## McKenna, Neil

From:	Church, Leslie (SPAC/PSPC) <leslie.church@canada.ca></leslie.church@canada.ca>
Sent:	Sunday, March 29, 2020 11:08 AM
То:	Gordon2, Travis (HC/SC)
Cc:	Stickney, Matt; Kim, Sabrina; Saini, Sabina (HC/SC); Murdock, Kelly (SPAC/PSPC)
Subject:	Re: Quick q from PM re mask orders

Just got some clearer guidance which is helpful:

The manufacturing facility must hold a medical devices establishment licence from Health Canada. The requirements for masks themselves vary by their intention. For example, N95 masks are certified by the National Institute for Occupational Health and Safety, but it is possible to use non-NIOSH masks as well.

See the link from Health Canada which is helpful in explaining how the process works for masks for covid-19

https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/masks-respirators-covid19.html

Resellers are not authorized, but HC needs to give a licence to their manufacturer, which has happened in all of our orders for masks.

Sent from my iPhone

On Mar 29, 2020, at 10:50 AM, Gordon2, Travis (HC/SC) <travis.gordon2@canada.ca> wrote:

And just to add on the HC side: for medical devices, if the manufacturer can show us an FDA auth, we fast track their licence review as we have a Mutual Recognition Agreement with them.

Notwithstanding FDA approval, all COVID-19 medical products are being reviewed on a priority basis. The timelines are all severely crunched and much, much shorter than ordinary.

TG

Travis Gordon Senior Policy Advisor 613-410-2938

------ Original message ------From: "Church, Leslie (SPAC/PSPC)" <leslie.church@canada.ca>

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Date: 2020-03-29 10:36 AM (GMT-05:00) To: "Stickney, Matt" </br/>Matt.Stickney@pmo-cpm.gc.ca> Cc: "Kim, Sabrina" </br/>Sabrina.Kim@pmo-cpm.gc.ca>, "Saini, Sabina (HC/SC)" <sabina.saini@canada.ca>, "Gordon2, Travis (HC/SC)" </travis.gordon2@canada.ca>, "Murdock, Kelly (SPAC/PSPC)" <kelly.murdock@canada.ca> Subject: Re: Quick q from PM re mask orders

Adding this HC doc which describes the licensing process for suppliers, including distributors. So yes, this is an important part of getting medical grade, FDA approved goods.