

Lockington, Elliott (SPAC/PSPC)

From: Taipalus, Madison (SPAC/PSPC)
Sent: March 26, 2020 1:57 PM
To: Cameron Scott; Logan, Tim (IC)
Cc: Phillips, Kylie (HC/SC)
Subject: RE: Thanks for the call today

Thanks for the info! Adding our counterpart at Health Canada.

Madison Taipalus

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From: Cameron Scott [mailto:cameronscott@apollomanagement.ca]
Sent: March 26, 2020 13:51
To: Logan, Tim (IC) <tim.logan@canada.ca>
Cc: Taipalus, Madison (SPAC/PSPC) <madison.taipalus@canada.ca>
Subject: Re: Thanks for the call today

No problem Tim,

I have a little understanding of what it can be like in Ministerial Offices and I know that if you are sending emails at 9pm it was a very long and busy day.

As for the incensing: We are finalizing our QA documents today to conform to the NHPD requirements for importers and expect that we will be submitting the SL with QAR today...Although, in a nearly comedic turn of events my Operations Lead who is helping me with creating some of the required forms specific to NHP's had his computer go down on him and we are unable to quickly trouble shoot due to the lack of availability of open computer / electronics stores. We are transitioning him over to an old desktop right now but this will be a bit of a process as we only use Mac's at our office now....

As for relevant information that may be of assistance in processing or advising us regarding our application/license. The product that we are attempting to import would be triaged as a Level 2 item on the *Health Canada Application and Notification Form for Exceptional Release of Disinfectant and Sanitizing Products*.

We believe that our product absolutely qualifies for immediate release pursuant to the information given at the top of the form as we have the CE Certificate of Compliance as well as a copy of our Vendors FDA Registration. This product would be permitted for use in the USA and the EU(MRA Partner).

We have also cross referenced the ingredients in our Formula with NHPD Ingredient Monographs and have ensured that our Label and MSDS sheets contain all of the appropriate warnings and are conformant to Canadian Bilingual Labelling requirements. We have also obtained the testing reports for the current batch of

product to confirm that there are no trace contaminants or prohibited ingredients. We have also obtained numerous Manufacturing Audit / Assessment Reports of the vendor from TUV Rheinland (Quality Assurance Company) and we have had one of our International Partners in Guangzhou visit the factory to confirm capacity and ability of the vendor.

Let me know if this information helps at all. We will be submitting all of our documents with SL and QAR but I will also gladly share anything needed if we are able to confirm that we can begin production and shipping while we are waiting for our SL/QAR to be approved.

I am unsure of the intent or purpose of the Exceptional Release Form, or if it will permit us to bring our product here without the SL but given the wording in the document it seems to imply that we should be able to begin import immediately given the product conformance but I have not received a very clear answer on that, except from the CBSA who said that they feel the same as I do and that I probably meet the requirements but that they couldn't guarantee anything on the Health Canada side.

Honestly, any advise or direction would be great. Like I said on our call, we have pre-vetted vendors on our end who can produce quality, consistent, constant, high volume quantities of Niosh N95 Respirators, Cleaning Wipes and Hand Sanitizer and we can help manage a supply chain on our end where we can be processing order quantities in the 100,000's pcs weekly and just keep it coming in automatically. We just need the go ahead and a Purchase or Sales Order. We even made contact with the largest pharmaceutical manufacturer in Bangladesh to get things lined up there just in case it was something that was needed to assist in the response.

Sorry, for writing an essay and rambling a bit..its been a long week of 2am shutdowns and 7am startups to make sure everything is set to go if needed. There is a lot of information involved on our end and I could bore you for weeks on how the logistics and distribution will work.

Talk to you soon,