# FDA Increase Supplies in Response to COVID-19

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PRACTICES FDA Regulatory and Compliance, Healthcare and Life Sciences, Healthcare Transactions and Regulatory, Life Sciences

***FDA Takes Action to Increase U.S. Supplies in Response to COVID-19***. The FDA took action to increase U.S. supplies to support the U.S. response to COVID-19 by providing instructions to manufacturers importing personal protective equipment and other devices. The FDA is engaging the import trade community during this pandemic to facilitate the entry of needed products, including PPE, into the U.S. The FDA provided the below instructions to importers to clarify the types of PPE that can be imported without engaging with FDA:

1. **Non-FDA-regulated general purpose personal protective equipment (masks, respirators, gloves, etc.)**. Personal protective equipment for general purpose or industrial use (that is, products that are not intended for use to prevent disease or illness) are not regulated by the FDA and entry information should not be transmitted to FDA. At the time of entry for these products, importers should transmit entry information to US Customs and Border Protection using an appropriate HTS code with no FD Flag or using an appropriate HTS code with an FD1 flag and a 'disclaim' for FDA.

2. **Products authorized for emergency use pursuant to an Emergency Use Authorization (EUA).** Entry information should be submitted to the FDA, however reduced FDA information is required for review. At the time of entry, importers should transmit an Intended Use Code of 940.000: Compassionate Use/Emergency Use, and an appropriate FDA product code. A list of products and the appropriate product codes that are currently authorized by an EUA, include: Diagnostic tests – QPK, OTG, QKO, QJR and Masks/Respirators – NZJ.

3. **Products regulated by FDA as a device, not authorized by an EUA, but where an enforcement discretion policy has been published in guidance.** When importing such devices, entry information should be submitted to FDA. At the time of entry, importers should transmit an Intended Use Code of 081.006: Enforcement discretion per final guidance, and an appropriate FDA product code.

For further information regarding entry submission requirements, see the FDA Supplemental Guidance for ACE.

Haynes Boone has a COVID-19 task force in place and continues to monitor the global impact of COVID-19 on various industries. For questions on the FDA's evolving COVID-19 policies or food safety during the COVID-19 crisis, please contact Suzie Trigg or any member of the Healthcare and Life Sciences Group.