



Date: May 18, 2020

To: Cassie.Edgar@ipmvs.com

RE: Unapproved Drug Products Related to Coronavirus Disease 2019  
(COVID-19) and Other Diseases

Dear Ms. Edgar,

Thank you for your April 24, 2020 and May 12, 2020 letters, submitted on behalf of Prefense LLC (Prefense), responding to the warning letter issued by the Food and Drug Administration on April 23, 2020 regarding the Prefense Hand Sanitizer product line. We appreciate the steps Prefense has taken to bring its products into compliance.

Based on a review performed on May 15, 2020 of the Prefense website [www.prefense.com](http://www.prefense.com) and social media sites, it appears that your previous claims that the Prefense Hand Sanitizer product line is effective in preventing infection or disease from specific pathogens such as the novel coronavirus that causes COVID-19, as well as your previous time-specific extended efficacy claims, have been removed. Please be aware that we will continue to monitor the Prefense website and social media sites.

Lastly, you have requested that your response letter dated April 24, 2020 be posted on FDA's website. FDA has reserved the right not to post certain warning letter responses to its website. See Regulatory Procedures Manual, Chapter 4, Advisory Actions, Section 4-1-8 (<http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm>). At this time, we are not posting COVID-19 warning letter responses to FDA's website. Therefore, your response will not be posted. We will, however, update FDA's website to indicate that Prefense has taken appropriate corrective action.

Sincerely,

Carolyn E. Becker  
Director  
Office of Unapproved Drugs and Labeling Compliance  
Office of Compliance  
Center for Drug Evaluation and Research  
Food and Drug Administration