



November 21, 2023

BY EMAIL AND OVERNIGHT DELIVERY
SIGNATURE REQUIRED

Douglas Lex Howard
Evig, LLC dba Balance of Nature
1568 S River Rd, Ste 200
St. George, UT 84790
[REDACTED] bonadmin.com

Re: Resumption of Operations under Consent Decree of Permanent Injunction entered in *United States v. Evig, LLC dba Balance of Nature and Douglas Lex Howard*, No. 4:23-cv-00089-DN-PK (D. Utah) (Nov. 15, 2023)

Dear Mr. Howard:

This letter is regarding the resumption of operations of Evig, LLC in accordance with the above-referenced entered Consent Decree of Permanent Injunction (“the Decree”). The U.S. Food and Drug Administration (“FDA”) has determined that you appear to be in compliance with the Decree, the Federal Food, Drug, and Cosmetic Act (“the Act”), and its implementing regulations. Specifically, you appear to be in compliance with the Dietary Supplement CGMP and Labeling requirements described in Paragraphs 6(A)-(F) of the Decree. Therefore, this letter serves as the written notice described in Paragraph 6(G) of the Decree, and you may resume “manufacturing, preparing, processing, packing, labeling, holding, and/or distributing any . . . dietary supplement[s].”

We wish to remind you that the terms of the injunction under which your firm is operating require that you maintain compliance with the Decree, the Act, and implementing regulations. Our approval to resume operations should not be construed as approval for any conditions that may be found in the future. Should it be determined during any future inspection or other activities that you have failed to maintain compliance, we will take the steps necessary and appropriate to ensure compliance.

If you have any questions regarding this letter, please contact Compliance Officer Hanna Potter at [REDACTED] or [REDACTED] fda.hhs.gov.

Sincerely,

Jennifer A.
Hicks -S

Digitally signed by
Jennifer A. Hicks -S
Date: 2023.11.21
13:26:35 -07'00'

For: E. Mark Harris
Program Division Director
Office of Human and Animal Food Operations – West Division 4

MH/hlp

cc:

Scott A. Kaplan (by email)
Counsel for Defendants
[REDACTED]@[sidley.com](mailto: [REDACTED]@sidley.com)

Rebecca K. Wood (by email)
Counsel for Defendants
[REDACTED] [sidley.com](mailto: [REDACTED]@sidley.com)

Todd Miller (by email)
Counsel for FDA
[REDACTED]@[fda.hhs.gov](mailto: [REDACTED]@fda.hhs.gov)