

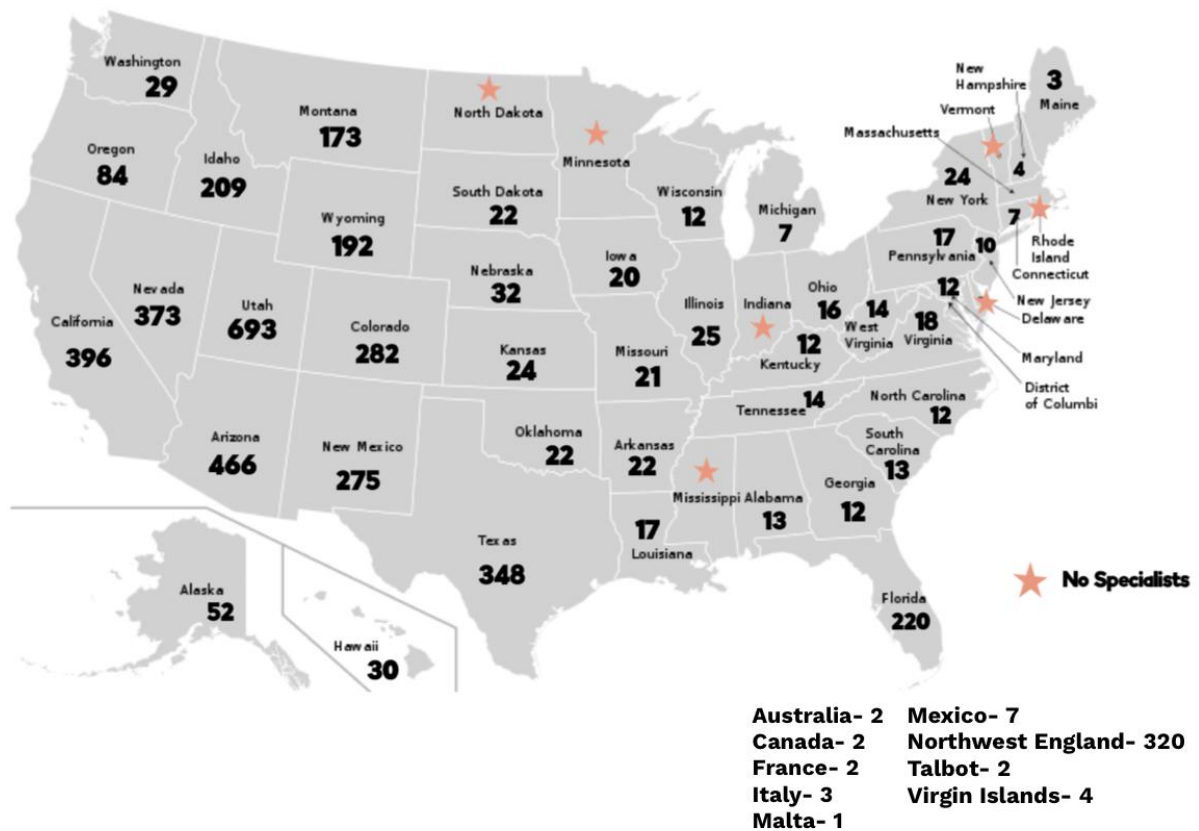
### Something to consider: Legalities + state to state info

Pristine Teeth Whitening Academy supplies around 150 dentist offices in the state of Utah with our whitening gel + blue de-sensitivity gel. We've been supplying our \*American Dental Association\* approved products through our Academy since 2017.

All of our products go through an FDA approval process, where certifications and MID numbers are provided just to pass through customs. The dentist offices are obviously very specific on products they are using and need to know \*down to the gram of hydrogen peroxide\* what each whitening pen contains. It's quite an extensive process!

Fun fact! Our first certified students worked at a dentist office where we trained the entire team. We now have thousands of specialists including dentists & hygienists in all 42 states & 10 countries!

## Pristine Teeth Whitening Specialists



Keep reading, for some vital information as you are thinking of pursuing a teeth whitening career...

In order to lead with integrity, we want to provide you with necessary information and help answer any and all questions as you begin this business. Much research and time has been taken to ensure you have as much knowledge as possible when it comes to legalities and state to state procedures.

The FDA classifies our services and whitening gel products as non-medical, but rather cosmetic. We are essentially offering a glorified whitening, spa-like, experience with high quality products. A luxury option for client's who do not want to go to the drug store for an at home whitening kit that hurts their enamel.

Since 2014 the FDA has classified hydrogen peroxide based whitening products as cosmetics. Since they are federally classified, a state cannot re-classify them.

#### **D. Peroxide-Containing Tooth Whiteners for OTC Use**

In the Petition, you assert that the expansion of peroxide-containing tooth-whitening products available directly to consumers, and application of these products in venues such as shopping malls, cruise ships, and salons is troubling because consumers have little or no assurance regarding the safety of product ingredients, doses, or the professional qualifications of individuals employed in these non-dental settings (Petition at cover page). You note concerns about the safe use of peroxide-containing tooth-whitening products without the benefit of professional consultation or examination (Petition at cover page), and you refer to States that have adopted legislation “preventing

---

<sup>40</sup> Li 1996; Tooth Whitening/Bleaching Report p.3.

non-dentists from applying or assisting a person in applying tooth-whitening material being sold as a safe alternative to dental office whitening procedures” (Petition at p. 2).

More generally, you argue for dental professional involvement in tooth bleaching (Petition at p. 2 and Tooth Whitening/Bleaching Report at pp. 3-5, 7-9). You note many factors may influence the effectiveness of a chemical tooth whitener (e.g., tooth/enamel cracks and related sensitivity, exposed root surfaces, inherited/developmental aspects, among others (Tooth-Whitening/Bleaching Report at p. 5)), which are best assessed by a dental professional.

As a preliminary matter, to restrict use of chemical tooth whiteners to dental professionals (i.e. practitioners licensed by law), the products would have to meet the definition of a drug (see section 201(g) of the FD&C Act), and meet the standard for classification as a prescription only product (see, e.g., section 503(b) of the FD&C Act). There is not sufficient evidence for us to determine, even if the products meet the FD&C Act’s definition of a drug, that because of their “toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to [their] use,” they would meet the standard for classification as prescription drugs. See section 503(b)(1)(A) of the FD&C Act. More information would be needed to establish specific peroxide concentration ranges appropriate for use in different settings (e.g., consumer use and practitioner-supervised use). In addition, factors other than peroxide concentration, such as frequency and duration of exposure, may also be relevant to these determinations.

Peroxide tooth whiteners have been available for consumer use for 20 years, and we have limited information regarding safety risks associated with their use. As mentioned above, we have permitted marketing of hydrogen peroxide as an active ingredient in certain OTC oral antiseptics<sup>41</sup> and antigingivitis/antiplaque agents (at concentrations of up to 3 percent)<sup>42</sup> until a final monograph for these drug products is finalized. Hydrogen peroxide has been a component of many OTC drugs, including topical anti-infectants, canker sore treatments, and earwax softeners. A 3 percent hydrogen peroxide solution can be marketed under the tentative final monograph and used by a consumer as a debriding agent/oral wound cleanser.<sup>43</sup>

FDA believes peroxide-containing tooth whiteners may be suitable for use without the supervision of a licensed practitioner and used safely. However, there is insufficient data regarding the risks posed by the use of hydrogen peroxide for tooth whitening to draw a definitive conclusion. We also do not have sufficient evidence from literature as to what an appropriate concentration limit would be for safe use of these products in the consumer setting.

---

<sup>41</sup> 59 FR 6084 at 6121.

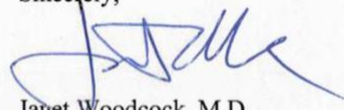
<sup>42</sup> 68 FR 32232 at 32257-60.

<sup>43</sup> “Oral Health Care Drug Products for Over-the-Counter Human Use; Tentative Final Monograph,” 53 FR

### III. CONCLUSION

For the reasons described in this response, we deny your request that FDA review and establish a regulatory classification for tooth-whitening preparations that act by chemical means to lighten tooth color. You did not provide information in your citizen petition that would allow us to classify the group of chemical, peroxide-containing tooth whitener products as drugs. Further information, including which ingredients and which concentrations of peroxide-containing tooth whiteners may affect the structure or function of the body and/or the intended uses of such products would be required before we could evaluate whether such a regulatory classification would be appropriate. In addition, to help improve reporting of any potential safety concerns associated with these products we encourage the ADA to publicize information about FDA's adverse reporting system to its members.

Sincerely,



Janet Woodcock, M.D.  
Director  
Center for Drug Evaluation and Research

Watch this video by Dr. Josh Brower:

[https://youtu.be/jOx\\_Er7i3ts](https://youtu.be/jOx_Er7i3ts)

We encourage you to go to social media, search your state and key words "teeth whitening" ... Most likely you will find many legitimate businesses, salons and specialists who have conducted successful whitening services for years. There's plenty of business for ALL OF US!

Finding fellow entrepreneurs in your state will help inform you on what to avoid, not because you are doing anything wrong, but to be aware of the proper state practices, etc.

These are the guidelines that Pristine has put in place: Because there is no way to keep up with every state and ever-changing information. It's up to the potential student to check into what other entrepreneurs are doing in your state and if they have run in to any problems.

Check out this Facebook group "[Cosmetic Teeth Whitening Laws](#)" and do a quick search in your state for more info.

When training with Pristine, you will learn two different methods, one where you administer the gel on to the client's teeth and a self-administered method where they apply the gel themselves and you facilitate. The service

we are providing is a non-invasive, cosmetic procedure. With both of these methods, your hands will NOT be in your client's mouth at all, the whitening gel is administered through non-invasive techniques, an abundance of caution is taken into sanitization, through gloves, disposable retractors, medical grade cleaning and sterilization.

We always fall back on the Supreme Court ruling that says "[Dentists can't control who gets to whiten your teeth](#)".

Here are a few links to individual articles stating that Dentists can't regulate who whitens teeth:

<https://health.wusf.usf.edu/consumer/2015-02-26/dentists-cant-limit-teeth-bleachers-court> <http://campbelllawobserver.com/teeth-whitening-case-a-win-for-non-dentists/>

[http://www.myfloridalicense.com/dbpr/re/documents/FREC Meeting Documents/2016/07JUL/0716FREC Antitrust Info.pdf](http://www.myfloridalicense.com/dbpr/re/documents/FREC%20Meeting%20Documents/2016/07JUL/0716FREC%20AntitrustInfo.pdf)

<https://www.1818legal.com/teeth-whitening-and-the-law-the-battle-over-an-11-billion-industry/>

Legal cases:

Pristine's legal team has been called to court multiple times as potential specialists search for more info before becoming certified. They will call the State Dental Board or DOPL (Dept of practicing Licenses) to check first. (understandable) Each time a case has been brought to court, nothing comes of it and they remain in business. This is the same for other companies offering Teeth Whitening Certification in other states. At one point the Dental Association tried to close down Pristine and the lawyer for the Dental Association actually apologized for even contacting Pristine because it WAS legal and there were no grounds for termination.

No one has ever been terminated or in trouble with our academy.

Many Pristine whitening specialists have Dental Hygienist clients who say the same thing, when you try to contact someone... it sparks unwanted attention because the Dental board is so finicky.

Here are some tips and the problems you might run into: If you contact state licensing, they will tell you to contact, cosmetology board, then they will send you to state Dental Board. We know this from personal experience and many hours of phone tag. The Dental Board is made up of the educators for the Dentists. Their job is to advocate for Dentists so if there is an entity in

competition with you and profiting off of something that you think you can regulate, they won't want to be in support of your business, which is why you see that Dental boards aren't in favor of anyone but Dentist offices whitening.

Testimonial from Certified Teeth Whitening Specialist:

"I have a close family member who is a very well-known and established Dentist in my area. I was telling him when I was getting certified to whiten and he said "I would be ALL in favor of that because in order to offer whitening to my patients, the cost is so high because I have to pay my hygienists for training and their time, plus their personal insurance in some cases. I'd much rather send someone the business who has gone through the certification and training". That is most Dentist's stance, it's the dental board that wouldn't be in favor, which explains the conflicting information out there."

-Lauren, owner of [Gussied Academy](#)

Insurance companies like State Farm, and other well-known companies, are insuring certified teeth whiteners in every state. They are not going to violate a state law, if so, that's a huge liability for them.

When starting ANY business, there are always options to weigh and risks to consider. If you have taken the time to look into your state's guidelines and feel confident to join our Academy, we would be THRILLED to have you as part of our community!

We are extremely grateful for our own teeth whitening businesses. The opportunity to be a female owned business, as busy women, who can contribute financially without sacrificing long hours in exchange for great pay.