



**FDA** U.S. FOOD & DRUG  
ADMINISTRATION



## **WARNING LETTER**

Date: June 15, 2020

TO: [customerservice@frs.com](mailto:customerservice@frs.com) – Thomas C. Lines  
FRS International, LLC  
75 Arlington St., Ste 500  
Boston, MA 02116

RE: Unapproved and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19)

This is to advise you that the United States Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) reviewed your websites at the Internet addresses [www.frs.com](http://www.frs.com), [www.healthyenergy.com](http://www.healthyenergy.com), and [www.frs-international.com](http://www.frs-international.com) on April 1, 2020, and June 4, 2020, respectively. We also reviewed your social media website at [www.facebook.com/FRSEnergyEndurance](https://www.facebook.com/FRSEnergyEndurance), where you direct consumers to your websites [www.frs.com](http://www.frs.com) and [www.frs-international.com](http://www.frs-international.com) to purchase your products. The FDA has observed that your websites [www.frs.com](http://www.frs.com) and [www.frs-international.com](http://www.frs-international.com) offer quercetin-containing soft chew and liquid concentrate products for sale in the United States under the brand names Q-Force and FRS Healthy Energy and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19<sup>1</sup> 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 declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.<sup>2</sup> In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.<sup>3</sup> Therefore, FDA is taking urgent measures to protect consumers from certain products that, without approval or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described below, you sell products that are intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. We request that you take immediate action to cease the sale of such unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19.

Some examples of the claims on your websites that establish the intended use of your products and

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<sup>1</sup> As explained in the next paragraph, there is currently an outbreak of a respiratory disease named “Coronavirus Disease 2019” (COVID-19).

<sup>2</sup> Secretary of Health and Human Services Alex M Azar II, Determination that a Public Health Emergency Exists. Jan. 31, 2020. (Accessible at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>). The declaration was renewed for 90 days on April 21, 2020. Secretary of Health and Human Services Alex M. Azar II, Renewal of Determination that a Public Health Emergency Exists. April 21, 2020. (Accessible at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-21apr2020.aspx>).

<sup>3</sup> President Donald J. Trump, Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19). Mar. 13, 2020. (Accessible at <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>).

misleadingly represent them as safe and/or effective for the treatment or prevention of COVID-19 include:

- “BIG NEWS! DOCTORS ARE TESTING QUERCETINS AS A POTENTIAL DEFENSE VS. CORONAVIRUS” [from the homepage of your website [www.frs.com](http://www.frs.com)]
- “WHY STUDY QUERCETINS VS. COVID-19? . . . ANTI-VIRAL STUDIES There are many studies reporting that Quercetins are effective at inhibiting production and replication of a number of different viruses.” [from your website [www.frs.com/why-study-quercetins.html](http://www.frs.com/why-study-quercetins.html)]
- “Lung inflammation is a significant complication of coronavirus infection. Multiple studies have reported that Quercetin displays strong anti-inflammatory capabilities.” [from your website [www.frs.com/why-study-quercetins.html](http://www.frs.com/why-study-quercetins.html)]
- “COVID-19 causes respiratory infection. Many studies have reported that flavonoids, including Quercetin, decrease Upper Respiratory Tract Infections (URTI).....” [from your website [www.frs.com/why-study-quercetins.html](http://www.frs.com/why-study-quercetins.html)]
- “CORONAVIRUS NEWS: DOCTORS TESTING QUERCETIN – Click here for more info! \$250 ORDER LIMIT / 12 CHEW BAGS PER ORDER” [from the homepage of your website [www.frs-international.com](http://www.frs-international.com)]
- “DOCTORS WORLDWIDE ARE TESTING QUERCETINS AS A POTENTIAL DEFENSE AGAINST COVID-19..... ‘A MADE-IN-CANADA SOLUTION TO THE CORONAVIRUS OUTBREAK?’” [from your website [www.frs-international.com/pages/coronavirus-news](http://www.frs-international.com/pages/coronavirus-news); internal quotation marks indicate statements your website attributes to the Maclean’s Magazine]
- “‘AS CORONAVIRUS SPREAD SPEEDS UP, MONTREAL RESEARCHERS WILL TRIAL AN ANTI-VIRAL TREATMENT FOR COVID-19 IN CHINA’ ‘Quercetin has already proven successful at treating Ebola and Zika viruses [in mammals].’” [from your website [www.frs-international.com/pages/coronavirus-news](http://www.frs-international.com/pages/coronavirus-news); internal quotation marks indicate statements your website attributes to the Canadian Broadcasting Corporation (CBC) ]
- “‘CANADA TO HELP LEAD HUMAN TRIALS ON ANTIVIRAL DRUG FOR COVID-19’ ‘ . . . Montreal lab is in the final stages of plans ..... to test plant compound quercetin’” [from your website [www.frs-international.com/pages/coronavirus-news](http://www.frs-international.com/pages/coronavirus-news) ; internal quotation marks indicate statements your website attributes to the CBC]
- “‘IN THE NEWS: DOCTORS ARE STUDYING QUERCETIN AS A DEFENSE AGAINST CORONAVIRUS’” [from a February 25, 2020 post on your social media website [www.facebook.com/FRSEnergyEndurance](https://www.facebook.com/FRSEnergyEndurance)]

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-CFSAN@fda.hhs.gov](mailto:COVID-19-Task-Force-CFSAN@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.

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-CFSAN@fda.hhs.gov](mailto:COVID-19-Task-Force-CFSAN@fda.hhs.gov).

In addition, it is unlawful under the FTC Act, 15 U.S.C. 41 et seq., to advertise that a product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made. For COVID-19, no such study is currently known to exist for the products identified above. Thus, any coronavirus-related prevention or treatment claims regarding such products are not supported by competent and reliable scientific evidence. You must immediately cease making all such claims. Violations of the FTC Act may result in legal action seeking a Federal District Court injunction and an order may require that you pay back money to consumers. Within 48 hours, please send an email to Richard Cleland, Assistant Director of the FTC's Division of Advertising Practices, via electronic mail at [rcleland@ftc.gov](mailto:rcleland@ftc.gov) describing the specific actions you have taken to address the FTC's concerns. If you have any questions regarding compliance with the FTC Act, please contact Mr. Cleland at 202-326-3088.

Sincerely,

William A. Correll Jr -S

Digitally signed by William  
A. Correll Jr -S  
Date: 2020.06.11 18:25:46  
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William A. Correll  
Director  
Office of Compliance  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration

Sincerely,

RICHARD  
QUARESIMA

Digitally signed by  
RICHARD QUARESIMA  
Date: 2020.06.02  
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Richard A. Quaresima  
Acting Associate Director  
Division of Advertising Practices  
Federal Trade Commission