US IN BRIEF – SHARING CURRENT DEVELOPMENTS WITH THE REST OF THE WORLD

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THE FDA IS RELAXING STANDARDS – THIS MAY BE GOOD FOR U.S. CONSUMERS, BUT IS DEFINITELY GREAT FOR FOREIGN COMPANIES

There are many aspects to the U.S. FDA's response to the COVID-19 pandemic. All of them involve reducing barriers and speeding introduction of critical drugs and medical devices to the U.S. For years to come we can debate whether these actions are a net positive or negative for consumers; but today we can absolutely say they are a HUGE positive for companies in the healthcare industry, no matter where in the world they are located.

As an example, the FDA is relaxing traditional clinical trial requirements and is lowering standards. An extreme example of this is that a drug can now be imported even though it is made by a company at a facility on the FDA's 'Import Watch Alert" list *(i.e., the banned list)*. And nearly every day the FDA publishes a list of new drugs that are experiencing shortages in the US – https://www.accessdata.fda.gov/scripts/drugshortages . If you are manufacturing a drug(s) but not yet exporting to the U.S., contact us, especially if it is on the shortages list. Times are changing and the FDA's barriers to entry for your product(s) may now be easier than ever to overcome

As another indication of how rapidly FDA regulations and requirements are changing, here's a list of FDA Guidances, Updates and documents relating to COVID-19 issued in the last week alone:

- March 31, 2020 - Daily Roundup including information about diagnostics and new warning letters
- March 30, 2020 - Daily Roundup including new Emergency Use Authorizations (EUAs) and enforcement policies to help expand the availability and capability of sterilizers, disinfectant devices and air purifiers, and expand the availability of gowns and other protective apparel
- March 30, 2020 - FDA Continues to Accelerate Development of Novel Therapies for COVID-19 - *Also see: Coronavirus Treatment Acceleration Program (CTAP)*
- March 30, 2020: FDA expedites review of diagnostic tests to combat COVID-19
- March 29, 2020 - HHS accepts donations of medicine to Strategic National Stockpile as possible treatments for COVID-19 patients - FDA issues EUA for donated hydroxychloroquine sulfate, chloroquine phosphate
- March 28, 2020 - FDA takes further steps to help mitigate supply interruptions of food and medical products
- March 27, 2020 - Daily Roundup on topics including diagnostics, guidance for manufacturers to make sure that they continue to notify FDA of any permanent discontinuance or interruption of drug and biological product manufacturing in a timely manner, and a letter to stakeholders about the imminent threat to the health of consumers who may take chloroquine phosphate products used to treat disease in aquarium fish, thinking the products are interchangeable with FDA-approved drugs (used to treat malaria and certain other conditions in humans) that are being studied as a COVID-19 treatment for humans.

- March 27, 2020 - Consumer Update: Food Safety and Availability During the Coronavirus Pandemic
- March 27, 2020 - Consumer Update: Safely Using Hand Sanitizer
- March 27, 2020 - FDA takes action to help increase U.S. supply of ventilators and respirators for protection of health care workers, patients
- March 26, 2020 - Daily Roundup, including questions and answers related to consumer use of hand sanitizer during the COVID-19 public health emergency
- March 25, 2020 - Daily Roundup, including guidances for industry, and an EUA (PDF) for ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators (collectively referred to as "ventilators"), ventilator tubing connectors, and ventilator accessories.

The FDA is also working on 'public-private partnership' agreements with other government agencies to facilitate 3D manufacturing techniques on open source medical devices:

- **FAQs on 3D Printing of Medical Devices, Accessories, Components, and Parts During the COVID-19 Pandemic** - Manufacturers and facilities may email COVIDManufacturing@fda.hhs.gov with questions.
- America Makes COVID-19 Health Care Needs and AM Capabilities Repository
- VA VHA Innovation Ecosystem: 3D Printing for COVID-19
- NIH 3D Print Exchange: COVID-19 Supply Chain Response

Here are some of the other actions the FDA has taken in the past two weeks:

FDA Sets up 24/7 Hotline (1-888-INFO-FDA [1-888-463-6332] to Help Labs with Diagnostic Test Issues regarding difficulties obtaining supplies for collecting patient samples for COVID-19 testing.

22 diagnostic Emergency Use Authorizations (EUAs) issued to date
More than 160 test developers who have said they will be submitting applications to make tests that detect the coronavirus. Under the laboratory developed test policy (PDF), the FDA has been notified by more than 65 laboratories.

High Complexity Molecular-Based Laboratory Developed Tests
FDA concluded (PDF) on 31 March that molecular-based laboratory developed tests (LDTs) authorized for use by the singular developing laboratory are appropriate to protect the public health or safety, and can be used in the single laboratory that developed the test.

Reissued Respirator Emergency Use Authorizations

- March 29, 2020: FDA reissued an EUA for the Battelle Decontamination System for use in decontaminating compatible N95 respirators for reuse by health care personnel during the COVID-19 pandemic (initially issued March 28, 2020).
- March 28, 2020: FDA also reissued both the NIOSH-approved Respirator EUA (PDF) and the non-NIOSH approved Respirator EUA (PDF) to include N95 respirators that have been decontaminated with Battelle's new system under these EUA authorizations.

Related links:

- FAQs on Diagnostic Testing for SARS-CoV-2 (frequently updated)
- Emergency Use Authorizations (Devices)
- Information for Laboratories Implementing IVD Tests Under EUA
- FDA Issues New Policy to Help Expedite Availability of Diagnostics *(February 29, 2020*

IN CONCLUSION

For now and the next year, if you have a product that may help the U.S. healthcare system – medical device, diagnostic or drug – most of your assumptions about how the FDA works, what its requirements are, and how long it takes to get approvals for selling in the US are wrong. We are recommending to our clients they think of the U.S. as a brand new market, and re-consider as soon as possible taking steps to bring their products to the U.S.