

April 1, 2020

Re: Importation of Face Masks & Respirators

Dear Valued Client,

With the ongoing COVID-19 situation, some importers have begun to ask questions regarding requirements for importing face masks and respirators. This advisory intends to be a resource in providing helpful information regarding this topic.

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PHONE

Surgical masks (with or without liquid barrier protection) and N95 respirators that are intended to be sold and distributed among healthcare facilities are regulated by FDA as medical devices. Some of the data elements required are FDA registration numbers of the foreign exporter, manufacturer, device initial importer, commodity codes, and device listing numbers.

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Another category of N95 respirators and other face masks are used by industrial fields and construction. These masks do not require FDA reporting at the time of entry. The key indicator is knowing whether the masks make claims to prevent disease or illness.

ADDRESS

FDA is currently allowing entry of medically intended respirators and surgical masks (with and without liquid barrier protection) with minimum reporting requirements. Their reporting requirements are dependent upon the type of mask or respirator, and whether the article is approved under the Emergency Use Authorization (EUA) letter. This designation allows the importer to report a specific intended use code and the appropriate FDA commodity or FDA product code.

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Additionally, CBP is asking for prior notice of any pandemic relief materials. Good practice would be to notify CBP at the planned port of entry of any masks or respirators (whether for medical or non-medical use) so please notify your JAS representative for us to advise CBP prior to importing.

For indicators to distinguish between the various masks' types, please refer to link on FDA's website by clicking [HERE](#). For specific questions, FDA is accepting questions by emailing COVID19FDAIMPORTINQUIRIES@fda.hhs.gov.

Please direct any additional questions that you may have to your local JAS Representative.

Sincerely,

JAS Forwarding USA Inc.