DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Ave
Building 51
Silver Spring, MD 20993

FEB 11 2014

Rebecca L. Dandeker, Esq.
Partner
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Ave., NW
Washington, DC 20004

Re: FDA-2013-P-1711

Dear Ms. Dandeker,

This letter responds to your petition dated December 26, 2013 (Petition), in which you request that, "should the Commissioner of Food and Drugs formally submit recommendations to the U.S. Department of Health and Human Services [HHS]. . . to reclassify hydrocodone combination products [HCPs] as Schedule II drugs (as defined by the [Controlled Substances Act (CSA)]), that such rescheduling be limited only to hydrocodone combination products that contain hydrocodone bitartrate in a strength of 5 mg or higher in dosage" (Petition at 1). Your petition refers to the October 24, 2013 Statement on Proposed Hydrocodone Reclassification from Janet Woodcock, M.D., available at http://www.fda.gov/drugs/drugsafety/ucm372089.htm, and later reiterates its request as asking that the Food and Drug Administration (FDA) "For the myriad of public policy reasons set forth below ... refrain from submitting the stated recommendation to HHS to reclassify hydrocodone combination products that contain hydrocodone bitartrate in a strength that is lower than 5 mg in strength into Schedule II" (Petition at 1-2). We have reviewed the Petition carefully, but, for the reasons discussed below, deny the Petition as moot.

On December 11, 2013, the Commissioner of Food and Drugs, with the concurrence of the National Institute on Drug Abuse, formally submitted a scientific and medical evaluation and scheduling recommendation to HHS that all HCPs, regardless of the amount of hydrocodone they contain, be rescheduled under the CSA from Schedule III to Schedule II.[1] Six days later, on December 17, 2013, the Secretary of HHS submitted the same scientific and medical evaluation and scheduling recommendation to the Drug Enforcement Administration (DEA) for its consideration. Because your petition was submitted over two weeks after FDA already had taken the action you ask it not to take, the factual predicate for your request did not exist at the time of submission. For that reason, your petition was moot at the time of its submission, and must be denied.

The decision to schedule or reschedule a drug ultimately rests with DEA. Should DEA decide to reschedule HCPs, DEA will publish a Notice of Proposed Rulemaking (NPRM) proposing a schedule in which HCPs should be placed, and will invite public comments on this

[1] *See* 21 U.S.C. § 811-812; section 1139 of the Food and Drug Administration Safety and Innovation Act.

proposal. You may submit your input to DEA at that time, so that it may be considered in DEA's scheduling decision.

Sincerely,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research