



Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
555 Winderley Pl., Ste. 200  
Maitland, FL 32751

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

**WARNING LETTER**

**FLA-11-28**

**May 23, 2011**

Douglas J. Phillips, II  
Director of Research and Development  
Cerebral Health, LLC  
555 Heritage Drive  
Lab Suite 160  
Jupiter, FL 33458

Dear Mr. Phillips:

The United States Food and Drug Administration (FDA) conducted an inspection of your dietary supplement facility at the address referenced above from February 8-18, 2011. The inspection revealed that you failed to comply with the requirements for 21 CFR Part 111, Current Good Manufacturing Practice (CGMP) regulations for Dietary Supplements, causing your products to be adulterated within the meaning of Section 402(g)(1) [21 U.S.C. § 342(g)(1)] of the Federal Food, Drug, and Cosmetic Act (the Act), in that they have been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations. You can find the Act and the referenced regulations through links in FDA's homepage at [www.fda.gov](http://www.fda.gov).

Your significant violations include the following:

1. You failed to prepare and follow a written master manufacturing record for each unique formulation and batch size of dietary supplements that you manufacture to ensure uniformity in the finished batch from batch to batch as required by 21 CFR 111.205(a). Specifically, you verbally confirmed to our investigator that your firm does not have written master manufacturing records for any of your dietary supplements.
2. You failed to establish product specifications for the identity, purity, strength, and composition of each finished batch of your finished dietary supplement products as required by 21 CFR 111.70(e). Specifically, you verbally confirmed to our investigator that

your firm has not established product specifications for any of your finished dietary supplement products.

3. You failed to establish identity specifications for each component used in the manufacture of your dietary supplement products as required by 21 CFR 111.70(b)(1). Specifically, you verbally confirmed to our investigator that your firm has not established identity specifications for any dietary ingredient components used in the manufacture of your finished dietary supplement products.

4. You failed to either conduct at least one appropriate test or examination to verify the identities of components that are dietary ingredients as required by 21 CFR 111.75(a)(1). Specifically, you verbally confirmed to our investigator that your firm does not conduct any identity testing for dietary ingredient components.

5. You failed to establish and follow written procedures for the responsibilities of the quality control operations, including written procedures for conducting a material review and making a disposition decision, and for approving or rejecting any reprocessing as required by 21 CFR 111.103. Specifically, you verbally confirmed to our investigator that you did not have any written quality control procedures in place.

6. You failed to prepare and keep batch production records for every batch of dietary supplements you manufactured as required by 21 CFR 111.255. Specifically, you verbally confirmed to our investigator that you did not record or maintain any batch production records.

7. You failed to establish and follow written procedures to review and investigate product complaints as required by 21 CFR 111.553. Specifically, you verbally confirmed to our investigator that you did not have any written procedures for handling complaints.

FDA acknowledges receipt of your response letter to the FDA 483 dated February 22, 2011, in which you stated that you were in the process of having the manufacture of “all of [your] bottled products” outsourced to “GMP compliant contract manufacturers.” Although not mentioned in your response letter, the timeframe you verbally gave to our investigator for completing this corrective action was within the next six months (i.e., mid-August 2011). Your response is inadequate in that you provided us with no information about your firm’s manufacturing operations in the interim.

The above violations are not meant to be an all-inclusive list of deficiencies in your products or their labeling. It is your responsibility to ensure that all of your products are in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory actions without further notice, such as seizure and/or injunction.

Please respond to this letter within fifteen (15) working days from receipt with the actions you plan to take in response to this letter, including an explanation of each step being taken to correct the current violations and prevent similar violations. Include any documentation necessary to

show that correction has been achieved, such as a signed statement concerning the current status of your manufacturing operations and your intended corrective actions (if any) for the violative products in your inventory and on the market, the results of any and all component and finished product testing conducted since the inspection, and your complaint handling procedures,. If you cannot complete corrective action within fifteen (15) working days, state the reason for the delay and the time within which you will complete the correction.

You should direct your written reply to Matthew B. Thomaston, Compliance Officer, Food and Drug Administration, Florida District Office, 555 Winderley Place, Suite 200, Maitland, FL 32751.

Sincerely,

/s/

Emma R. Singleton  
Director, Florida District