RESEARCH CONCLUDES DENTAL WAX DISPENSED TO PATIENTS VIOLATES REGULATORY REQUIREMENTS AND COMPROMISES ADVERSE EVENT REPORTING

A Whitepaper By:
Dr. Michael Silver (PhD Chemistry) | Dr. Mart McClellan (DDS, MS) | Anne Armstrong | Ron Schutt
September 27, 2019

PRE-RELEASE DRAFT

***NOTE:** This whitepaper is in draft stage as it has been shared for input from stakeholders in the orthodontic industry and other subject matter experts until November 1, 2019 when it will be finalized and published.*

Table of Contents: **Page:**

Background

As covered in previous white papers, editorials, and survey results, the generic dental wax dispensed globally to patients in orthodontic treatment is believed to be the last commonly dispensed oral care product without several universally accepted quality and safety standards. Namely: unit of use/hygienic packaging, tamper-evident packaging, labeling with product traceability, and disclosure of ingredients.[1-4] This paper addresses the implications of providing generic/unlabeled dental wax without labeling or product traceability to the end patient. In particular, this paper outlines the noncompliance with local medical device requirements in many countries including the entire European Union. This paper also addresses how these same regulatory violations in the EU have compromised Adverse Event Reporting to the U.S. FDA.

Surprisingly, the need to comply with longstanding quality standards and regulations has been met with resistance. In March of 2019 OrVance notified over 30 suppliers to the orthodontic profession on the noncompliance of generic dental wax (see Exhibit A). Additionally, a full-page trade advertisement was run in both the U.S. and UK in May, 2019 to alert the orthodontic industry on the quality and compliance issues with generic dental wax (see Exhibit B). Exhibit C is a letter written in June 2019 to the American Association of Orthodontists, which outlined the specific quality and compliance issues with generic dental wax. None of these communications or advertisements have been met with any credible denial or pushback.

While several suppliers have agreed that generic wax is noncompliant, none have accepted that the global orthodontic industry should prioritize bringing this very old commodity product into full compliance with current quality standards and regulatory requirements. One of the most common points of resistance has been variations of the following question: "Can you prove that there have been significant safety issues or that patients have gotten sick or died from dental wax?"

Until recently, we have dismissed this question and advocated that it is simply the right thing to do for such a commonly dispensed product, primarily used by millions of children, to follow universally accepted quality standards and regulatory requirements. But since the question around the historical safety of traditional dental wax kept coming up, we've set out to research this question with third-party experts and report our findings here in this white paper.

Definition of "Dental Wax" as addressed in this Research

For the purpose of this white paper, we define dental wax as the generic/unlabeled "wax" composite in connected strips within a plastic case that is most commonly dispensed to patients in orthodontic treatment throughout the world (it does not address the dental wax that is sold to consumers at retail). The "wax" composite is intended to be used by tearing off a "pea-sized" piece and applied after drying the bracket. Given its intended purpose, the bulk piece of material is commonly known to repeatedly come in contact with saliva and even blood. It is also an accepted fact that the material commonly crumbles/falls off and is swallowed by patients during use, and occasionally shared among patients.[3]

In spite of the above, the common unlabeled wax offers no unit-of-use/hygienic packaging, no tamper-evident feature, no product traceability, and no disclosure of ingredients. Below is a picture of the typical generic dental wax that is most commonly dispensed globally to patients in orthodontic treatment.

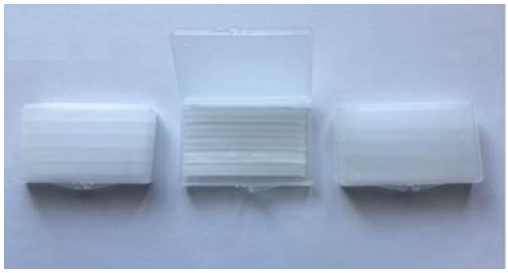
Known Regulatory Violations with Generic Dental Wax

For generations, the global orthodontic industry has been collectively selling and dispensing generic/unlabeled dental wax in virtually every country where orthodontic treatment exists. But while the absence of any labeling on the end unit has been a cheap and efficient way to supply the global market, it is not globally compliant. It is not feasible to cover local medical device labeling requirements for dental wax in all countries, but here we will explain how unlabeled wax is in violation with medical device labeling regulations in many countries, particularly the entire European Union (EU).

Certainly for all healthcare products that are used orally, it became a universally accepted practice in the U.S. and globally decades ago to provide the end consumer product traceability. This globally accepted standard also led to the adoption of medical device labeling regulations in many countries including the EU over 25 years ago.

OrVance has received consistent opinions from two global regulatory firms and an Authorized Representative (AR) in the EU stating that unlabeled dental wax is in clear violation of MDD 93/42/EEC. To further confirm this, a third party regulatory firm contacted the UK's MHRA to ask whether the

generic dental wax (as depicted in the shared photo below) is in compliance with the current labeling requirements in the EU.



This was their response:

> *"...the individual devices (wax packets) will be going to an end user and will not be used directly by the healthcare professionals who are supplied the bulk packages. MHRA therefore considers that information required on the label as per Annex I, section 13.3 (of MDD 93/42/EEC) must be provided on the individual devices..."*

Per the MHRA's feedback and the requirements of the current Medical Device Directive, at least the following items must appear on the product:

a. Name and address of manufacturer
b. Name and address of Authorized Representative
c. Identification of the device
d. Lot number

Furthermore, the new EU Medical Device Regulation 2017/745 [page L117/5, paragraph (35)] that goes into effect 26 May 2020 expands the accountability for noncompliance beyond manufacturers to also include importers and Authorized Representatives (AR). Responsibility is also specifically assigned to distributors to inform the manufacturer, AR, and importers if they know or have reason to believe that the device is not in conformity with the regulations.

Since medical device labeling requirements vary by country, it is no longer appropriate for the orthodontic industry to sell and dispense the same unlabeled product to all patients in treatment globally. We believe generic dental wax may be the last commonly dispensed Class I Medical Device that offers no labeling or product traceability to the end patient and is sold to practices in all markets regardless of local labeling regulations. Exhibit D is one of the several letters (redacted) that were sent to Authorized Representatives in the EU requesting immediate action to discontinue sales of mislabeled dental wax.

U.S. FDA Adverse Event Reporting Requirements

According to FDA guidance on Medical Device Reporting: "The FDA encourages healthcare professionals, patients, caregivers and consumers to submit voluntary reports of significant Adverse Events (AE) or product problems with medical products to MedWatch, the FDA's Safety Information and Adverse Event Reporting Program."[5]

While the FDA Class I medical device regulations do not specify the same labeling requirements as the EU regulations per se, US 21 CFR 803 does require manufacturers of medical devices to report Adverse

Events.[6] So while it can be argued that generic dental wax does not need any labeling or traceability to be compliant with U.S. FDA regulations, Adverse Event Reporting is clearly compromised by not making it possible for the patient or caregiver to identify and directly contact the manufacturer, who is mandated under FDA regulations to report AEs.

So since the patient is unable to contact the manufacturer of unlabeled dental wax, can we assume then that the orthodontic practice is investigating and submitting adverse event reports to bridge the gap between the patient and the manufacturer? Per US 21 CFR 803, healthcare providers are not required to file AEs and FDA regulations clearly put the responsibility for AE reporting on the manufacturers and importers – not the practice. Furthermore, suppliers of generic dental wax in the U.S. have clearly provided no communication or training to the practices on any need to serve as a liaison between the manufacturer and the patient to properly investigate and file Adverse Events for unlabeled product.

History of Adverse Event Reporting with Generic Dental Wax

So what can we conclude from the historical data on Adverse Events filed in the U.S. for generic wax?

It is estimated that over 100 million packs of dental wax, made by many different manufacturers, have been dispensed to patients in orthodontist treatment since 1996.[1] Yet only one manufacture that supplies the orthodontic industry filed a total of only 3 Adverse Events (AEs) for dental wax since 1996. And while we know much of the generic dental wax is made outside the U.S., not one AE was filed by a manufacturer outside the U.S. [7]

Most medical device manufacturers will agree that this number of AEs filed over 23 years is extremely low when comparing to other high-volume medical devices that are properly labeled and considered to be safe. Without proper labeling (e.g. identification of the device, name of the manufacturer, and lot number), there is no viable way for patients to notify the manufacturer directly of an Adverse Event as with virtually all other healthcare products.

Since the reported number of AEs for unlabeled/generic wax is unusually low and offers patients no way of contacting the manufacturers directly, isn't it likely that AEs have gone unreported? We acknowledge that there is no evidence here to prove generic dental wax is unsafe but it is clearly a risk that leaves our patients and the orthodontic industry vulnerable. Under the circumstances of violating labeling regulations and offering patients no traceability back to the manufacturer, the orthodontic industry cannot sufficiently prove that the commodity dental wax made by all manufacturers is safe.

The only way dental wax can be accepted as safe is to provide the end patient proper labeling and traceability as virtually all oral healthcare products have done for decades. And since virtually all dental wax dispensed to patients globally is unlabeled, it's not only incumbent on given manufacturers to prove that their own dental wax is safe, but it is also incumbent on the orthodontic industry to prove that all unlabeled dental wax from all manufacturers is safe.

For readers that remain skeptical on the need to provide compliant labeling with product traceability to our end patients, we must also consider the quality and safety issues of the past related to manufacturer product recalls and the investigation and containment of product tampering incidents. More recently, the romaine lettuce crisis in the U.S. has also taught us important lessons about the risks of not having adequate product traceability.[8] While generic dental wax may be perceived to be safe, it

is subject to the same risks that these standards and regulations were designed to address. As a result, there is no basis to claim that it shouldn't be held to the same standards and regulations as all other commonly dispensed healthcare products.

Summary & Conclusions

It's time for all orthodontic wax to immediately be brought into compliance with regulatory requirements wherever it's sold and to meet universally accepted healthcare quality and safety standards.

It is not the conclusion of this paper that manufacturers have intentionally suppressed AEs by selling mislabeled product, but we do conclude that it has likely been the unintended result. None of the leading suppliers to the orthodontic profession are Consumer Packaged Goods (CPG) companies. As a result, dental wax has simply not kept current with the quality standards and regulations over the last several decades. This is also because dental wax hasn't been treated as an important product by either the orthodontic product suppliers or the orthodontic practices. Avoiding these added quality and compliance standards from the 80's and 90's has also been a way to minimize costs and enable the same unlabeled wax to be sold anywhere in the world (i.e. by avoiding the costs to develop a global compliance program that provides product that is compliant with regulations wherever its sold).

We have also learned that there is the perception by many in the industry that dental wax is still OK because it has been "grandfathered in" as a very old product that is very commonly used - yet there is nothing in either the U.S. FDA regulations or EU regulations that make dental wax exempt from current or upcoming medical device regulations.

Leading orthodontic product suppliers and the orthodontic industry at large must also consider how it would contain a significant quality/safety issue or orchestrate a product recall in the event of any serious safety issue with generic/unlabeled dental wax. We must now consider that there are many millions of packs of unlabeled dental wax being used by patients all over the world right now that offer no way for patients to identify a product made from one manufacturer vs. another. As a result, the quality of unlabeled dental wax is really only as good as the manufacturer with the lowest quality and regulatory standards.

Dental wax is likely to be the last commonly dispensed Class I medical device without any of the aforementioned quality features and is knowingly violating current and upcoming regulations in many countries. So it is the final conclusion here that it's time for the orthodontic industry to make it a priority to address the obsolescence of dental wax not only in performance, aesthetics, and quality, but to also finally bring it into compliance with regulations wherever it's sold.

Addressing the obsolescence and noncompliance of dental wax must be led by the suppliers to the orthodontic profession, who are responsible under the law for the compliance of products they sell to practices. It is not a solution to simply wait until the practices stop buying the cheap (and in many cases free) generic wax that is still being pushed on their practices. The responsibility for meeting quality/safety standards and regulatory requirements for medical devices clearly falls on the manufacturers and suppliers – not the orthodontic practices.

In conclusion, we raise the following questions to be considered by the orthodontic industry, patients, parents, consumer/patient advocates, and regulators:

- Should we continue to dismiss the universally accepted quality standards and regulations that have now been in place for decades throughout the global healthcare industry? If so, what is it about dental wax that should make it exempt from the same standards patients have come to expect from all other oral healthcare products?
- How can all the orthodontic product suppliers collectively defend unlabeled dental wax as having a safe history when the AE reporting has been compromised by not providing patients traceability back to the manufacturer (as with virtually all other oral care products dispensed to patients)?
- Given the findings of this research, can we really say with confidence that patient safety is not compromised by continuing to ignore these longstanding, universally accepted quality standards and regulations?
- How would the orthodontic industry contain any potential quality or safety issue with generic wax from a given manufacturer? What responsibility would be placed on the practice to investigate and coordinate any recall of unidentifiable product they have given their patients? And if any safety issue was ever found to be caused or exacerbated by unmet quality standards or known regulatory violations, doesn't this leave the orthodontic profession vulnerable?
- Shouldn't orthodontic practices, orthodontic trade associations, and/or orthodontic resident programs hold suppliers and manufacturers accountable to the same standards followed by manufacturers of other commonly dispensed medical devices?
- What proactive measures should be taken within the orthodontic industry to address these known regulatory violations and noncompliance with current quality and safety standards? Since the new EU Medical Device Regulations that go into effect in May 26, 2020 expands accountability for regulatory violations, shouldn't the orthodontic industry embrace the need to bring all orthodontic wax into full compliance no later than that date?
- Doesn't the noncompliance of the most commonly dispensed product by the orthodontic profession undermine its claims made publically that patient safety is the profession's top priority?

Dr. Mart McClellan, Orthodontist, Author, and Advisor to OrVance stated, "Scrutiny of our profession is certain to increase if we continue to ignore the noncompliance and poor performance of the most commonly dispensed product in our profession. We need to demand that all suppliers to our profession stop pushing the cheap unlabeled wax on our practices and immediately bring orthodontic wax into full compliance with current quality standards and regulations."

In our continued research on this topic, we invite all readers to contact us with your feedback. Can you name any other oral care product, commonly dispensed by a doctor to many millions of patients that:

- Offers no disclosure of ingredients.
- Offers no hygienic/unit-of-use packaging.
- Offers no tamper-evident packaging feature.
- Offers the end patient no product labeling or product traceability.
- Knowingly violates regulations that have been in place for over 25 years.

We'd like to hear from you – please contact us at service@orvance.com. Please provide any feedback on the findings of this white paper so we can continue the dialogue on how best to maximize the quality, safety, and efficacy of products for all patients in orthodontic treatment.

AUTHOR BIOS

Michael E. Silver, PhD

Dr. Silver has a PhD in chemistry from Cornell University and is a professor emeritus at Hope College. Mike has over 30 years of experience in academia and working with industry to develop novel materials and intellectual property in the healthcare arena. Mike is also the principal inventor of OrthoDots, an inventor on numerous issued patents, and the co-author of the textbook Introductory Chemistry: Atoms First (Pearson, 5th edition). He currently leads product development, intellectual property, and technical affairs for OrVance LLC in Grand Rapids, Michigan.

Mart G. McClellan, DDS, MS

Dr. McClellan is a practicing orthodontist in Illinois, former President of the Illinois Society of Orthodontists, author, national lecturer, and on the advisory board of OrVance LLC. Mart received his dental degree from Northwestern University and did his orthodontic residency at the University of Michigan. He has written numerous articles for national publications and multiple books. He is also a Charter Member of the Forbes Speakers Group and has spoken all over the country, including numerous universities, and internationally. Mart is also President of Macro Wealth Management, a Registered Investment Advisor (RIA), and is registered in multiple states in the areas of securities and insurance.

Anne Armstrong

Anne has over 25 years of experience in Quality Control/Assurance at the management level in both the manufacturing and retail sides of the business. Anne has designed several Quality Programs for GMP start-up operations and also has an extensive background conducting training & audits to ensure Quality/Compliance, and interpreting/following FDA regulations.

Ronald J. Schutt

Ron has over 25 years of experience in healthcare and previously served as vice president of consumer healthcare marketing at Perrigo Company (NYSE: PRGO), where he championed major healthcare initiatives, product development, and led several of the most successful product launches in the company's history. He is also the founder and principal of RJ Schutt & Associates and serves as the founding president/CEO for OrVance LLC in Grand Rapids, Michigan.

REFERENCES

1. "Raising the Bar in Quality, Safety, and Compliance", Dr. Michael E. Silver, Dr. Mart McClellan, and Ron Schutt, May 2018, http://www.orvance.com/wp-content/uploads/2018/05/OrthoDotsClear_QualityWhitePaper_FINAL_0518.pdf
2. "Should a Modern Orthodontic Practice Still Dispense Dental Wax", Alison Werner, May 2019, http://www.orthodonticproductsonline.com/2019/05/orthodontic-practice-dispense-dental-wax-orthodots/
3. "Consumer Alert on Generic Dental Wax", Dr. Michael Silver, Dr. Eric Hannapel, Ron Schutt, July 2019, https://orvance.com/wp-content/uploads/2019/07/Consumer-Alert-Whitepaper-7-19-FINAL.pdf
4. "Survey Confirms Dental Wax is Obsolete and will be Discontinued by the Orthodontic Profession", OrVance Press Release, March 26, 2019, https://orvance.com/survey-dental-wax-is-obsolete/
5. "Medical Device Reporting (MDR): How to Report Medical Device Problems", https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems
6. Medical Device Reporting Regulation, US Code of Federal Regulations, Title 21,Part 803
7. FDA Manufacturer and User Facility Device Experience (MAUDE) Database, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM, Product Class = wax, dental, intraoral.
8. "Post-romaine lettuce outbreaks: Lessons in traceability", Michele Arcand, Food Dive, June 12, 2018; https://www.fooddive.com/spons/post-romaine-lettuce-outbreaks-lessons-in-traceability/525248/

Exhibit A - Notification OrVance sent to over 30 suppliers in March 2019

NOTICE TO SUPPLIERS OF NONCOMPLIANT DENTAL WAX

Generic dental wax is now believed to be the last healthcare product of its type that does not meet any of the following quality and safety standards: hygienic unit-of-use packaging for safe patient and in-office use, tamper-evident packaging, proper labeling with product traceability, and disclosure of ingredients.[1-3] Sold globally to orthodontic practices and dispensed primarily to children, generic dental wax is also in violation of the European Union Medical Device Directive as confirmed with the United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA), two global regulatory firms, and an EU Authorized Representative. Generic wax's regulatory noncompliance and omission of these basic healthcare product standards leaves our patients and industry vulnerable.

OrVance LLC is partnering with suppliers in the orthodontic industry to provide the first globally compliant orthodontic wax: OrthoDots® CLEAR. Following is a summary on where generic dental wax fails our patients in quality, compliance, performance, and aesthetics relative to OrthoDots® CLEAR.

Quality, Safety, and Compliance Features[1]	Generic Dental Wax	OrthoDots® CLEAR
Hygienic Unit-of-Use Packaging for safe patient and in-office use	NO	YES
Tamper Evident Packaging	NO	YES
Labeling with Product Traceability	NO	YES
Disclosure of Ingredients	NO	YES
Compliant with Regulations in the EU	NO	YES

Performance and Aesthetic Features[2]	Generic Dental Wax	OrthoDots® CLEAR
Sticks and Stays the Best (with proprietary adhesive)	NO	YES
Clear (17X more transparent that dental wax)	NO	YES
20X more pliable than dental wax (easier to mold)	NO	YES
Best for use on all appliances including Clear Aligner Trays	NO	YES

Made in U.S.A. I Patents Pending

In a recent survey of orthodontic residents in the U.S., residents could not identify one other healthcare product with none of the above quality and safety features.[3] In addition, the majority of residents surveyed believe that it is not acceptable to dispense a product to their patients that have none of these features.

OrVance is proud to partner with world-class suppliers including American Orthodontics, G&H, and others that have joined OrVance in actively promoting OrthoDots® CLEAR as the first orthodontic wax that meets global quality and regulatory requirements. With its partners, OrVance will continue to actively educate orthodontists and resident programs on the need to immediately stop dispensing dental wax that is lacking any of the necessary quality and safety features listed above.

Over half of the U.S. graduate resident programs have adopted OrthoDots® CLEAR, which they prefer overwhelmingly to wax, and 88% of the residents surveyed say they intend to use OrthoDots® CLEAR in their practice.[3] OrVance is seeking to expand its partnerships with leading suppliers in the orthodontic industry to provide all patients in treatment access to a higher quality and fully compliant replacement to traditional dental wax. Orthodontic product suppliers that are interested in making OrthoDots® CLEAR available to their customers can contact OrVance at service@orvance.com.

1. OrthoDots® CLEAR: Raising the Bar in Quality, Safety, and Compliance, May 2018
2. Why OrthoDots® CLEAR is Poised to Replace Dental Wax, November 2017
3. OrVance Survey to Orthodontic Residents in the U.S., March 2019

OrVance®
INNOVATION IN ORTHODONTICS

Exhibit B – Trade Advertisement run in the U.S. and UK in May 2019

INDUSTRY ALERT ON NONCOMPLIANT DENTAL WAX

Did you know that orthodontists are dispensing the last known product in all of healthcare with NONE of the quality and safety features below that patients have come to expect?

Dental wax is still the most commonly dispensed product by orthodontists and 75% of patients are children. Generic dental wax not only falls short of current healthcare product standards, it is also in violation of medical device regulations in the European Union, which leaves our patients and industry vulnerable.

OrthoDots® CLEAR is the world's first globally compliant solution that meets these critical healthcare product standards and offers superior performance and aesthetic benefits.

Quality, Safety, and Compliance Features[1]	Generic Dental Wax	OrthoDots® CLEAR
Hygienic Unit-of-Use Packaging for safe patient and in-office use	NO	YES
Tamper Evident Packaging	NO	YES
Labeling with Product Traceability	NO	YES
Disclosure of Ingredients	NO	YES
Compliant with Regulations in the EU	NO	YES

Traditional dental wax also is obsolete in both performance and aesthetics. OrthoDots® CLEAR is the first orthodontic wax to provide the following benefits for your practice and patients:

Performance and Aesthetic Features[2]	Generic Dental Wax	OrthoDots® CLEAR
Sticks and Stays the Best (with proprietary adhesive)	NO	YES
Clear (17X more transparent that dental wax)	NO	YES
20X more pliable than dental wax (easier to mold)	NO	YES
Best for use on all appliances including Clear Aligner Trays	NO	YES

Made in U.S.A. I Patents Pending

In a recent survey of orthodontic residents in the U.S., a majority of residents surveyed believe it is not acceptable to dispense a dental wax product to their patients without any of the above quality and safety features. OrthoDots® CLEAR is now the #1 orthodontic wax in U.S. orthodontic resident programs with over 80% of the residents surveyed saying they intend to use OrthoDots® CLEAR in their practice.[3]

OrthoDots® CLEAR is also now the only dental wax alternative that is available at leading suppliers and at major retailers in the U.S. for ongoing patient needs.

Ask your favorite supplier for OrthoDots® CLEAR, or learn where to buy at orthodots.com.

1. OrthoDots® CLEAR: Raising the Bar in Quality, Safety, and Compliance, May 2018
2. Why OrthoDots® CLEAR is Poised to Replace Dental Wax, November 2017
3. OrVance Survey to Orthodontic Residents in the U.S., March 2019

OrVance®
INNOVATION IN ORTHODONTICS

EXHIBIT C – Letter to the American Association of Orthodontics, June 2019

OrVance
INNOVATION IN ORTHODONTICS

June 18, 2019

Lynne Thomas Gordon, Chief Executive Officer
Sean Murphy J.D., Vice President, Advocacy and General Council
American Association of Orthodontists
401 North Lindbergh Boulevard
St. Louis, MO 63141-7816
(Delivered via Email)

Dear Lynne and Sean,

Thank you again for taking the time to review the quality and compliance issues associated with the generic dental wax that is still being dispensed globally to patients in orthodontic treatment. As you requested, this letter provides the specific information around known regulatory violations and the noncompliance with current healthcare quality standards.

As discussed, it is not our request that AAO takes a formal position on this matter. But we do respectfully request that this letter should be made available to all AAO members so they can be made aware of this issue and draw their own conclusions.

In addition to the content of this letter, we would encourage AAO members to read this third party editorial by Alison Werner, Chief Editor at Orthodontic Products titled "*Should a Modern Orthodontic Practice Still Dispense Dental Wax*".

Additionally, as OrVance will soon be extending this PR/awareness campaign to the general media and consumers, we'd suggest AAO members will want to be made aware of the questions that are likely to surface from their patients on this issue. While this new campaign will target the end consumer, it is very consistent with the content of this letter and our advocacy efforts within the orthodontic industry over that last 18 months.

Definitions:
For the purpose of this letter, we define generic or unlabeled dental wax as the typical "wax" composite in connected strips within a plastic case. This dental wax dispensed to the patient has no labeling, no lot codes, and no tamper-evident features. Below is a picture of the typical generic dental wax that is most commonly dispensed to patients globally.

6477 Cherry Meadow Dr. SE | Suite 5 | Caledonia, MI 49316 | **p** 888-508-1290 | *www.orvance.com*

Below we address four areas in particular where generic dental wax violates commonly accepted healthcare product quality standards as well as clear violations of longstanding regulations in many of the world's leading orthodontic markets: namely unit-of-use/hygienic packaging, tamper-evident packaging, proper labeling with product traceability, and disclosure of ingredients. This letter also addresses the implications of upcoming EU Medical Device Regulations (MDR's) on 26 May 2020, which adds even more stringent requirements for medical devices and expands the scope of liability/accountability for known regulatory violations.

Unit-of-Use Packaging

Since dental wax comes in contact with saliva and even blood, we believe traditional dental wax is not appropriate for patients to repeatedly handle the same piece of composite over and over. Also, it should never be shared among patients — and we know this occasionally happens, particularly with the many children in orthodontic treatment in our schools. We have also encountered known cases where elementary schools have dispensed dental wax to different children from the same pack. And in many instances, schools are receiving these cases of generic wax from local orthodontists to promote their practice in the community.

Safe and convenient use for our patients is the primary reason why we found it essential to package OrthoDots® CLEAR in hygienic, single-use applications. We believe generic wax is the last commonly dispensed healthcare product used for a similar purpose that is not in hygienic single-use packaging. When you stop and think about it, why has it taken so long for a product used for this purpose to be packaged in hygienic applications? It's what we've expected for decades from bandages and all other types of medical devices.

Our research also proves that orthodontic residents are embracing the need for more hygienic packaging. When we surveyed orthodontic residents from dental schools across the U.S., 69% said it was either 'important' or 'very important' that a product used for this purpose is hygienic and in single-use packaging. And the majority of residents surveyed also indicated that the product should be in unit-of-use packaging in order to be used in the practice setting.

Tamper-Evident Packaging

For decades now, virtually all consumable healthcare products have had packaging with a tamper-evident feature. The tamper-evident packaging feature was primarily born out of the Tylenol® tampering incident in 1982 that resulted in seven murders.

According to the regulations of the Food and Drug Administration, a tamper-evident package "is one having one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred."

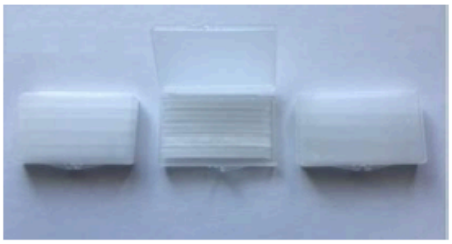
The traditional dental wax that is still commonly dispensed to patients offers no protective barrier or indication whether tampering may have occurred. So we are encouraging leading suppliers and orthodontists to consider whether orthodontic wax should have a tamper evident feature when it's the most commonly dispensed product in our profession, where 75% of our patients are children.

Proper Labeling with Product Traceability

Unlabeled dental wax provides no information or product traceability to the end patient. Certainly for all healthcare products that are put into the mouth, it has become a widely accepted practice in the U.S. and globally decades ago to provide the end consumer product traceability. This global healthcare product standard has also led to the adoption of regulations in the EU over 25 years ago which unlabeled dental wax clearly violates.

6477 Cherry Meadow Dr. SE | Suite 5 | Caledonia, MI 49316 | **p** 888-508-1290 | *www.orvance.com*

During the development of OrthoDots® CLEAR, OrVance has received consistent opinions from two global regulatory firms and a highly respected Authorized Representative (AR) in the EU stating that unlabeled dental wax is in clear violation of MDD 93/42/EEC. And to further confirm, a third party regulatory firm contacted the UK's MHRA on OrVance's behalf to ask whether the dental wax (as depicted in the shared photo below) is in compliance with regulations in the EU.



This was their response:

> ***"...the individual devices (wax packets) will be going to an end user and will not be used directly by the healthcare professionals who are supplied the bulk packages. MHRA therefore considers that information required on the label as per Annex I, section 13.3 (of MDD 93/42/EEC) must be provided on the individual devices..."***

Per the MHRA's feedback and the requirements of the current Medical Device Directive, at least the following items must appear on the product:

a. Name and address of manufacturer
b. Name and address of Authorized Representative
c. Identification of the device
d. LOT number

Furthermore, the new EU Medical Device Regulation 2017/745 [page L117/5, paragraph (35)] that goes into effect 26 May 2020 expands the accountability for non-compliance beyond manufacturers to also include importers and Authorized Representatives (AR's). Responsibility is also specifically assigned to distributors to inform the manufacturer, AR's, and importers if they know or have reason to believe that the device is not in conformity with the regulations.

<u>Performance, Aesthetics, and Product Costs</u>

While not the primary focus of this letter, generic dental wax is also obsolete in performance and aesthetics. And while OrVance has made substantial investments in the development of a superior performing product with aesthetic benefits, it is important to note that the majority of the incremental cost over traditional wax comes from the added quality and compliance features addressed in this letter. OrthoDots® CLEAR wins on every attribute but it is not viable to compete with the price of generic wax that avoids the costs of meeting these basic quality and regulatory standards.

Therefore, we believe it unfair that OrthoDots® CLEAR must compete on price with a product that avoids the costs of current quality and regulatory requirements. Even putting aside the performance and aesthetic benefits of OrthoDots® CLEAR, is it really worth saving only $1 to $2 per patient to dispense an inferior product that knowingly violates current quality and regulatory requirements?

6477 Cherry Meadow Dr. SE | Suite 5 | Caledonia, MI 49316 | **p** 888-508-1290 | *www.orvance.com*

In Conclusion

Generic dental wax is in clear violation of longstanding regulations within the EU as well as globally accepted healthcare quality and safety standards. Furthermore, the majority of Orthodontic Residents surveyed said it is not acceptable to dispense an orthodontic wax to patients with none of the features highlighted in this letter. So we'd like to expand the dialog among orthodontists to consider whether traditional dental wax should continue to be the go-to product in our profession for pain and irritation during orthodontic treatment.

Perhaps most importantly, we encourage a dialog between the practice and their suppliers as to why traditional dental wax continues to be sold into our profession when it falls short of today's quality and compliance standards.

Lynne and Sean, we trust this letter provides you with the information you requested so AAO members can be made aware of this emerging issue (more information can also be found at orvance.com). We look forward to hearing from you.

Sincerely Yours,

Ron Schutt
President/CEO, OrVance LLC

Dr. Michael E. Silver, PhD (Chemistry)
Director or R&D and Technical Affairs, OrVance LLC

Eric Hannapel, DDS, MS, PC
Orthodontist & Co-Founder of OrVance LLC

Scott Tyler, DDS, MS
Orthodontist, OrVance Advisory Board Member

Mart McClellan, DDS, MS
Orthodontist, Author, OrVance Advisory Board Member

EXHIBIT D – Letter to Authorized Representatives in Europe (redacted)

OrVance
INNOVATION IN ORTHODONTICS

September 27, 2019

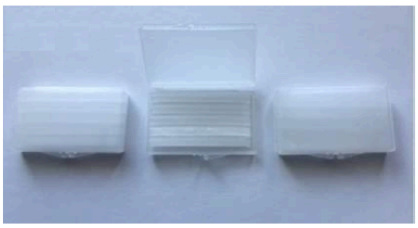
RE: Non-Compliant Dental Wax

To: [redacted]

Dear Sir:

We are the manufacturer of OrthoDots® CLEAR, a modern replacement for intraoral dental wax. As you are acting as the Authorized Representative on behalf of [redacted], [redacted], [redacted], and [redacted], we are informing you that intraoral dental wax from these suppliers is not compliant with current MDD 93/42/EEC, Annex I, Section 13.

OrVance has received consistent opinions from two global regulatory firms and an Authorized Representative (AR) in the EU stating that unlabeled dental wax is in clear violation of MDD 93/42/EEC. To further confirm this, a third party regulatory firm contacted the UK's MHRA to ask whether the generic dental wax (as depicted in the shared photo below) is in compliance with the current labeling requirements in the EU.



This was their response:

"...the individual devices (wax packets) will be going to an end user and will not be used directly by the healthcare professionals who are supplied the bulk packages. MHRA therefore considers that information required on the label as per Annex I, section 13.3 (of MDD 93/42/EEC) must be provided on the individual devices..."

Per the MHRA's feedback and the requirements of the current Medical Device Directive, at least the following items must appear on the product:

a. Name and address of manufacturer
b. Name and address of Authorized Representative
c. Identification of the device
d. Lot number

6477 Cherry Meadow Dr. SE | Suite 5 | Caledonia, MI 49316 | **p** 888-508-1290 | *www.orvance.com*

Accordingly, our Authorized Representative has required that the above labeling be present on all individual packs of OrthoDots® CLEAR distributed by orthodontists to their patients throughout the European Union.

Furthermore, the new EU Medical Device Regulation 2017/745 [page L117/5, paragraph (35)] that goes into effect 26 May 2020 expands the accountability for noncompliance beyond manufacturers to also include importers and Authorized Representatives (AR). Responsibility is also specifically assigned to distributors to inform the manufacturer, AR, and importers if they know or have reason to believe that the device is not in conformity with the regulations.

Finally, as shared in the attached white paper, our research with third party experts concluded that the above labeling violations has also resulted in the compromising of Adverse Event Reporting. Additional information on OrthoDots® CLEAR and the quality and compliance issues with generic dental wax can be found in the white papers at orvance.com.

It is our request that [redacted] immediately notify [redacted], [redacted], [redacted], and [redacted] on the above labeling violations and discontinue your role as Authorized Representative for all noncompliant dental wax in the EU no later than May of 2020 when the new MDR goes into effect. We would appreciate acknowledgement of your receipt of this letter and your prompt attention to this matter.

Sincerely,

Michael E. Silver, PhD
Director of R&D and Technical Affairs
OrVance®
Phone: 616-460-7191
Email: mike@orvance.com
www.orvance.com