

**From:** [noreply@pharmacy.ohio.gov](mailto:noreply@pharmacy.ohio.gov)  
**To:** [MMC Petitions](#)  
**Subject:** Add Form/Method Petition for Peter W. Nischt  
**Date:** Tuesday, December 1, 2020 9:23:45 AM

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This message was sent from the Add Form/Method page on [medicalmarijuana.ohio.gov](http://medicalmarijuana.ohio.gov).

#### Section A: Petitioner's Information

Name: Peter W. Nischt  
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#### Section B: Form or Method of Administration You Are Requesting Be Added

Edible for Buccal or Sublingual Administration Buccal or sublingual administration is a topical route of administration by which drugs held or applied in the buccal area (in the cheek) or sublingually (under the tongue) diffuse through the oral mucosa (tissues which line the mouth) and enter directly into the bloodstream. Medical cannabis preparations can be administered in this way. These preparations could take the form of sublingual fast-dissolving strips, sprays, oral salves, tablets, lozenges, lollipops, or pouches.

#### Section C: Anticipated Benefits from the Proposed Form or Method of Administration

When administered in the buccal or sublingual area, cannabinoid bioavailability is estimated to be around 13%, versus traditional edibles, which typically have a bioavailability of around 6%. The increased bioavailability of buccal/sublingual administration versus a traditional edible is due to the fact that cannabinoids absorbed through the oral mucosa bypass breakdown in the stomach and first-pass metabolism in the liver. This increased bioavailability is coupled with a quicker onset time relative to traditional edibles for oral administration. Based upon these facts, buccal or sublingual administration offers a quicker, more efficient way to administer medicine than traditional cannabis-infused edibles for patients who may be seeking these benefits without wanting to vaporize their medicine. Given the pulmonary risks associated with COVID-19, buccal or sublingual administration offers patients looking for a quicker, more efficient way to administer their medicine with a better option than traditional cannabis-infused edibles. Additionally, due to qualifying conditions, some patients may not be able to keep food down and others may not be able to ingest the large amounts of sugar that traditional edibles contain. So, an edible for buccal or sublingual administration offers a fast-acting, more efficient alternative to patients who can't vape or who can't use the more traditional forms of edibles available on the market. See: Karschner, E.L., Darwin, W.D., Goodwin, R.S., Wright, S., and Huestis, M.A. (2011). Plasma cannabinoid pharmacokinetics following controlled oral delta9-tetrahydrocannabinol and oromucosal cannabis extract administration. *Clin. Chem.* 57, 66–75.

#### Section D: Reported Adverse Effects of Proposed Form or Method of Administration

There are no known adverse effects of this proposed form or method of administration outside of those generally anticipated from medical cannabis use.

#### Section E: Acceptance by the Medical Community

The efficacy of the sublingual and buccal administration of various drugs is well documented.

Opioids, benzodiazepines, nitroglycerin, loratidine (Claritin), mirtazipine, rizatriptan and others can be administered sublingually or buccally to treat everything from pain, depression, anxiety, allergies, migraines, angina, and other conditions. Specific to cannabis, GW Pharmaceuticals has produced three cannabis-derived preparations of cannabinoids called TETRANABINEX, which is high in THC, NABIDIOLEX, which is high in CBD, and SATIVEX, which is a combination of Tetranabinex and Nabidiolex. These preparations are administered sublingually to avoid first-pass metabolism by the liver. Sativex is approved in Canada for the treatment of neuropathic pain associated with multiple sclerosis, and in three European countries for a number of indications, with further clinical trials of the efficacy of this extract for analgesia, spasticity and other conditions ongoing. While sublingual/buccal administration of different medications is well known and popular around the world, the drugs referenced above represent a major pharmaceutical company being approved by various regulatory agencies specifically to sell cannabinoid preparations for sublingual/buccal administration. See: Huestis, M.A. (2007) Human Cannabinoid Pharmacokinetics. *Chem Biodivers*. 2007 Aug; 4(8): 1770–1804.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2689518/> See: GW Pharmaceuticals Sativex website - <https://www.gwpharm.com/healthcare-professionals/sativex#>

#### Section F: Expert Support