

From: [Maerten-Moore, Sharon](#)
To: [Economus, Paula](#)
Subject: FW: new form/method petition
Date: Wednesday, December 9, 2020 4:29:33 PM
Attachments: [image004.png](#)
[image003.png](#)

Paula – Can you add this to the new forms/methods petition? Thanks!



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From: Pete Nischt <Pete.Nischt@klutchcannabis.com>
Sent: Wednesday, December 9, 2020 4:19 PM
To: Maerten-Moore, Sharon <Sharon.Maerten-Moore@pharmacy.ohio.gov>
Subject: RE: new form/method petition

Hi, Sharon.

Thank you for this follow-up. I reached out to Stephen about this, as the phrasing of the question in the petition seemed like it pertained only to specific diseases or conditions: "Please provide evidence supporting the use of medical marijuana to treat or alleviate the disease or condition, including but not limited to journal articles, peer-reviewed studies and other types of medical or scientific documentation." He had told me to leave it blank and that someone may be in touch for more information.

Based upon the language you've referenced, I am wondering if general scientific evidence/studies/journal articles/real world applications pertaining to the buccal/sublingual administration of cannabinoids would suffice (the question in the form referenced journal articles, peer-reviewed studies, etc. as satisfying this requirement). If that is the case, I think the studies I referenced in prior questions should be responsive. However, I have supplied more below with links. Collectively, these studies not only demonstrate the bioavailability of cannabinoid preparations administered buccally/sublingually, but also demonstrate the efficacy of such administrations when treating chronic pain and other symptoms relating to qualifying conditions.

I also wanted to note that GW Pharmaceuticals (the company that makes Epidiolex) also markets a product called Sativex (Nabiximols) in the UK, EU, and Canada that is a THC/CBD preparation administered via an oral mucosal spray. Sativex provides a good example of the efficacy of a buccal/sublingual/oromucosal administered cannabinoid preparation, as it has been proven effective

and approved in other countries for treating spasticity, pain, and urinary dysfunction related to multiple sclerosis, as well as pain related to cancer and chemotherapy where conventional pain medications have proven ineffective.

Please let me know if the studies below satisfy the requirement, or if you have any further questions.

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7. Guy G. W., Robson P. J. (2004b). A phase I, open label, four-way crossover study to compare the pharmacokinetic profiles of a single dose of 20 mg of a Cannabis Based Medicine Extract (CBME) Administered on 3 different areas of the buccal mucosa and to investigate the pharmacokinetics of CBME per Oral in Healthy Male and Female Volunteers (GWPK0112). *J. Cannabis Ther.* 3, 79–120. 10.1300/J175v03n04_01 - http://www.cannabis-med.org/data/pdf/2003-03-04-4_0.pdf

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Sincerely,

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From: Sharon.Maerten-Moore@pharmacy.ohio.gov <Sharon.Maerten-Moore@pharmacy.ohio.gov>
Sent: Wednesday, December 9, 2020 2:10 PM
To: Pete Nischt <Pete.Nischt@klutchcannabis.com>
Subject: new form/method petition

Pete,

The Board is in receipt of the petition to add a new form or method of administration of medical marijuana that you submitted on December 1, 2020. However, an initial review indicates that the petition does not comply with OAC 3796:8-2-02(C)(2) in that it does not contain “[a]n opinion from at least one scientific expert supporting the addition of the form or method of administration. The scientific expert must have specialized knowledge acquired through experience, education or observation, or study that is not possessed by the average layperson[.]” (Section F of the submission form.)

Please forward a response to Section F and any additional information related to the petition that you would like the Board to consider.

Thank you,

Sharon



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