WARNING LETTER

Date: July 6, 2020

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RE: Unapproved and Misbranded Products Related to Coronavirus Disease 2019 (COVID-

_____, where you direct consumers to your website, www.butterflyexpress.shop, to purchase your products. The FDA has observed that your website offers blessed waters, essential oils, hand sanitizers, homeopathic products, and tinctures for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19[1] in people. Based on our review, these products are unapproved new drugs sold in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 355(a). Furthermore, these products are misbranded drugs under section 502 of the FD&C Act, 21 U.S.C. § 352. The introduction or delivery for introduction of these products into interstate commerce is prohibited under sections 301(a) and (d) of the FD&C Act, 21 U.S.C. § 331(a) and (d).

There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named “severe acute respiratory syndrome coronavirus 2” (SARS-CoV-2). The disease caused by the virus has been named “Coronavirus Disease 2019” (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a deT.6 (s)-2 (s)-2us8.9 (3a and H)2-2 (s)-onf

- "I recommend the use of viral fighting essential oils right now and every day. Essential oil blends such as Butterfly's [Le]Deliverance would be an excellent choice. . . . The use of this blend in an inhaler, both as a preventative measure and as a response to exposure to the illness itself will be my first line of defense."
- "[P]urchasing name-brand sanitizers can be costly, and most of them contain alcohol and anti-bacterial products that also kill the 'good' germs on the skin. . . . A great solution to this problem is the natural hand sanitizer sold by Butterfly Express. The essential oils and witch hazel will kill both bacteria and viruses."
- "RC-L is made exactly like the RC formula except that it contains Lomatium. The Lomatium makes this formula especially effective for viral infections. Lomatium is being touted by those who should know as specific to coronavirus and similar viruses."
- "LCON . . . I would certainly recommend it if you do get sick with, or even exposed to, one of the strong strains of viruses such as the current coronavirus."
- "For something as potentially deadly as coronavirus pneumonia, the first thing that I would reach for (after Deliverance or Deliverance (Plus) is a high potency homeopathic remedy. . . . The Flu Kit includes the Blessed Water versions of the homeopathic remedies of Arsenicum album, Eupatorium perforatum, Gelsemium sempervirens, and Veratrum album." [from your website at http://www.butterflyexpressions.net]

x "Butterfly's CF Formula . . . This formula is perfect for the fight against this most recent pandemic, COVID-19." [from your website at http://www.butterflyexpressions.net]

x In a video titled "Coronavirus Live"[4] on your YouTube account, you represent the following:
  - Around minute 13:00, you state "Wash your hands add a drop of essential oil and squish it around on your hands and you'll be fine. You know, it's gonna do as good as a hand sanitizer."
  - Around minute 19:58, you state "It says Grab and Go flu kit. What are we talking about here? We're talking about viral flus related to the same coronavirus family that we're talking about here with coronavirus. To fight coronavirus, to fight a viral thing, the same things apply." [from a March 11, 2020, video on your YouTube account at https://www.youtube.com/c/ButterflyExpressEssentialOils]

You should take immediate action to correct the violations cited in this letter. This letter is not meant to be an all-inclusive list of violations that exist in connection with your products or operations. It is your responsibility to ensure that the products you sell are in compliance with the FD&C Act and FDA's implementing regulations. We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your products as safe and effective for a COVID-19-related use for which they have not been approved by FDA and that you do not make claims that misbrand the products in violation of the FD&C Act. Within 48 hours, please send an email to COVID-19-Task-Force-CDER@fda.hhs.gov describing the specific steps you have taken to correct these violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. Failure to immediately correct the violations cited in this letter may result in legal action, including, without limitation, seizure and injunction.

FDA is advising consumers not to purchase or use certain products that have not been approved, cleared, or authorized by FDA and that are being misleadingly represented as safe and/or effective for the treatment or prevention of COVID-19. Your firm will be added to a published list on FDA's website of firms and websites that have received warning letters from FDA concerning the sale or distribution of COVID-19 related products in violation of the FD&C Act. This list can be found at http://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-covid-19-products. Once you have taken corrective actions to cease the sale of your unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and such actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken appropriate corrective action.

[4] Accessed on Jun 22, 2020, at https://www.youtube.com/watch?v=mtVQExfcekU.

If you cannot complete corrective action within 48 hours, state the reason for the delay and the time within which you will complete the corrections. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration.

If you are not located in the United States, please note that products that appear to be misbranded or unapproved new drugs are subject to detention and refusal of admission if they are offered for importation into the United States. We may advise the appropriate regulatory officials in the country from which you operate that FDA considers your product(s) referenced above to be unapproved and misbranded products that cannot be legally sold to consumers in the United States.

Please direct any inquiries to FDA at COVID-19-Task-Force-CDER@fda.hhs.gov.

Donald D.