DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Dianne Feinstein
Co-Chairman
Caucus on International Narcotics Control
United States Senate
Washington, D.C. 20510-1501

OCT 05 2015

Dear Senator Feinstein:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity to testify at the June 24, 2015, hearing before the Senate Caucus on International Narcotics Control (the Caucus) entitled "Cannabidiol: Barriers to Research and Potential Medical Benefits." This letter is a response for the record to questions posed by the Caucus.

If you have further questions, please let us know.

Sincerely,

Dayle Cristinzio
Acting Associate Commissioner
for Legislation

Enclosure

cc: The Honorable Charles Grassley
Chairman

We have restated your questions below in bold, followed by our responses.

1. **I understand that DEA has, or soon will, initiate the scientific and medical evaluation of cannabidiol, commonly known as "the eight factor analysis."**

    a. **When does FDA anticipate that it will complete its part of the evaluation of cannabidiol?**

FDA, with our Federal partners, will work diligently to complete it as soon as possible, but we are unable to provide a timeline.

    b. **If the evaluation finds that cannabidiol should be rescheduled or decontrolled, what impact would that have on the schedule of marijuana, if any, given that cannabidiol is derived from marijuana?**

Final scheduling determinations are made by DEA, and DEA would be best able to answer this question. Should an FDA scientific and medical evaluation of cannabidiol (CBD) lead to any HHS recommendations to DEA about scheduling, they would be specific to cannabidiol, not the Schedule I status of marijuana.

    c. **If the evaluation finds that cannabidiol should be decontrolled, how would it be defined, and how would cannabidiol-based products be regulated – as supplements, drugs, or something else?**

Under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" qualify as drugs. This definition applies regardless of the product's form, the product's active or inactive ingredients, or the way in which the manufacturer chooses to market and label the product.

Based on available evidence, FDA has concluded that CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B)(ii) of the FD&C Act. Under that provision, if a substance (such as CBD) has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are outside the definition of a dietary supplement. There is an exception if the substance was "marketed as" a dietary supplement or as a conventional food before the new drug investigations were authorized; however, based on available evidence, FDA has concluded that this is not the case for CBD. For more information on this provision, including an explanation of the phrase "marketed as," see *Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues*.

FDA's scientific and medical evaluation of CBD, for purposes of a scheduling action under the CSA, will be based on all available public data pertaining to CBD and the characteristics of any material, compound, mixture, or preparation that contains the substance. It is

possible that the available data will be insufficient to form a final recommendation, and in that situation, additional research would be required.

2. **It is my understanding that marijuana is a Schedule I drug, not because it is as dangerous as heroin, but because Congress originally placed it in that schedule and because the Departments of Health and Human Services and Justice have considered the potential medical value of marijuana multiple times and found that it has no acceptable use.**

   a. **Is this correct?**

Schedule I includes those substances that have a high potential for abuse, have no currently accepted medical use in treatment in the United States, and lack accepted safety for use under medical supervision.[1] Scheduling determinations are made either legislatively (by Congress) or by DEA; the latter after requesting and receiving scientific and medical evaluations and scheduling recommendations from HHS. Congress placed marijuana in Schedule I through passage of the Controlled Substances Act (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970; P.L. 91-513, 84 Stat. 1236 (Oct. 27, 1970)). In its reviews to date, DEA has determined that marijuana continues to meet the CSA standards for placement in Schedule I, including the criteria that marijuana "has no *currently* accepted medical use in treatment in the United States." 21 U.S.C. 812(b)(1)(B) (emphasis added). These findings were supported by HHS scientific and medical evaluations and scheduling recommendations. Please note that the CSA does not permit either the DEA or HHS to evaluate the *potential* medical value of a substance when evaluating its placement in the schedules.

3. **I am told that the Departments of Health and Human Services and Justice are currently considering the medical benefits of marijuana again.**

   a. **When will this review be complete?**

The process is ongoing. At this point, we are unable to provide a timeline.

   b. **Does the current evaluation take into consideration the fact that specific components of marijuana may have medical value, or is the evaluation on marijuana as a whole plant?**

The scheduling evaluations for marijuana and CBD are separate administrative actions. For a Schedule I controlled substance, such as marijuana or CBD as a derivative of marijuana, to be placed administratively in a schedule other than Schedule I, the CSA requires a finding that the specific substance has a currently accepted medical use in treatment in the United States or, for Schedule II, a currently accepted medical use with severe restrictions. To assess whether a substance has a currently accepted medical use, DEA has set forth a five-part test: (1) the drug's chemistry must be known and reproducible, (2) there must be adequate safety studies, (3) there must be adequate and well-controlled studies proving

[1] 21 U.S.C. 812(b)(l)(A)-(C)

efficacy, (4) the drug must be accepted by qualified experts, and (5) the scientific evidence must be widely available. The most direct way to demonstrate accepted medical use is to have a drug approved by FDA.