



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Silver Spring, MD 20993

JUL 08 2015

The Honorable Edward M. Chen  
United States District Court  
Northern District of California  
450 Golden Gate Avenue, Box 36060  
San Francisco, CA 94102-3489

Re: Referrals to the United States Food and Drug Administration in *Swearingen v. Late July Snacks LLC*, No. C-13-4324 EMC (N.D. Cal.) and *Swearingen v. Healthy Beverage, LLC*, No. C-13-4385 EMC (N.D. Cal.)

Dear Judge Chen:

This letter responds to your Order issued on May 15, 2015 in the above-referenced cases, which requested the Food and Drug Administration ("FDA" or "Agency") to inform the Court whether a final determination regarding whether "evaporated cane juice" (ECJ) is the common or usual name for certain sweeteners is "feasible within agency priorities and resources" under 21 C.F.R. § 10.25(c). Your Order also asked whether FDA is "likely to issue any further guidance regarding ECJ within the next 180 days."

FDA is actively working on a final guidance to address this issue under the notice and comment procedures prescribed by its good guidance practice regulation (21 C.F.R. § 10.115). However, because of competing priorities, FDA cannot commit to issuing a decision within 180 days. Further, the Agency must comply with the good guidance practice regulation before issuing final guidance on the use of the term "evaporated cane juice." FDA issued draft guidance for comment in October 2009. In March of 2014, we reopened the comment period seeking further comments, data, and information about the basic nature and characterizing properties of the ingredient sometimes declared as "evaporated cane juice," including the production process and comparisons of this substance with other sweeteners (79 Fed. Reg. 12507). We have received a substantial number of comments and extensive amounts of supporting materials. FDA is obligated to review and consider all of this material under its GGP regulation before issuing final guidance (21 C.F.R. § 10.115(g)(iv)(A)). The Agency currently anticipates that a final guidance will issue before the end of 2016.

Very truly yours,

A handwritten signature in black ink, appearing to read "Leslie Kux".

Leslie Kux  
Associate Commissioner for Policy