FULL SPECTRUM OMEGA, INC.

A PHYTOCANNABINOID LIFE SCIENCE CORPORATION

FDA's Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds Public Hearing

May 31, 2019

Corporate Overview

- FULL SPECTRUM OMEGA, Inc. is a privately held phytocannabinoid company based in Los Angeles, CA focused on development of FDA approved phytocannabinoids to resolve unmet acute and chronic medical conditions improving the quality of life

- FULL SPECTRUM OMEGA products are non-euphoric extracts of full plant phytocannabinoids including cannabidiol (CBD) that contain less than 0.3% delta-9-tetrahydrocannabinol (Δ9-THC) with integral cannabis elements and essential fatty acids

- FULL SPECTRUM OMEGA has signed agreements with the U.S. Federal Government to test its products for multiple applications supporting national security and specific military needs

Challenges of Moving Forward

- Provide access to industry proprietary cannabis-derived products for FDA drug development activities
- How to partner with state sponsored cannabis programs to facilitate the development of cannabis-derived products for FDA approval

Discussion Point #1:

Issue: The FDA requested recommendations on data sources useful in providing safety and efficacy information.

Problem: The legal restriction to the type of product available from current sources (NIDA Mississippi Farm) does not allow for well-controlled studies of medical cannabis products in use in State programs or developed by US industry, even if suitable for most academic research on cannabis and cannabis components.

Solution 1: Many States are establishing patient registries that either are or could be sources of fully documented Real World Data (RWD). FDA and Congress should work on ways to facilitate leveraging of this RWD for Real World Evidence (RWE).

Solution 2: FDA should work with DEA to facilitate approval of interstate transport of low THC products made under State program licenses for the purposes of research required for FDA approval without requiring DEA to approve the source (e.g., use hemp exclusion).

Discussion Point #2:

Issue: The new definition of hemp, when incorporated into the Controlled Substance Act (CSA), will not exempt from schedule I those products only made from plants that meet the % THC limit. The definition confers non-schedule I status to products containing no more than 0.3% THC as made from ANY type of cannabis. Hemp-derived is only a sub-class.

Problem: Lack of understanding of the 2018 Farm Bill definition of hemp. The new hemp definition applies to Cannabis Sativa plants, parts of Cannabis Sativa plants, products of Cannabis Sativa plants, etc. that meet the % limit as defined in the Farm Bill.

Solution: WHO (0.2%) and FDA (0.1%) have already made recommendations for products at low THC levels to be de- or re-scheduled. FDA needs to be proactive in working with the DEA on rescheduling actions to facilitate R&D supporting FDA approval of low THC products. Alignment with 0.3% THC hemp limit should be actively considered.

Discussion Point #3:

Issue: Product development research requires industry control of plant varieties and manufacturing processes. Most historic medical cannabis products are botanical blends of multiple components as determined by plant variety and extraction/manufacturing processes. Those are the majority of products already in use in State programs, with demonstrated, but not fully documented, positive results. Such products are not available from NIDA Drug Supply Program.

Problem: Congressional supporters of medical research are embracing the position that medical products are best derived from generic cannabis/cannabis components supplied by a few bulk suppliers. There is a lack of understanding of industry requirements for product development activities vs. research activities and the viability of FDA approval under FDA drug development guidelines.

Solution: FDA should work to educate Congressional members and staff on the botanical drug approach and press Congress and DEA to provide access to industry developed products for the purposes of product development “research” activities leading to FDA approval.

Discussion Point #4:

Issue: The FDA doesn't want patients to forgo appropriate medical treatments by substituting unapproved products for approved medicines used to prevent, treat, mitigate or cure a particular diseases or conditions.

Problem: The timelines for approval are long and patients will continue to demand access to State program products. Significant amounts of epidemiological data are available on the safety and efficacy of cannabinoids, but additional data is being generated every day that is not available to the FDA.

Solution: While companies go through the FDA regulatory process, the FDA should use an expedited review process and consider making products available to, and data from, patients under the Right to Try and/or Expanded Access/Compassionate Use – **i.e. FDA "Project Facilitate."** The FDA should work with industry to establish protocols, so as to make accommodations to utilize existing epidemiological data to reduce unnecessary study size and duration of clinical trials.

Discussion Point #5:

Issue: The FDA has pathways and guidelines that support seeking approval of cannabis-derived products but can't make access to US-made products legal. The DEA has provisions to make foreign made medical cannabis products legally available for medical R&D supporting FDA approval (import provisions), but no clear provisions for US industry made products.

Problem: The path to FDA approval of U.S. made cannabis-derived products are far more difficult than approval of foreign made products.

Solution: FDA and all federal agencies join in supporting a change to DEA policies and/or legislation that would fulfill their responsibilities to support US based companies as they seek FDA approval for cannabis-derived products.

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THANK YOU