

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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ELYSIUM HEALTH, INC.,	:	
	:	Civil Action No. 1:17-cv-07394 (VEC)
Plaintiff,	:	
vs.	:	DECLARATION OF DAVID KUPFER IN
	:	SUPPORT OF DEFENDANTS’ MOTION
CHROMADDEX, INC.,	:	TO DISMISS
	:	
Defendant.	:	
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**DECLARATION OF DAVID KUPFER IN SUPPORT OF
DEFENDANTS’ MOTION TO DISMISS**

I, David Kupfer, make the following declaration under 28 U.S.C. § 1746:

1. I am an attorney with the law firm of Cooley LLP, counsel for Defendant ChromaDex, Inc. (“CMDX”) in this case. I am a member in good standing of the bar of the state of New York and am admitted to practice before this Court.

2. I submit this declaration in support of Defendant’s Motion To Dismiss.

3. I have personal knowledge of the documents attached to this declaration, and I declare that the attached copies are true and correct copies of the documents they purport to be.

4. Attached hereto as **Exhibit A** is a true and correct copy of the submission “Citizen Petition To Find Elysium Health, Inc.’s Basis Product To Be Adulterated” and its attached summary report, filed by CMDX with the U.S. Food and Drug Administration (“FDA”), dated August 18, 2017 and available at <https://www.regulations.gov/document?D=FDA-2017-P-5082-0001> (petition) and <https://www.regulations.gov/document?D=FDA-2017-P-5082-0003> (report).

5. Attached hereto as **Exhibit B** is a true and correct copy of a letter from the FDA to CMDX acknowledging receipt of the citizen petition, dated August 21, 2017 and available at <https://www.regulations.gov/document?D=FDA-2017-P-5082-0002>.

6. Attached hereto as **Exhibit C** is a true and correct copy of the submission “Comment on Citizen Petition from ChromaDex, Inc.,” filed by Elysium Health, Inc. (“Plaintiff”) with the FDA, dated September 22, 2017 and available at <https://www.regulations.gov/document?D=FDA-2017-P-5082-0008>.

7. Attached hereto as **Exhibit D** are true and correct copies of the two attachments to Plaintiff’s September 22, 2017 submission to the FDA (Exhibit C). The first attachment is a “Certificate of Analysis” from CMDX for the ingredient pterostilbene, dated August 9, 2013. The second attachment is a “Certificate of Analysis” from CMDX for the ingredient pterostilbene, dated May 4, 2015.

8. Attached hereto as **Exhibit E** is a true and correct copy of the report titled “Public Health Statement: Toluene,” published by the FDA’s Agency for Toxic Substances and Disease Registry, Division of Toxicology and Human Health Sciences, dated September 2015 and available at <https://www.atsdr.cdc.gov/ToxProfiles/tp56-c1-b.pdf>.

9. Attached hereto as **Exhibit F** is a true and correct copy of the report titled “Review of the Food and Drug Administration’s Citizen Petition Process,” published by the Office of the Inspector General, Department of Health and Human Services, dated July 17, 1998 and available at <https://oig.hhs.gov/oas/reports/phs/c9750002.pdf>.

10. Attached hereto as **Exhibit G** are true and correct copies of four letters from the FDA to parties who submitted citizen petitions denying those parties’ petitions. The first letter is to Wood, Herron & Evans, LLP, dated February 28, 2017 and available at <https://www.regulations.gov/document?D=FDA-2016-P-3195-0004>. The second letter is to the Fluoride Action Network, dated November 29, 2016 and available at <https://www.regulations.gov/document?D=FDA-2016-P-1288-0020>. The third letter is to King

& Spalding, dated July 19, 2010 and available at <https://www.regulations.gov/document?D=FDA-2002-P-0381-0004>. The fourth letter is to The Pharmaceutical Security Institute, Inc., dated March 2, 2012 and available at <https://www.regulations.gov/document?D=FDA-2011-P-0881-0004>.

11. Attached hereto as **Exhibit H** are true and correct copies of two letters from the FDA to parties who submitted citizen petitions converting those parties' petitions into trade complaints. The first letter is to Koch, Parafinczuk & Wolf, PA, dated March 26, 2015 and available at <https://www.regulations.gov/document?D=FDA-2015-P-0569-0005>. The second letter is to Inrange Systems, Inc., dated March 2, 2015 and available at <https://www.regulations.gov/document?D=FDA-2015-P-0051-0004>.

I declare under penalty of perjury that to the best of my knowledge the foregoing is true and correct.

Executed on October 19, 2017 in New York, New York.

S/David Kupfer

David Kupfer