PUBLICATION

Understanding FDA Terminology in the COVID-19 Pandemic

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Over the last several weeks it has become apparent that there is a great deal of confusion about FDA regulated products including drugs, diagnostics, medical devices (including personal protective equipment) and prevention strategies of various types. This confusion arises because most people, including the press and public, and even some in the very highest offices within government, do not understand the hierarchy of the FDA's well-established regulatory process.

Start with a fundamental fact: There are currently NO drugs or diagnostics which are "Approved" for use with COVID-19. Not one. What, then, has happened?

- **Approved:** FDA reserves the terminology "Approved" for drugs and devices which are able to be marketed (usually by prescription) only after a rigorous premarket review of data, importantly including controlled clinical studies, identification of needed warnings and other labeling. Only when this process is completed does FDA permit the terminology "Approved" to be applied to a New Drug.

- **Investigational New Drug (IND):** During the clinical investigation phase, use of a New Drug candidate is confined to specific investigators, following a pre-approved protocol. At this point such a product is considered to be an Investigational New Drug ("IND"). But even the authority to pursue a clinical investigation for an IND requires prior review and acceptance by FDA.

- **Investigational Device Exemption (IDE):** There is a similar hierarchy for medical devices, where "Approved" is reserved for those devices at the top tier which have had extensive submissions of data assembled under authority of an Investigational Device Exemption ("IDE") and reviewed prior to marketing. Devices such as diagnostics are typically not eligible for "Approved" status because the rigors of the pre-market submissions for Class II devices address performance and safety issues do not involve the extent of review of devices requiring pre-market approval. When FDA has accepted the submission of a Class II device (typically pursuant to Section 510(k) of the Federal Food Drug and Cosmetic Act) it does not regard completion of the process as an "Approval", even though completion of the FDA acceptance process is required.

So, what has happened in the COVID-19 context?

While the press and administration are talking about various new 'approvals' for diagnostics and even new drug therapies, what factually is happening is that FDA is aggressively using Emergency Use Authorizations ("EUA") as a tool, not carte blanche to all comers, but restricted to qualified and credentialed entities based on prior notice and acceptance by FDA.

- **Emergency Use Authorizations (EUA):** The EUA notification includes submission of scientific rationale and other information. A very usual requirement is that the product subject to a EUA explicitly disclose limitations which are understood to exist, the possibility of false positive results in a diagnostic test as one typical illustration.

Utilizing the EUA mechanism, FDA, at this writing has authorized use of ventilators, personal protective equipment and approximately a dozen different diagnostic tests for COVID-19 testing which would normally

require full 510(k) submissions. In the drug and plasma area, several EUA-IND investigations have been authorized addressing both treatment and prophylaxis.

The EUA's are being issued selectively to various product categories. Certainly, there is reason for optimism that some or many will prove to be acceptable at the appropriate approval level, it is predictable that some will not. In that context, as more is known, it is important to understand and be prepared for the fact that as there is more information and understanding, an EUA can disappear almost as quickly as it appeared.

Beware of both the Scammer and the Uninformed, even though Well-Intentioned

Times of crisis can bring out the best of humanity – but it can also bring out the worst, and a lot in between. At this time, any business proposition which expressly or by implication purports to identify, cure, treat, protect from or prevent COVID-19 must be considered with great skepticism unless it is wrapped around FDA's EUA processes. Any individual or business claiming "FDA Approved" for any COVID-19 related product or service at this time, has, at the very least, overstated the facts.

The seriousness of the issue has caused both FDA and FTC enforcement to bear down on false or deceptive advertising or promotion of regulated products offering unproven benefits in connection with COVID-19. Any COVID-19 related consumer or professional product bearing labeling that either claims to be "FDA Approved" or which bears the FDA logo would be subject to immediate regulatory action.

Finally, there has been a great deal of misunderstanding of some of the specifics of FDA's actions. As an example, the grant of an EUA to a specific company to address a specific situation is NOT equivalent to deregulation of the category. FDA continues to require those operating under an EUA to be in compliance with quality regulations, establishment registration, record-keeping and other details of compliance.

For more information about how this issue may affect your business or related matters, please contact any member of Baker Donelson's FDA Group. For more information and general guidance on how to address legal issues related to COVID-19, please visit the Coronavirus (COVID-19): What You Need to Know information page on our website.