

May 28, 2020

Food and Drug Administration (FDA):

John Verbeten, Division Director
Division of Import Operations
John.Verbeten@fda.hhs.gov

Melissa D. Gonzalez, Branch Chief
Import Compliance
Melissa.Gonzalez@fda.hhs.gov

Bill Maisel, M.D., MPH. Director
Office of Product Evaluation and Quality
William.Maisel@fda.hhs.gov

Federal Trade Commission (FTC):

Todd M. Kossow
Director, Midwest Region
tkossow@ftc.gov

U.S. Customs and Border Protection:

Submitted via e-allegation portal on CBP
website
<https://eallegations.cbp.gov/Home/allegation>

Dear Agency Officials:

In the interests of the health, safety, and well-being of patients in orthodontic treatment, we write to express our concern regarding the pervasive importing, repackaging and distribution of misbranded dental wax¹ by the identified companies in this letter that continue to distribute noncompliant dental wax throughout the orthodontic industry.

The vast majority of dental wax dispensed to patients has been unlabeled (or misbranded) for decades by many manufacturers and suppliers in the orthodontic industry. There is also concern that the adverse event reporting itself may have been compromised by these companies by blatantly omitting labeling mandated by FDA to inform patients who to contact to report an adverse event. As a result, there is no credible data to prove conventional dental wax is safe.

Not only is the dental wax sold by these companies misbranded, but it also lacks several other universally accepted quality and safety standards such as hygienic packaging, tamper evidence, and disclosure of ingredients. And since these products are currently in an FDA product classification that is exempt from GMP requirements, we express concern that it is also likely that many of the violating companies may not even be following GMP's for a product where the ingredients are unknown and is dispensed to millions of patients, most commonly children.

¹ Dental wax is applied by a patient or caregiver in the mouth to relieve irritation caused by braces. It can remain in the mouth for hours and is commonly known to be ingested from crumbling and/or falling off. It is regulated by FDA under 21 CFR 872.6890 as a medical device with the designation "Intraoral dental wax". The conventional dental wax dispensed to patients fails to disclose ingredients but the principal ingredients are believed to be beeswax, carnauba, and/or paraffin, to which must be added several other ingredients to make the wax more pliable. It should be noted that honey imported from China and other countries has a history of contamination with antibiotic, pesticide, and microbial contaminants, and beeswax has been similarly determined to be contaminated. Antibiotic, Pesticide, and Microbial Contaminants of Honey: Human Health Hazards, Noori Al-Waili, et al., Scientific World Journal. 2012: 930849, (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3477659/>)



Typical dental wax sold to orthodontic and dental practices: No FDA required labeling (manufactured and distributed globally with blatant disregard for in-country medical device labeling regulations - including the U.S. and European Union), no hygienic/unit-of-use packaging, no tamper-evidence or safety seals, no disclosure of ingredients. Most is imported - most commonly from China.

Furthermore, the majority of the “dental wax” composite dispensed to patients and on the retail shelves is imported from outside the U.S., most commonly from China. Mandated Country of Origin labeling for these products is also not provided on the individual product containers dispensed to the end user. So when considering that most conventional dental wax does not comply with current quality and regulatory standards, is imported from outside the U.S. and offers no disclosure of ingredients or country of origin, we submit that this presents a public health risk and the identified companies responsible should be held accountable.

For additional evidence on the pervasive noncompliance of conventional dental wax, please refer to Exhibit A (Summary of Evidence against Conventional Dental Wax) and Exhibit B (redacted Cease and Desist Letter citing specific regulatory violations).

OrVance LLC is a Michigan company that has borne the cost of developing and manufacturing the first orthodontic wax to meet all the aforementioned quality and regulatory standards - and as a result faces unfair trade from the following suppliers in the U.S. that avoid the cost of meeting these quality and regulatory standards:

American Orthodontics, Benco Dental Supply Company, DB Orthodontics, Dental Health Products Inc. (DHPI), Dentaurem GmbH & Co. (Dentaurem Inc. (USA)), Dentsply Sirona/GAC/Raintree Essex Glenroe, Dynaflex, Forestadent USA, G&H Orthodontics, Henry Schein Dental, iD-Logical, Lancer Orthodontics Inc., Leone s.p.a., OC Orthodontics, Oraline Inc./OraBrite, Ortho Arch, Ortho Essentials, Orthomechanic LC, Ortho Technology, Orthodontic Supply and Equipment Co. Inc., Pearson Dental Supply Co., Practicon Inc., Space Maintainer Laboratories, US Orthodontic Products Inc., Young Innovations Inc./OrthoQuest/Nexadental, Young Innovations Inc./Plak Smacker

Exhibit C is a complete list of 78 manufacturers, organized by region, that are registered with the FDA for product code EGD (Intraoral Dental Wax) and may be manufacturing and/or importing misbranded dental wax into the U.S.

Conclusion

Dental wax, which typically resides in a user’s mouth for hours, much of which is ingested, is less regulated by FDA than imported food, and even those regulations that do apply to dental wax are being widely ignored.

We the undersigned express our strong support of the FDA, FTC, and U.S. Customs and Border Protection to investigate the identified companies responsible to ensure they comply with regulations and are not misleading consumers or causing them harm. We would appreciate your commitment to undertake such a review in a swift manner in order to ensure

the protection of patient safety and fair trade as it relates to orthodontic wax throughout the orthodontic industry.

Sincerely,

Primary Contacts from OrVance LLC:

Michael E. Silver PhD, Director of Technical Affairs, mike@orvance.com

Ronald J. Schutt, President/CEO, ron@orvance.com

Orthodontists & Dentists that Support this Letter:

David Allen, DDS, MS, Wheaton IL
Michael Behnan, DDS, MS, Rochester Hills MI
Adjunct Clinical Professor, University of Michigan

Bojana Bojovic, DDS, Wyoming MI
Ed Borio, DDS, Bloomfield Hills MI
Danial Briskie, DDS, Rochester MI
Donald Burkhardt, DDS, MS, Okemos, MI
Dean Burnett, DDS, MS, Bellevue WA
Art Carpenter, DDS, Kenilworth, IL
Erin Charnley, DDS, Hudsonville MI
Jason Charnley, DDS, MS, Grand Raven MI
Cory Coe, DDS, MS, JD, MBA, Byron Center MI
Brandon Comella, DDS, MS, Rochester, NY
Dave Cramer, DDS, MS, Grandville MI
Curtis Dailey, DDS, Hampton VA
Dale Davis, DDS, MS, Midland MI
Lisa Davis, DDS, MS, Midland MI
Matthew Dery, Bingham Farms MI
Robert Dery, DDS, Bingham Farms MI
Clay Dietz, DDS, Troy MI
Larry Duffield, DDS, Royal Oak MI
John Dumas, DDS, Birmingham MI
Michael Erhart, DDS, MS, Naperville IL
Former President, Illinois Society of Orthodontists

Larry Evans DDS, MS, PC, Lawrenceville GA
Clare Fedore, DDS, MS, Charlotte NC
Craig Fedore, DDS, East Lansing MI
Jim Fraser, DDS, MS, Birmingham MI
Thomas M Fredal, DDS, Utica MI
Mark Farina, DMD, Tampa FL
Michael Gabler, DDS, MS, Appleton WI
Thomas Gebeck, DDS, MS, Birmingham MI
Justin Geller, DDS, Novi MI
Robert Girgis, DDS, MS, Naperville IL
Former President, Illinois Society of Orthodontists

Lisa Goldberg, DDS, PC, Rochester Hills MI
Robert Gorski DDS, Harper Woods MI
Ken Grabowski, DDS, MS, Portage MI
Effie Grias, DDS, Caledonia MI
Tom Grias, DDS, Caledonia MI
Christian Groth, DDS, MS, Birmingham MI
Director, Michigan Association of Orthodontists

Burt Hagler, DDS, MS, Xenia OH
Reem Hallal, DDS, MS, Birmingham MI
Schuyler Hamill, DDS, PC, Birmingham MI
Timothy Hanigan, DDS, MS, Lamar CO
Beth Hannapel, DDS, Caledonia MI
Eric Hannapel, DDS, MS, PC, Caledonia MI
Adjunct Clinical Professor, University of Michigan

Craig Hanson, DDS, PC, Bloomfield Hills, MI
Travis Harshman, DDS, MS, Ionia MI
Nancy Hartrick, DDS, Royal Oak MI
Brittney Hazard, DDS, MS, Del Mar CA
James Hazlett, DDS, PA, Sarasota, FL
Chris Hier, DDS, Caledonia MI
Joseph Hildebrand, DDS, PC, Bloomfield Hills MI
Greg Hummon, DDS, MS, Birmingham MI
Stephen Jarvie, DDS, Novi MI
Bruce Kennedy, DDS, Rochester MI

Brett Kingma, DDS, Grand Rapids MI
Kevin R. Knapp, DDS, MS, Byron Center MI
Eric J. Kosnic, DDS, Rochester Hills MI
Randy Kunik DDS, Austin TX
Jeffrey Lee, DDS, MS, Palo Alto CA
Shari Lisann, DMD, Brookline MA
Ed Lin, DDS, MS, Green Bay WI
Matt Lineberger, DDS, MS, Charlotte NC
Megan Lineberger, DDS, MS, Charlotte NC
Robert R. Lokar, DDS, MS, Lathrup Village MI
Former President, Michigan Association of Orthodontists
Associate Professor of Orthodontics, University of Detroit
Joan March, DDS, PC, Millford MI
Michael Marderosian, DDS, Bloomfield Hills MI
Lindsey McClellan, DDS, Libertyville IL
Mart McClellan, DDS, MS, Kenilworth IL
Former President, Illinois Society of Orthodontists
Brian McLean, DDS, PC, Rochester MI
Ronald Miakinin, DDS, Rochester MI
Mitchell Milan, DDS, Birmingham, MI
Lathe Miller, DDS, MS, Grand Rapids MI
Immediate Past President, Michigan Association of Orthodontists
John Monticello, DDS, MS, Grand Rapids MI
Former President of Michigan Association of Orthodontists
Immediate Past-President Great Lakes Association of Orthodontists

Kistama Naidu, DMD, MS, U.S. Virgin Islands
Gordie Niles, DDS, MS, Birmingham MI
Greg Oppenhuizen, DDS, MSD, Holland MI
Mike Papastamatis, DDS, Rochester MI
Chris J Paulson, DDS, Novi MI
Sonni Pellillo, DDS, MS, Caledonia MI
Jon Potocki, DDS, MS, Stockbridge MI
Grady Randall, DDS, Grand Rapids MI
Katie Randall, DDS, MS, Grand Rapids MI
Paul Reed, DDS, MS, Petoskey MI
Jamie Reynolds, DDS, MS, Novi MI
Darren Riopelle DDS, Grand Haven, MI
Tim Sagun, DDS, MS, Kenilworth IL
Scott Sakowitz, DMD, MS, Orlando FL
Abbey Sayed, DDS, PC, Birmingham MI
Jake Schering, DDS, MS, Birmingham MI
Timothy Schmakel, DDS, MD, Bingham Farms MI
Sarah Schutte, DDS, MS, Denver CO
Gary Scott, DDS, Caledonia MI
Thomas Stout, DDS, Holland MI
Michael Thomas, DDS, MS, Saginaw MI
Linda Toth, DDS, MS, Sherman Oaks, CA
Brian Tyler, DDS, Rochester, MI
Scott Tyler, DDS, MS, Birmingham, MI
Craig Valassis, DDS, Bloomfield Hills MI
Aimee Valteau, DDS, Grand Rapids MI
Mark Vanderkaay, DDS, Royal Oak MI
Paul VanRaaphorst, DDS, MS, Rochester Hills MI
Angie Vredenburg, DDS, Hastings MI
Martin Vredenburg, DDS, Lowell MI
Chase Walby, DDS, Rochester MI
Thorpe C Whitehead, DDS, PLLC, Sanford NC

Exhibit A - Summary of Evidence against Conventional Dental Wax Gathered and Reported by OrVance LLC

1. The market for dental wax in both the professional and retail channel is driven by the orthodontic industry, as it has been sold to practices for generations as the only solution for “irritation caused by braces”. As a result, conventional wax remains to be the most commonly dispensed take-home product in the orthodontic profession as it is given to virtually every patient in treatment. In the U.S. alone, it is estimated that over 5 million packs of conventional wax is dispensed annually by the orthodontic profession, 75% of which is given to children. It is also estimated that up to 10 million packs of misbranded dental wax is still in the possession of practices and households in the U.S.
2. It is an undisputed fact that conventional dental wax is one of the most antiquated products in all of healthcare from a quality, safety, and compliance perspective (see [With Hygienic Precautions at the Forefront, Here are 5 Reasons to Stop Using Dental Wax](#)). In over five years of due diligence, no one has identified even one other similar product in all of healthcare that offers no hygienic packaging, no tamper-evidence or safety seal, knowingly violates regulations by omitting required labeling for product traceability, and offers no disclosure of ingredients.
3. OrVance has completed a [Lunch and Learn Presentation](#) with two thirds (45) of the Orthodontic Resident Programs in the U.S. to educate residents on the benefits of OrthoDots® CLEAR and why conventional dental wax should be banned from their profession. Not only were none of the residents able to name any commonly dispensed healthcare product worse than dental wax from a quality/safety perspective, but here were other key findings in a [Survey of Orthodontic Residents](#):
 - a. 100% of residents agree that “mitigation of pain and irritation is an important part of orthodontic treatment.”
 - b. The majority of residents surveyed said it is no longer appropriate to dispense conventional dental wax to patients.
 - c. Over 80% of residents said that it is essential for orthodontic wax to be in hygienic/unit-of-use packaging for chairside application within the practice.
4. The demand for this same substandard product at the retail shelves is simply driven by the high volume of conventional wax that it is still being dispensed to patients in orthodontic treatment. Virtually all the dental wax on the retail shelves in the U.S. is made in China and none offer hygienic/single-use packaging or disclosure of ingredients.
5. [Undisputed research](#) concludes that the vast majority of dental wax sold to practices blatantly violate longstanding medical device labeling regulations. These regulations have been in place for over 25 years in both the U.S. and European Union.
6. In early 2019, OrVance has notified over 30 orthodontic product suppliers and even did a full-page trade advertisement to notify the industry about noncompliant dental wax. Not one supplier has refuted any of the evidence citing noncompliance. OrVance also represents that many suppliers have in fact acknowledged to us that they know the dental wax they and their competitors are still selling to practices is noncompliant.
7. As of this writing, there have been only a few companies that have voluntarily discontinued conventional dental wax after receiving the attached Cease and Desist Letter (redacted), which outlines specific regulatory violations. While this is very small

positive step for our industry, these suppliers that have done the right thing now also face the same unfair trade practices by their many competitors that choose to simply ignore the violations cited in this letter.

8. The top reasons cited to OrVance from competitors that continue to sell conventional wax have been variations of the following reasons:
 - a. Everyone else is still selling it so we need to as well to stay competitive.
 - b. We'll stop when the regulatory authorities force us all of us to stop.
 - c. Dental wax has been around forever and we're not aware of patients getting sick or dying from it.
9. As explained in our [Published Research](#), there is absolutely no credible data to prove conventional dental wax is safe. In fact, the adverse event data on conventional dental wax may suggest that the pervasive labeling violations (providing no required labeling or traceability to the end patient) actually compromises Adverse Event Reporting.
10. Especially since most of the dental wax sold to practices violates regulations by providing no traceability to the end patients, OrVance refuses to accept that we must first prove that patients have gotten sick or died from dental wax before all dental wax must comply with such basic quality and compliance standards. If the collective industry believes conventional wax should continue to be an exception to these basic quality and regulatory standards, the burden of proof must shift to these manufacturers to explain to practices and the public why.
11. OrVance has made substantial investments to be the first globally compliant orthodontic wax that follows all the aforementioned quality, safety, and regulatory standards. The cost of meeting these quality and compliance standards has included substantial up-front costs and also makes our product more expensive to manufacture on a variable cost basis than conventional wax. It is therefore our position that this pervasive noncompliance not only makes our patients and practices vulnerable, but it also clearly results in unfair trade practices within the orthodontic industry.
12. OrVance has also invested substantially in research and legal/regulatory expenses in an attempt to educate and motivate the industry to do the right thing. If we must continue to invest in legal expenses to force compliance with such universally accepted quality and regulatory standards, we believe it points to more systemic issues within our industry from a quality and fair trade perspective.
13. OrVance sent several letters, emails, and participated in several calls with the American Association of Orthodontists (AAO). In May 2019, AAO's stated position was that OrVance should educate the industry on these matters via paid advertising through the AAO. As suggested, OrVance ran an ad in AAO's AJO/DO publication in December 2019. However, AAO refused to allow any content associated with the quality and compliance issues with conventional dental wax.
14. In May, OrVance was referred by the AAO to the President of the Orthodontic Manufacturers Association (OMA). OrVance has made repeated attempts to work with OMA but has found no cooperation to get our information to their members. Additionally, the given contact from OMA explained that the OMA is a closed group of members and their bylaws require that the list of members and its officers must remain confidential and can't be shared. In days where transparency is the gold standard, we raise the question on how an association made up of a secret group of members is good for the orthodontic

industry.

15. OrVance also found agreement and support from Authorized Representatives (AE) in the EU. As an example, one AE informed OrVance that over 10 years ago they worked with a company wanting to import and sell unlabeled dental wax into the EU. The AE informed them it was a violation of labeling laws so this particular supplier simply pursued other avenues. This AE was surprised to learn that to this day, most of the dental wax still sold throughout the EU is in violation of these same regulations.
16. Additional evidence indicates there are clearly unfair trade practices in the global orthodontic industry as it relates to dental wax. For example, it has certainly been the norm where manufacturers and several global suppliers sell the cheapest unlabeled dental wax globally with blatant disregard for labeling regulations in the countries they are sold (including but not limited to the U.S. and entire EU). This makes it unfairly difficult to compete with a product that is fully compliant.
17. Aside from quality and compliance, conventional dental wax is also obsolete in both performance and aesthetics. The opaque dental wax still being dispensed today was developed many decades ago only for the intended use to “relieve irritation from braces”. Clear aligners is the fastest growing segment and we now have evidence that there is an unmet need for patients in clear aligner treatment (see: [Clear Aligner Patient Need Discovered in New Consumer Research](#)). It is also a well-accepted fact that virtually all patients in treatment prefer transparent solutions, which also makes the traditional opaque wax obsolete for today’s orthodontic treatment.

Exhibit B - Cease & Desist Letter (redacted)



[REDACTED], 2020

Via Fed Ex

[REDACTED], [REDACTED]
[REDACTED] Company
Address
City, State Zip

Re: Noncompliant Orthodontic Patient Relief Wax

Dear [REDACTED],

On behalf of OrVance and its partners, we are contacting [REDACTED] with serious concerns about the lawfulness of orthodontic patient relief wax manufactured or otherwise distributed by your company. More specifically, [REDACTED] appears to be introducing into interstate commerce dental wax medical device products¹ which are misbranded under the Federal Food, Drug, and Cosmetic Act, and also in violation of the European Union (EU) Medical Device Directive.

As is the case with all medical devices, patient relief dental wax is misbranded and in violation of Section 502(b) of the FD&C Act (21 U.S.C. 352(b)) if it is distributed in package form without a label that includes conspicuously the name and place of business of the manufacturer, packer, or distributor (See also 21 CFR 801.1). Section 301 of the FD&C Act clearly states "the introduction or deliver for introduction into interstate commerce of any... device... that is adulterated or misbranded" is a prohibited act (21 U.S.C. 331(a)).

Furthermore, dental wax is in violation of MDD 93/42/EEC in the European Union if it is distributed in package form without a label that includes the name and address of the manufacturer, the name and address of the Authorized Representative (for devices imported into the E.C.), and a lot number as per Annex I, Section 13.3.

Please note that OrVance is preparing to commence in earnest a regulatory campaign in order to address the pervasiveness of noncompliant dental wax being distributed in the U.S., E.U. and elsewhere. Accordingly, we also want to provide you with the opportunity to rectify any nonconformances prior to potentially more public and/or litigious circumstances. We would be remiss if we did not disclose to you that our immediate plans may include but shall not be limited to the following:

- Reporting allegations of regulatory misconduct (including the specific manufacturers and distributors) to the U.S. FDA.
- Filing formal notifications of violations of MDD 93/42/EEC to the Authorized Representatives of each of the liable companies in the EU, accompanied with requests to immediately terminate the representation of each company's noncompliant dental wax.

¹ See Attachment A for a pictorial representation of the allegedly violative medical devices, which are distributed without the legally required labeling.

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- Notifying distributors of violative dental wax about these conspicuous deficiencies. And for distributors who are not also the manufacturer, we intend to encourage them to seek full refunds from the manufacturer(s) for all the noncompliant dental wax they, or their customers, have in inventory.
- Finally, OrVance (with its partners) will continue to educate, advertise and promote OrthoDots® CLEAR as a fully compliant alternative while highlighting the obsolescence of conventional dental wax in performance, aesthetics, quality, safety, and regulatory compliance.

But before OrVance crosses that bridge, I want to personally assure you that we would instead prefer to explore whether our companies can work together to offer the orthodontic industry a more effective and globally lawful solution. Thus, we kindly request a scheduled call with [REDACTED] to explore a partnership opportunity on the distribution of OrthoDots® CLEAR as a superior and fully compliant alternative to conventional dental wax. Otherwise, we request a written response no later than [REDACTED], 2020 which sets forth [REDACTED]'s plans concerning the:

- Immediate cease and desist of sales/distribution of noncompliant dental wax.
- Replacement of your in-stock and previously distributed noncompliant dental wax with a fully compliant alternative.

OrVance has worked tirelessly to provide orthodontic patients with a more effective, safe, and lawful alternative (See, e.g., Attachment B trade advertisement re. OrthoDots® CLEAR vs. conventional dental wax). We are proud of our commitment to business / regulatory compliance and ethics, and we trust that these same issues are just as important to [REDACTED]. Accordingly, we hope you agree with our position that neither OrVance nor our partners can continue to abide the commercialization of dental wax that is in clear violation of longstanding and globally accepted quality, safety, regulatory and statutory standards.

Please contact me directly at ron@orvance.com regarding your intended next steps by no later than [REDACTED], 2020 so we can proceed accordingly.

Sincerely Yours,

Ron Schutt
President/CEO, OrVance LLC

CC: [REDACTED]
Dr. Michael E. Silver, PhD
Eric Hannapel, DDS, MS, PC
Scott Tyler, DDS, MS
Mart McClellan, DDS, MS
Brian Tyler, DDS

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Attachment A: Conventional Dental Wax as Sold to Practices for Take-Home Patient Use



As typically sold to orthodontic and dental practices globally:

- Blatant disregard for local medical device labeling regulations in the countries it is sold - including but not limited to the U.S. and the entire European Union. Selling the exact same unlabeled wax globally without bearing the cost of meeting local labeling requirements also contributes to unfair trade practices against the companies that comply with local labeling regulations.
- No Hygienic/Unit-of-Use Packaging
- No Tamper-Evidence or Safety Seals
- No Disclosure of Ingredients

Attachment B: Example of Trade Advertisement

**OrthoDots® CLEAR makes Dental Wax Obsolete in:
Performance • Aesthetics • Quality • Safety • Compliance**

Introducing the new standard of care that works on ALL orthodontic appliances - including Clear Aligner Trays.



Performance and Aesthetic Features	OrthoDots® CLEAR	Conventional Dental Wax
Sticks and stays the best (with proprietary adhesive)	✓	✗
Clear (17X more transparent than dental wax)	✓	✗
20X more pliable than dental wax (easier to mold)	✓	✗
Best for use on all appliances including clear aligner trays	✓	✗
Quality, Safety, and Compliance Features	OrthoDots® CLEAR	Conventional Dental Wax
Hygienic unit-of-use packaging for safe patient and in-office use	✓	✗
Tamper-evident packaging	✓	✗
Labeling with product traceability	✓	✗
Disclosure of ingredients	✓	✗
Compliant with FDA medical device regulations ¹⁻²	✓	✗

Made in U.S.A. | Patents Pending



- **FIRST/ONLY** product that adheres to wet aligner tray edges and gum tissue
- Transparent (a **MUST** for patients in clear aligner treatment)
- >20% of dental wax sales to patients were purchased for relief from clear aligner trays³

**Now the #1 Orthodontic Wax in
U.S. Orthodontic Resident Programs!**



**Available from Leading Suppliers:
Learn where to buy at orthodots.com**



1. "Research Concludes Dental Wax Dispensed to Patients Violates Regulatory Requirements in the U.S. and European Union", December 2019.
 2. Unlabeled dental wax is misbranded as defined by the FD&C Act enforced by the U.S. FDA. If your practice still has unlabeled dental wax in inventory, ask your supplier for a full refund or a credit towards OrthoDots® CLEAR.
 3. "Clear Aligner Patient Need Discovered In New Consumer Research", January 2020.

Exhibit C - Companies Registered with FDA under Product Code EGD Class I Medical Devices (Intraoral Dental Wax) that may be Manufacturing, Importing and/or Repackaging Misbranded Dental Wax

CHINA: [AIDITE \(QINHUANGDAO\) TECHNOLOGY CO., LTD.](#); [CANGZHOU LANKANG MEDICAL INSTRUMENTS DEVELOPING CO., LTD.](#); [CANGZHOU LANKANG MEDICAL INSTRUMENTS DEVELOPING CO., LTD.](#); [CHANGSHU SHANGCHI DENTAL MATERIALS CO., LTD.](#); [CHANGZHOU DAYA IMPORT & EXPORT CORPORATION LTD.](#); [CORAL HEALTHCARE PRODUCTS MANUFACTURER CO.,LTD.](#); [DIGITAL DENTAL DEPOT](#); [HANGZHOU PENGWU MEDICAL EQUIPMENT CO.,LTD.](#); [HUANGHUA PROMISEE DENTAL CO., LTD.](#); [NEW PHENIX HOME PRODUCTS MANUFACTORY CO., LTD.](#); [NISSIN-METEC CHINA CO., LTD.](#); [PESITRO HEALTHCARE PRODUCTS CO., LTD.](#); [QINGDAO SANTEC INTERNATIONAL TRADE CO., LTD.](#); [Shandong Huge Dental Material Corporation](#); [SHANGHAI ZOGEAR INDUSTRIES CO.,LTD.](#); [SHENZHEN DENCO MEDICAL CO., LTD.](#); [SHENZHEN KANG SHENG BAO BIO-TECHNOLOGY CO., LTD.](#); [SHENZHEN ROGIN MEDICAL CO., LTD.](#); [SHUMEI INDUSTRIAL \(HEBEI\) CO., LTD.](#); [SHUMEI INDUSTRIAL \(SHEN ZHEN\) CO., LTD.](#); [TANGSHAN ZHENG TONG EXHIBITION CO., LTD.](#); [UNITED DENTAL CHANGZHOU](#); [Yamahachi Dental Material \(Changshu\) Co., Ltd.](#); [Yangzhou Yichuan Plastic Technology Co., Ltd.](#); [ZHEJIANG JASMINE ORALCARE PRODUCTS CO., LTD.](#); [ZHEJIANG MEDIUNION HEALTHCARE GROUP CO.,LTD](#)

USA/CANADA: [ADVANCED DENTAL DESIGNS](#); [ALMORE INTL., INC.](#); [ALUWAX DENTAL PRODUCTS CO.](#); [CAMCUBE INC.](#); [CARMEL INDUSTRIES](#); [CMP INDUSTRIES LLC.](#); [COLTENE/WHALEDENT INC.](#); [Comfort Solutions Orthodontics Inc.](#); [DEN-MAT HOLDINGS, LLC](#); [DENPLUS, INC.](#); [DENTSPLY PROSTHETICS](#); [Dentsply Sirona Orthodontics Inc.](#); [FREEMAN MANUFACTURING & SUPPLY CO.](#); [GARRECO, LLC](#); [Integra LifeSciences Production Corporation](#); [KULZER, LLC](#); [MEMPHIS DENTAL MFG. CO., INC.](#); [O&S Dental, Inc.](#); [PRIME DENTAL MANUFACTURING, INC.](#); [SAGEMAX BIOCERAMICS, INC.](#); [Ultradent Products Inc. / OraTech LLC](#); [VITA North America](#)

GERMANY: [BEGO BREMER GOLDSCHLAEGEREI WILH. HERBST GMBH & CO](#); [BREDENT GMBH & CO.KG](#); [DENTACO GmbH & Co. KG](#); [Dentaurum GmbH & Co. KG](#); [GEBDI DENTAL PRODUCTS GMBH](#); [VITA ZAHNFABRIK H. RAUTER GMBH & CO. KG.](#); [YETI DENTALPRODUKTE GMBH](#)

AUSTRIA: [Amann Girrbach AG](#) **BRAZIL:** [DENTAL MORELLI LTDA.](#) **COLOMBIA:** [PLACECOL S.A.](#) **COSTA RICA:** [LABORATORIOS DENTALES DE ZONA FRANCA, S.A.](#) **CZECH REPUBLIC:** [SpofaDental a.s.](#) **INDIA:** [PREVEST DENPRO LIMITED](#); [Shiva Products](#) **ITALY:** [LEONE SPA](#); [ZHERMACK S.P.A.](#) **JAPAN:** [DENKEN - HIGHDENTAL CO LTD](#) **KOREA:** [DENTOS, INCORPORATED](#); [DIO Corporation](#) **LIECHTENSTEIN:** [IVOCLAR VIVADENT AG](#) **MEXICO:** [MANUFACTURERA DENTAL CONTINENTAL](#); [PACIFIC EDGE DENTAL LABORATORIES, SA DE C.V.](#) **NETHERLANDS:** [CAVEX HOLLAND B.V.](#) **PAKISTAN:** [ACCOMPANY SURGICAL](#); [ATLANTIC ENTERPRISES](#) **SPAIN:** [UNION DENTAL S.A.](#) **TAIWAN:** [Shummi Enterprise Co., Ltd.](#) **TURKEY:** [BILKIM LTD CO.](#) **UNITED KINGDOM:** [ASSOCIATED DENTAL PRODUCTS LTD](#) **VIETNAM:** [JADE DENTAL SOLUTIONS COMPANY LIMITED](#)

Endorsements for OrVance and OrthoDots® CLEAR

“We are pleased to award OrVance the Michigan State Trade Expansion Program (MI-STEP) grant to support their efforts in expanding their international sales for their innovative OrthoDots® CLEAR product... We are proud to have OrVance as an emerging company in the healthcare sector here in Michigan and we are committed to support their growth globally.”

Jeff Mason, CEO Michigan Economic Development Corporation (MEDC)

“OrVance is a great example of an emerging specialty medical device company right here in Michigan that is bringing real innovation in patient care. Their flagship OrthoDots® CLEAR product delivers much needed advancements in the quality, safety, and efficacy to patients in orthodontic treatment.”

**Norman Beauchamp MD MHS, Dean College of Human Medicine
Michigan State University**

“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 more urgency within our profession to address this patient need.

**Dr. Mart McClellan, Orthodontist, Author, Advisor to OrVance
Former President, Illinois Society of Orthodontists**

“OrthoDots® CLEAR not only performs and looks much better than generic wax, but it is the only ortho wax that meets current healthcare product quality standards. Now that we finally have a better solution that complies with today’s healthcare standards, we need all dental wax suppliers to our profession to address the inadequate quality of what they’re offering or get out of the ortho wax business.”

Scott Tyler DDS MS, Orthodontist and Advisor to OrVance, TDR Orthodontics

“OrthoDots not only offers a better product to maximize patient satisfaction, but it also offers a better option for more hygienic use. The OrthoDots® ProPack provides the only single-use application on the market and is fully compliant with CDC and FDA guidelines for products used on multiple patients in healthcare settings.”

Andrea Cook, Orthodontic Clinical Consultant

“I have appreciated learning about OrthoDots® CLEAR and the noncompliance of generic wax as a case study in my MBA program. As someone that works in the medical device industry, OrthoDots® clearly addresses long overdue quality and safety needs for patients in orthodontic treatment.”

**Yujing Xue, Portfolio Manager, Stryker
MBA Candidate, University of Chicago Booth School of Business**

“Clearly, OrVance has brought to market a meaningful innovation to enhance orthodontic treatment and our students came up with some highly creative approaches that will accelerate acceptance, particularly among moms and children who are undergoing orthodontic treatment.”

Louis Schiavone III, Advertising Professor, Michigan State University

“We’re proud to have OrVance as one of our newest members. The needed innovation they bring to the orthodontic profession shows how the Grand Rapids area is such a vibrant place to develop and commercialize real solutions within healthcare.”

Rick Baker, President & CEO, Grand Rapids Chamber of Commerce