Cooley

Anthony M. Stiegler
+1 858 550 6035
astiegler@cooley.com

Via ECF

January 19, 2018

Honorable Valerie E. Caproni
United States District Court
Southern District of New York
500 Pearl Street
New York, New York 10007

Re: **In Re: *Elysium Health—ChromaDex Litigation:* 17-cv-07394-VEC**

Dear Judge Caproni:

This letter is to inform the Court of a new development relating to the above-captioned action. On January 16, 2018, ChromaDex, Inc. ("CMDX") filed a Supplemental Citizen Petition with the U.S. Food and Drug Administration ("FDA") clarifying the original Citizen Petition, which is the basis of Elysium Health's complaint in this action. CMDX brings the Supplemental Petition to the attention of the Court because Elysium's complaint arises from the FDA proceeding in which the Supplemental Petition was filed.

CMDX filed the original Citizen Petition with the FDA on August 18, 2017 (the "Petition"), requesting that the agency take action under its discretionary authority to investigate, seize, and enjoin the sale of BASIS, a dietary supplement product marketed by Elysium Health, Inc. ("Elysium"). Elysium filed a response to the Petition with the FDA on September 22, 2017. The FDA has not yet issued a decision on the substantive merits of the Petition.

CMDX filed the Supplemental Petition with the FDA on January 16, 2018 to request that the agency take additional administrative action. The submission is authorized under FDA regulations permitting supplementation at any time prior to a final decision. 21 C.F.R. § 10.30(g). The Supplemental Petition is attached hereto for reference as Exhibit A.

As discussed in more depth in the Supplemental Petition, CMDX requests that the FDA take the following additional administrative actions:

1) State in a public guidance or similar announcement that the guidelines published by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ("ICH") addressing residual solvents in drugs do not apply to dietary supplements;

2) Issue an order pursuant to Section 413(b) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") that nicotinamide riboside chloride ("NR") is not reasonably expected to be safe if it contains new impurities such as toluene or any other Class 1 or Class 2 drug solvents that were not included in the toxicology studies conducted to establish the safety of NR for its intended use; and

3) Finalize the 2016 FDA draft guidance on New Dietary Ingredient Notifications ("NDINs") and clarify that the FDA will prioritize enforcement of the NDIN requirement established in Section 413(a)(2) of the FD&C Act in circumstances where a dietary supplement manufacturer has taken the necessary steps to comply with the notification requirement, but other manufacturers

Cooley

continue to distribute products containing the same New Dietary Ingredient without complying with that law.

These requests call for the FDA to take actions that fall under the agency's broad "authority to promulgate regulations for the efficient enforcement" of the FD&C Act, 21 U.S.C. § 371(a), as well as its specific responsibility to issue regulations implementing statutory requirements from the FD&C Act pertaining to New Dietary Ingredients, 21 U.S.C. § 350.

As the Court is aware, Elysium's complaint in the above-captioned action rests on allegations of defamation and deceptive business practices arising from the Petition. Elysium filed suit on September 27, 2017 (Dkt. No. 1); CMDX moved to dismiss on October 19, 2017 (Dkt. Nos. 14 & 20); and the parties completed briefing that motion on November 9, 2017 (Dkt. No. 30). The court issued an order on November 3, 2017 (Dkt. 27) ordering the parties to mediation, which was completed (without settlement) on Friday January 12, 2018, and staying all discovery pending the resolution of any motions to dismiss. The motions to dismiss are, therefore, ripe for oral argument and/or for the court to take under submission.

Very truly yours,

Anthony M. Stiegler

cc: All counsel