



BY FACSIMILE/CONFIRMATION COPY BY MAIL

August 1, 2008

Dr. Tod Cooperman  
ConsumerLab.com, LLC  
333 Mamaroneck Avenue  
White Plains, NY 10605

Re: Red Yeast Rice Products

Dear Dr. Cooperman:

Thank you for providing your citrinin test results. As previously indicated, our periodic screening of raw material as well as finished goods had confirmed no detectable amounts of citrinin and we have been testing to the limit of 1 ppm. Your group apparently tested older batches from a supplier that we no longer use.

We are glad that ConsumerLab acknowledged in its review that there is no scientific basis to determine whether or not the levels of citrinin that ConsumerLab claimed to have found in our Products and other products has any adverse health effects. We have consulted an independent toxicologist who has confirmed to us that the levels referenced in the ConsumerLab report do not raise a safety issue and therefore there is no need to conduct a recall. Nevertheless, in order to continue to assure the highest level of quality for our products, we have expanded our screening program to test for citrinin in all Red Yeast Rice raw material down to 1 ppm.

In your July 18, 2008 letter, you state that FDA has not established an acceptable level of lovastatin in red yeast rice supplements and that "any red yeast rice supplement containing more than trace amounts of lovastatin may *technically* be in violation of FDA rules." [emphasis added] We are not sure what you mean by "technically" but are glad that you have acknowledged the regulatory status of red yeast rice. We ask that you revise your review to reflect this – what your review should state is that the tested Nutraceutical products (Solaray, VegLife and Natural Balance) and the Walgreens product were the *only* products tested that had what FDA would view as trace amounts of lovastatin. We believe that your report also should be revised to inform consumers that all other tested products appear to be in violation of FDA rules and recommend that consumers not purchase these products (rather than suggest that these are the products they should consider purchasing).

Regarding ConsumerLab's communication of standards to the public and the industry, as far as we can tell, the standards that ConsumerLab creates are communicated simultaneously with its test results. In other words, after it is too late for manufacturers to comply. A regulatory agency would typically create a draft standard, announce it, accept comments, then provide the final standard and allow a period for manufacturers to get into compliance. ConsumerLab, on

the other hand, appears to create standards, test products, then announce the standards and the test results at the same time. We do not believe this is the appropriate approach. It creates confusion in the marketplace and leaves ConsumerLab open to criticism when the standards it creates may be based on incorrect assumptions (such as the question of lovastatin in red yeast rice). We believe that it is the FDA that should be setting standards according to its normal rule-making process. However, if ConsumerLab wishes to create its own separate standards, we think ConsumerLab should improve its process and include a step that involves peer-review as well as publication of draft standards, invitations to interested parties to comment, and communication in advance to the industry and public.

As far as the ConsumerLab business model goes, we believe that ConsumerLab should revise its practices to eliminate its Voluntary Certification Program or any other program that accepts money from manufacturers or retailers. While we don't have access to ConsumerLab contracts with manufacturers and cannot confirm that our beliefs are correct or not, it is our understanding that those who join the Voluntary Certification Program are not subject to the public dissemination of test results – in other words, if their products fail the test, the failure is not disclosed but is instead provided to the member company. We note that many brands of red yeast rice did not appear in the recent ConsumerLab review and wonder whether some of those brands are participants in the Voluntary Certification Program or some other ConsumerLab program? If this is correct, how unfortunate for the consumers who pay an annual fee and don't receive this information! We also note that ConsumerLab provides a link next to the tested products on its website where consumers can click through to an Internet retailer and purchase the product. Does ConsumerLab receive a commission or other payment for any resulting sales? If so, we believe this is a conflict of interest.

We believe that if ConsumerLab wishes to be a watchdog group on behalf of consumers, it should eliminate all possible conflicts of interest and cease accepting payments from manufacturers or retailers. We also believe it should become a non-profit group rather than a for-profit enterprise. We recommend that ConsumerLab consider the simple model adopted by Consumer Reports, which is clearly stated on its website:

“We are a non-profit organization that is supported by the subscriptions to our web site and magazine. To maintain our independence, we do not accept any outside advertising and any free test samples.”

We are hopeful that ConsumerLab can use our suggestions and recommendations to revise its review and to adopt a business model that is consistent with a mission to provide unbiased information to consumers.

Sincerely,  
NUTRACEUTICAL CORPORATION



Jeffrey A. Hinrichs  
Executive Vice President and Chief Operating  
Officer