THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

DEC 16 2014

The Honorable Charles Grassley
Co-Chairman
Senate Caucus on International Narcotics Control
United States Senate
Washington, DC 20510

Dear Mr. Co-Chairman:

Thank you for your letter sharing your concerns about existing regulations that may have the unintended consequence of inhibiting research on medical marijuana and its derivatives, particularly cannabidiol (CBD). Your letter requests that the Department of Justice and the Department of Health and Human Services (HHS) examine and consider revising both existing regulations, as well as the need for the Public Health Service (PHS) review, to ensure that important research related to marijuana, specifically CBD, is not unduly hampered.

The Food and Drug Administration (FDA) understands there is considerable public interest in developing new therapies from marijuana and its constituents and is strongly supportive of appropriate, scientific research into their safety and efficacy. Understanding the challenges for researchers interested in conducting scientific study on these products, FDA has taken a number of steps to facilitate the research process. For example, FDA has placed resources on the web that outline relevant procedures for researchers who wish to conduct research using marijuana and its constituents as a part of the FDA drug approval process. These materials include information about clinical research, including information about the roles that FDA, the Drug Enforcement Administration, and the National Institute on Drug Abuse play in conducting and overseeing clinical research using marijuana. FDA is also centrally tracking all of the requests for information about research with marijuana to help coordinate efforts to facilitate research conducted under the Federal Food, Drug, and Cosmetic Act (FDCA).

In May 1999, HHS created a mechanism to provide research-grade marijuana not only for research funded by the National Institutes of Health (NIH), but also for scientifically valid research that is funded by other sources. A multi-agency PHS committee now reviews non-NIH funded studies and assesses them both for scientific quality and for the likelihood that they will yield scientifically valid data on the safety and efficacy of marijuana and its constituent cannabinoids. Please know that HHS and FDA are working to alleviate any unnecessary burdens that inhibit research and development in this area, and are assessing ways to streamline the review of and provision of marijuana to investigators for non-NIH funded studies.

Drug development grounded in rigorous scientific research represents the best way to ensure the safety and efficacy of new products to market. FDA is committed to supporting the efficient and timely development of safe and effective new medicines and is actively considering options

within our regulatory paradigm to enable more scientific study on marijuana. In the meantime, we are to helping support new research into the use of marijuana and its constituents under the FDCA.

Thank you, again, for contacting me concerning this important matter. I will also provide this response to Senator Dianne Feinstein.

Sincerely,

Sylvia M. Burwell