From:	noreply@pharmacy.ohio.gov
To:	MMC Petitions
Subject:	Add Form/Method Petition for Ander Wensberg
Date:	Thursday, May 20, 2021 4:34:14 PM
Attachments:	Gefion MSDS Plain Plus Xtracts Base-final GCI-040919[1].pdf Energy-GF-011421.pdf

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This message was sent from the Add Form/Method page on medicalmarijuana.ohio.gov.

Section A: Petitioner's Information
Name: Ander Wensberg
Address: 126 RIVERVIEW AVE, MIDDLETOWN, RI, 028425323
Phone: (203) 644-2976
Email: ander@yellowlabsinc.com

Section B: Form or Method of Administration You Are Requesting Be Added
The product types are: THC Mist Sublingual Mouth Spray High THC Transdermal Lotion The base ingredient pre-infusion is licensed by Yellow Labs from Synaptic™, a proprietary, patent-pending technology that uses a complex emulsion of lipophilic (lipids) and hydrophilic (water loving) compounds in proprietary emulsions. The emulsions have the capability of using the lipid components to penetrate the lining of the mouth and under the tongue, and then use the hydrophilic components to penetrate deeply in the dermis. The spray also has induces a temporary protection from saliva to allow the absorption to fully take place. Once in the dermis, the emulsion releases vasodilators, in addition to the THC and/or CBD. The vasodilators increase the blood flow through that specific area of skin. This blood flow flushes the THC and CBD into the blood stream for a very efficient and rapid absorption.

Section C: Anticipated Benefits from the Proposed Form or Method of Administration
Yellow Labs - Powered by Synaptic™ Yellow Labs Sublingual Mouth Spray and Transdermal Lotion provide fast onset, under one minute, and long duration up to 3 to 4 hours. Synaptic™ is a more body friendly delivery system for high potency THC performance. - Body friendly = THC through the skin - Not through your Lungs - Not through your Stomach and Liver - No smoke, no vape, no calories - Recover from physical exertion and achieve more fulfilling physical activity - Achieve body-friendly psychoactivity with the utmost discretion - Achieve mindful psychoactivity and lose weight - Heightened libido and virility through body-friendly pyschoactivity THC Mist Sublingual Mouth Spray Spray variants deliver beneficial botanical entourage effects, as follows: - Energy, Relax, Recovery, Curb Appetite, Her Libido, His Virility High THC Transdermal Lotion The most frequent outcomes we find from our transdermal lotion include but are not limited to calm, less or no pain, focus, energy, creativity and appetite. This is accompanied by a full body calm feeling. Highly effective for pain and anxiety. The patient is left feeling relief in 3 to 5 minutes and wellness as described for 3 to 4 hours. Effective with Distillate or Full Spectrum Cannabis oil. True to strain specific broad spectrum experience through a transdermal lotion.

Section D: Reported Adverse Effects of Proposed Form or Method of Administration
There are no known adverse effects. Transdermal lotion is a topical, not to be ingested. The Synaptic™ Transdermal and Sublingual base ingredients which are sold in the United States consist of excipients which are generally recognized as safe by the Food and Drug

Administration.

Section E: Acceptance by the Medical Community

Evidence of Claims Because of Food and Drug Administration restrictions on generating data for cannabis products, Synaptic™ has an ongoing initiative with Health Canada to generate bioavailability certification data for Synaptic™ sublingual and transdermal technology. This initiative has been delayed by the COVID-19 crisis. Once completed, this data will be made available, likely in Q4 2021. FDA/GMP/Safety The Synaptic™ Transdermal and Sublingual base ingredients which are sold in the United States consist of excipients which are generally recognized as safe by the Food and Drug Administration. Because there are no active ingredients in the bases, the bases by themselves are not intended to treat, cure or prevent disease. This means that the bases can be shipped in interstate commerce for blending with cannabis by licensed distributors, dispensaries and co-packers where cannabis is legal. The bases also comply with local state regulations. Synaptic™ is made by Gefion Canada Inc., a specialty pharmaceutical company with dispensary and prescription drug product businesses in the US and Canada. Statement on Patent Pending The Synaptic™ delivery system patent was filed in October of 2018. It is under a confidentiality agreement with the US Patent Office and fully protected during the review period. Since filing it has passed the international phase and is now in a national phase review. Overall patent approval times can vary. The company and its affiliates own 200 completed patents at present in a variety of areas in medical and pharmaceutical science.

Section F: Expert Support

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