regulates import dental restorations, this product area was on their list for further analysis within the realm of other products they regulate.

FDA contacted NADL on several occasions in June and July to collect updated information about the dental laboratory industry and to share information about the increase in dental restorations coming in from foreign dental laboratories and resulting discussions the agency was having on increasing its oversight of the industry. The agency's representatives told NADL that there was concern about the government's ability to adequately track the material safety of import dental restorations being used by U.S. consumers.

Since 2004, communication with the Food and Drug Administration initiated by NADL has been infrequent at best. Until recently, NADL's work with the FDA was on behalf of specific laboratory members and limited to help clarify existing requirements on establishment registration, QS/GMP requirements, and device labeling and import procedures.

Most interaction between the FDA and individual dental laboratories during this time has been either due to inspections of dental laboratories on quality system/good manufacturing practices or to help a dental laboratory comply with registration with the agency when required.

With recent developments, NADL leadership and staff fully discussed and deliberated the pending outcomes of this increased scrutiny by the FDA. NADL's board of directors concluded that it is in the members' best interests for the association to be proactive by developing a framework of best practices and guidelines for the dental laboratory industry. The board wanted NADL to go on record with such recommendations.

NADL did so by sending a written letter to the Presidential Interagency Working Group on Import Safety on Sept. 10 and testified before the same group at a meeting on October 1st.

The key NADL recommendations submitting to the Working Group are:

- *Dentists and dental schools, who outsource directly to a foreign dental laboratory for services, should be required to follow the same QS/GMP regulations and registration requirements that a dental laboratory currently outsourcing such work has to follow and register as initial importers.*
- *FDA places an importance on employees being competent in skills and knowledge to perform their work as it relates to quality system regulations. NADL's model bill of regulation for state dental practice acts, recommends that each dental laboratory employ at least one Certified Dental Technician. This same approach could be considered by the federal government or recommended to the FDA's state agency counterparts. For foreign dental laboratories, a reference to that country's certification process would be appropriate.*
- *The FDA does not have enough manpower to physically inspect dental laboratories and has recently provided an option where certain medical device manufacturers would not have to be inspected by the FDA if they go through an approved third party audit. The dental laboratory industry already has a third party audit requirement for its DAMAS program. NADL is recommending that FDA see this process as an acceptable inspection process to meet FDA enforcement needs*
- *Dental laboratories are subject to current FDA labeling requirements on point of origin of manufacture of their products. However, there are no similar requirements for disclosure of material content of the actual dental device. Many dental laboratories voluntarily use the Identalloy program, www.identalloy.org for metals and ceramic materials. NADL recommends FDA to put this forward as a guideline for industry. Further, NADL recommends that material content and point of origin information be placed in the patient's dental records.*
- *FDA has expressed a concern about material traceability due to potential product recalls. Currently, only foreign dental laboratories and their U.S. agents and initial importers are required to register with the Food and Drug Administration. NADL's position paper recommends the FDA should consider whether all dental laboratories should register with the FDA or their state counterpart's, which are generally state departments of health so that an official registry of dental laboratories could be established.*

The rationale for NADL's board decision is clearly illustrated in the September 2007 issue of the *Harvard Business Journal*, in an article authored by Andrew Hoffman. The article is entitled *If You're Not at the Table, You're on the Menu*. The article speaks to the need for trade associations to control their own destiny by participating in the policy making process as government works to develop regulations and standards.

The article illustrates that if you sit out as a bystander when new policies or regulations are being discussed and decided, the outcomes are generally not positive for the affected industry.

The intent of the NADL board is that any proposed recommendations would meet the FDA's and other government agencies' objectives, while at the same time, not bring forth additional regulatory requirements or guidelines that are not developed, initiated or administered by the industry itself. A key consideration was that any new regulations or guidelines will be unnecessarily burdensome or financially impactful to members of the industry.

One of an association's primary roles, especially a trade association, is to develop minimum standards, best business practices and guidelines for operation. NADL and its affiliated certifying body, the National Board for Certification in Dental Laboratory Technology, have consistently done that during their 50-year histories as each organization addresses in their respective missions and purposes. Hence, the development and administration of programs such as the CDT process, CDL program, DAMAS accreditation and facilitation of competency standards.

Many industry associations do this, and there are hundreds of examples. For comparison, the National Institute for Automotive Service Excellence, which is an association, does this for automotive service technicians and auto repair facilities by offering ASE certification for mechanics and the Blue Seal of Excellence Recognition program for the auto shop facility. This was done originally as a voluntary process but then became more prominent as a government recognized best practice after developing concern about automobile safety due to faulty repairs. In many ways, NADL is responding for the same reasons and a very similar scenario.

The next step for the dental laboratory industry and NADL is to cooperatively and openly work with governmental officials during the next few months as they determine potential action steps that may be implemented to further ensure the safety of dental restorations.

NADL will do its part to provide consistent communication to its members and the dental laboratory industry about further developments and actions the association may take. Your input is welcome and valued. Please post your comments on the NADL forum at <http://www.nadl.org/frm/index.cfm> under the sub-section entitled *FDA Oversight*. The forum is open to members and non-members. You just need to enter your own username and password which you select.

As a stakeholder in this vibrant industry, take the time to stay informed on the facts. NADL will continue to post the most up to date information on this subject matter on its Web site at www.nadl.org

Sincerely,

NADL Board of Directors and Executive Staff

Timeline of Events Food and Drug Administration Interaction with NADL 2007

Spring 2007 – Food and Drug Administration (FDA) and other federal agencies face scrutiny from the press and Congress about the safety of imported products

June - July 2007- FDA officials from the Anchorage, Alaska field office and Rockville, Md., headquarters contact NADL about the agency's need to expand or further enforce existing regulations that affect dental laboratories. This is due to the continued increase of dental restorations coming in from foreign dental laboratories. These contacts during the two-month period consisted of nearly 15 hours of e-mails and phone calls between FDA and NADL. It was made clear to NADL that FDA was on a timeframe to make adjustments to such regulations in the short-term to address these issues. During this same time, NADL received calls from two congressional offices in Washington, D.C., with concerns about potential safety problems with imported dental restorations.

July 2007 - President Bush appoints an Interagency Working Group on Import Safety, www.importsafety.gov that is comprised of the secretaries and agency heads of seven federal agencies who have a relation to the import of products including the FDA, Consumer Product Safety Commission, Department of Transportation, Department of Homeland Security, etc.

August 2007 - NADL Board of Directors and NBC Trustees meet in Chicago and discuss potential actions on the issue and potential actions related to FDA's approach to the dental laboratory industry.

September 2007 – Interagency Working Group on Import Safety submits initial report to the president. The working group and FDA ask for public comment from the industry and recommendations.

NADL develops a recommendation letter that NADL executive officers, NBC executive officers and general counsel was reviewed and signed off on before being sent to the Interagency Working Group.

NADL releases a press release about to the letter submitted to the Interagency Working Group.

October 2007 – The Interagency Working Group holds an in-person meeting in Washington, D.C. NADL testifies at the meeting.

OSHA and the U.S. Small Business Administration contact NADL about participating in a project to research the use of beryllium in import and domestic dental restorations.

The FDA contacts NADL about the possibility of developing a unique identifier code for dental restorations under their Unique Device Identification program (<http://www.fda.gov/cdrh/ocd/udi>)

November 2007 – Interagency Working Group on Import Safety is expected to release a final report to the president that would address recommendations for each federal agency involved.

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