



September 10, 2007

Division of Dockets Management (HFA 305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Interagency Working Group on Import Safety,

I am writing on behalf of the National Association of Dental Laboratories to submit recommendations relative to the safety concerns of dental devices that are imported into the U.S. market for consideration by the Working Group. This document is for submission for the October 1st meeting of the Working Group.

Currently, the dental laboratory industry makes up approximately \$5.5 billion of the over \$80 billion in annual sales for dentistry overall in the U.S. As it relates to the specific interest of the Working Group, the dental crown and bridge market (which appears to be highest percentage of types of dental devices being imported), represents millions of devices being imported into the U.S. annually for use by U.S. dental patients. Although dentists prescribe the type of device they deem appropriate for a dental patient and write a prescription for such device, the device is actually manufactured by a dental technician employed by a dental laboratory, which could be foreign or domestically headquartered.

The current environment of dentistry lends itself to the attractiveness of using foreign dental laboratories to supply services for the U.S. dental patient population. The factors that have set this in motion are:

- a) A focus on the price of dental devices driven by dentists seeking a lower cost product and reimbursement levels set by dental insurance plans and*
- b) An increasing demand for dental services by U.S. patients, predicted to double by 2015 that corresponds with a declining percentage of dentists to U.S. citizens and a decreasing number of U.S. dental laboratories and dental technicians in the workforce.*

By definition, dental laboratories fall under oversight by the FDA relative to QS/GMP regulations. However, the majority of domestic dental laboratory establishments are exempt from registering with the FDA based on current regulations. Dental laboratories are significantly different from most medical device manufacturers that the agency regulates, both in terms of scope of the manufacturing process (devices are custom designed based on a prescription for an individual patient as prescribed by a licensed dentist) and the size of business in comparison with other regulated entities, in that a typical dental laboratory in the U.S. employs 3.5 people.



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The NADL represents over 1,400 members, comprised mostly of commercial dental laboratories that manufacture their products domestically and serve the needs of U.S. dentists and patients. However, we also have members that utilize the services of foreign dental laboratories as outsource vendors for varying percentages of their production needs.

Our association has aggressively educated our membership during the last six years about the already present regulatory requirements administered by the Food and Drug Administration that apply to dental laboratories. We have also worked to educate affiliated organizations that represent our members' clients, such as the American Dental Association, the Academy of General Dentistry and related prosthodontic organizations. The key elements of interest are QS/GMP standards and those that relate most closely to import trade, labeling and disclosure a products point of origin.

The dental laboratory industry through the efforts of our association and our affiliate certifying body, the National Board for Certification in Dental Laboratory Technology have provided numerous tools to assist dental laboratories and individual dental technicians in improving their operations and service delivery for U.S. dentists and patients.

The resources already present and utilized by dental laboratory facilities include:

- The Dental Appliance Manufacturers Audit Scheme (DAMAS) Quality Assurance process (a process which follows closely the FDA's QS/GMP regulations but is tailored to the dental laboratory industry)
Web Link: <http://www.nadl.org/DAMAS.cfm>. The DAMAS process provides stringent protocols for raw material traceability; vendor qualification; and corrective action procedures. The program requires a third party audit of the dental laboratory once a year for the first three years, and then every three years thereafter.
- The Certified Dental Laboratory program focuses on OSHA infection control and Bloodborne pathogen standards and product remake procedures
Web Link: <http://www.nbccert.org/CDL.shtml>

The resources already present and available for the individual dental technician include:

- Competency Standards, a 300 page step by step guide for the manufacture of dental devices by an individual technician. The standards cover the five main disciplines of dental technology: partial dentures, full dentures, crown and bridge, ceramics and orthodontics.
- Certified Dental Technician program, which is accredited by the American National Standards Institute.
Web Link: <http://www.nbccert.org/CDT.shtml>.



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The programs above are intended to achieve accountability from within our industry. Nonetheless, even with these voluntary programs and standards in place, there are some areas that are lacking relative to further assurance of products being imported, but this could also be the case for domestic products as well.

According to the American Dental Association's *Future of Dentistry Report* "Dentistry is part of the broad spectrum of health services that address the needs of the general population. Its mission is to guard the oral health of the public." (2001, page 3).

Interestingly enough, only three of the states in the U.S., through state dental practice act statutes, require a dental laboratory to either register with an appropriate state agency and/or employ a qualified workforce such as a Certified Dental Technician (CDT). This is concerning since the FDA through its own regulations, seeks to ensure that medical device manufacturers have the proper training and knowledge in order to place a product on the market.

Our association's contention would be that the Certified Dental Technician program meets that skill and knowledge objective. The training, testing and continuing education that CDT's must have include study of material science, training on proper selection of dental materials for use in dental devices and regulatory standards

In many cases, the dental technician, not the prescribing dentist makes the selection of dental materials that will be used for a particular patient's restoration. Without having some requirement for the person (the manufacturer) creating the device to have the appropriate training and knowledge, the issue of material selection and/or safety is left to chance.

The majority of dental devices being imported into the U.S. seem to focus on crowns and bridges as mentioned earlier in this document. In this vein, many are porcelain fused to metal (PFM). However, there are non PFM restorations also being imported such as gold crowns, partial denture frames and implant abutments. These particular products would be most prone for lead contamination in the casted alloy. The glaze for finishing a PFM could also have lead contamination.

The issue of material safety in this product area is due to the possible use of non approved metal alloys. "It's too costly to make lead-free products," says alloy company owner Wang Qinjuan. "Chinese products have to be sold cheaply in foreign markets, or they are not competitive." (Fairclough, para. 25).

The alloy supply chain worldwide serves many industries, and certain alloys are not safe for use in the human body. It is extremely difficult to determine the material content of every restoration that is being imported into the U.S.



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If a problem occurs with a U.S. patient due to a dental restoration that contains a toxic material, chances are that the patient would report their health issue to a medical doctor and not their dentist to determine the root of the health problem. Its unlikely that the problem would be immediately traced back to the dental device, as most patients are unaware of what materials are in their dental restoration and even less likely to know where it was manufactured.

After serious analysis of the issues that face the Working Group, NADL would propose the following recommendations for FDA consideration to improve the environment for import of dental devices:

- 1) *The FDA should expand its regulatory interpretation of "qualified to place a product on the market" to include a reference to the Certified Dental Technician designation when speaking about the manufacture of dental devices, whether that product is foreign or domestic.*
- 2) *The FDA should remove the exemption of U.S. dentists from having to comply with Q/S GMP regulations which includes labeling and disclosure. There are U.S. dentists and dental schools that are directly purchasing their dental laboratory work from foreign dental laboratories and there is no current requirement for them to comply with the same requirements that a dental laboratory has to do in the same scenario. This scenario leaves a void in transparency and traceability for product recalls*
- 3) *The FDA should grant approval of the Dental Appliance Manufacturers Audit Scheme (DAMAS) to be an approved third party verification/inspection mechanism as it relates to FDA inspections.*
- 4) *The FDA should review the voluntary material content disclosure program for dental devices, Identalloy and IdentCeram for compliance for labeling elements of CFR 820, weblink: www.Identalloy.org*
- 5) *The FDA should consider requiring all dental laboratories, both foreign and domestic to register either with the FDA, or encourage such requirement of registration through appropriate agencies at the individual state level, namely state Departments of Health.*
- 6) *The FDA should conclude that the end user for dental devices is the patient, not the prescribing dentist, and as such, the point of origin of manufacture of where a dental restoration was created should be given to the individual patient. It is a consumer's right to know where their dental device was manufactured and what materials are in their mouth.*
- 7) *Dentists should be required to include the registration number of their contracting dental laboratory on the prescription that is kept in the patient's record. Such registration information could be the FDA registration number or state specific registration number (in those states where required) for the dental laboratory.*

We appreciate the time and consideration of the Working Group on these recommendations. Although this facet of import products is statistically smaller than other product areas the Working Group has been exposed to, it is extremely important due to the classification of the



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products as medical devices. The proliferation of import trade in dentistry will only go up as the demand for dental services in the U.S. increases as predicted by the U.S. Department of Health and Human Services.

Sincerely,

A handwritten signature in black ink that reads "Bennett Napier". The signature is fluid and cursive.

Bennett Napier, CAE
Co Executive Director

Reference Documents:

American Dental Association (2001). *Future of dentistry report, today's Vision: Tomorrow's reality*. American Dental Association. Retrieved July 30 2007 from
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