November 25, 2020

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm. 1061, HFA-305
Rockville, MD 20852

Dear Persons:

RE: **Time Limits for EUAs**

The undersigned submits this petition under the Federal Food, Drug, and Cosmetic Act and the applicable Amendments; the applicable portions of the Code of Federal Regulations, Title 21; the FDA's January 2017 Guidance on Emergency Use Authorization, EUA, of Medical Products and/or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR 5.10 to request the Commissioner of Food and Drugs:

Set time limits for EUAs for regulated Medical Products within FDA's jurisdiction.

This is the ACTION REQUESTED in this petition.

The STATEMENT OF GROUNDS for requesting the aforementioned action are as follows:

1-FDA, via its internal records, has a rich history of the time required for the development of regulated Medical Products:

This robust data base, i.e., rich history of development times, should be applied, within reason, to setting a time interval for a particular EUA. The time interval may be set by 'class', e.g., within certain types of coronavirus tests. Various regulated products, e.g., drugs and devices, will have correspondingly different time intervals, crafted to their own unique development timelines.

2-By applying a reasonable timeline to EUAs on a product specific basis, FDA will incent the regulated industry to do its mission of timely health product development and submission for final approval/clearance of its EUA'd product.

Allowing the regulated industry to 'rest on its EUA' for marketing and revenue purposes is not in keeping with FDA's Watchdog Role [see: https://www.fda.gov/drugs/drug-information-consumers/cder-consumer-watchdog-safe-and-effective-drugs]. While this 'Watchdog Role' is currently articulated for drug products, the Petitioner sees no reason why other regulated medical products, originating from other healthcare product industries, should be treated differently than drug products. The benefit/risk of a medical

test deserves the same type of "Gold Standard" review and evaluation by the FDA as does a drug or device.

3-It is more likely than not that FDA's enforcement tasks will lessen with the application of the aforementioned timelines.

Illegal and fraudulent Medical Products, sourced from unsophisticated and fringe providers, [see: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-warning-letters-companies-inappropriately-marketing-antibody], may be less likely to enter the EUA marketplace. If there is a timeline that is required, these fraudulent actors may not seek market entry. This would be a risk reduction for the American public, consistent with FDA's role.

4-FDA has successfully implemented timelines, in conjunction with the regulated industry.

The Prescription Drug User Fee Act, PDUFA, for drugs and the Q-submission Guidance for Devices [see: https://www.fda.gov/media/114034/download] have been successfully implemented by FDA since the mid-1990s and 2019, respectively. Thus, both FDA and the regulated industries have had experience in interfacing over and complying with timelines.

ENVIRONMENTAL IMPACT: A categorical exclusion is requested under 21 CFR 25.34 for this petition.

CERTIFICATION: The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.*

Sincerely,

(Dr.) S. Albert Edwards, PharmD, RAC, FRAPS

*The petitioner acknowledges that the usual, initial industry reaction to any, new imposed control, e.g., a timeline, is negative. However, based on the Petitioner's three years of FDA review experience and 25 years of food additive & prescription drug experience, the industry will usually find a way to productively use a timeline to their and their stockholders' collective benefit.