

TRIUNITY LAW GROUP LLC

Law • Business • Technology

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December 13, 2017

David Butler
Cell Wellbeing Ltd.
David@Cell-Wellbeing.com

Dear David:

This letter is in response to your inquiry regarding statements that can be made relating to the benefits of using Cell Wellbeing's S-Drive device.

The S-Drive qualifies as a general wellness product under the United States Food and Drug Administration Center for Devices and Radiological Health's compliance policy entitled "General Wellness: Policy for Low Risk Devices" issued on July 29, 2016", FDA guidance 1300013 (UCM429674). A general wellness product that is compliant with FDA guidance 1300013 (UCM429674) has (1) an intended use that relates to maintaining or encouraging a general state of health or a healthy activity, or (2) an intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition.

Consistent with qualifying as a general wellness product, it is permissible to make the following (or similar) statements regarding use of the S-Drive:

- Promotes good health
- Promotes a healthy lifestyle
- Motivates/encourages/supports the achievement of health and wellness goals

The FDA does not consider such statements to be "health claims", which would require prior FDA approval following an evaluation of the scientific evidence supporting such claims. Health claims in this context are those that describe the relationship between a substance and a disease or condition.

Please let me know if you have additional questions.

Sincerely,



Wendy E. Rieder, Esq.
Managing Member