STATEMENT OF GREENWICH BIOSCIENCES
MARCH 13, 2019 AMS LISTENING SESSION

BY EMAIL TO farmbill.hemp@usda.gov

Good afternoon. My name is Deborah Walter and I am the Director for U.S. Federal Policy & Advocacy with Greenwich Biosciences. Greenwich, and its parent company GW Pharmaceuticals, are the world leader in advancing the therapeutic potential of cannabinoids. By leveraging over 20 years of research and development in plant genetics and evaluation of cannabinoids as active pharmaceutical ingredients for the treatment of complex disease states, in June 2018, Greenwich Biosciences became the first and only company to develop an FDA-approved, plant-derived prescription cannabinoid product, EPIDIOLEX®.

We appreciate this opportunity to share our truly unique experience and expertise in an effort to help inform the Division's implementation of an industrial hemp program, and wish to share three observations.

First, several of the USDA's sister agencies, including the FDA, the Drug Enforcement Administration, and the Environmental Protection Administration have experience with botanical raw materials such as the cannabis plant. These agencies are all highly knowledgeable about the cultivation, production, and processing of such materials, and must play a central role in the regulation of legal hemp cultivation and processing. Regulation of finished CBD products is a critical public health and public safety issue. Based on our own clinical trials and other data sources, we know that at higher concentrations, CBD has drug interactions with various widely-used prescription drug products and can result in liver complications. Furthermore, CBD products available on the internet and in retail outlets are often marketed with unproven claims of therapeutic benefit. We therefore urge the USDA to work closely with its sister agencies, most notably the FDA, throughout the regulatory process.

Second, we believe that AMS will play a critical role in guiding the States and tribes on standards around cannabis crop selection and sampling and analytical testing for THC content. Establishing clear sampling and testing protocols will reduce the risk that cannabis crops will exceed the 0.3% THC threshold established in the Farm Bill. Better controls on the crop, which could include selection of traditional certified hemp seed lines, will also diminish the likelihood that derivatives and finished products will exceed the 0.3% limit. Critical components of a sampling and testing protocol that will further the intent of the Farm Bill—that farmers are producing hemp, not marijuana—include sampling only the flowering tops of cannabis plants, where the cannabinoid expression occurs; sampling at or near harvest; and performing analytics testing using high-performance liquid chromatography mass spectrometry methods to determine THC content. Less precise sampling and testing protocols will inevitably lead to large-scale production of low-potency marijuana similar to that which was in common circulation in the United States in the 1960s and 1970s.

The risk of high THC concentration in finished products is our third and final point. Today, many online and retail CBD products contain significant levels of THC, more than enough to cause an intoxicating effect. We urge careful consideration, in consultation with FDA and DEA, on how to assure that the total THC content in hemp derivatives and other finished products remains negligible and non-impairing, as we believe was intended in the Farm Bill.

We at Greenwich Biosciences look forward to serving as a resource to AMS on the hemp marketing program in the months ahead. Thank you.