DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	7/29/2021-8/20/2021* FEI NUMBER 3011105330

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Christopher D. Alexander, CEO

FIRM NAME	STREET ADDRESS
Bodyhealth.com, LLC	745 Main St
CITY, STATE, ZIP CODE, COUNTRY Dunedin, FL 34698-5018	TYPE ESTABLISHMENT INSPECTED Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

You did not establish component specifications for purity, strength and composition.

Specifically,

On 7/29/21 and 8/10/21, I found you did not establish component specifications for identity, purity, strength, or composition, for your Bodyhealth Metal-Free Dietary Supplement and your Bodyhealth Body Detox Dietary Supplement. Each product has multiple, unique ingredients such as Hyaluronic Acid and Acetylcystine listed on the product label with no component specifications for each ingredient. Written instructions and associated records you use to manufacture these dietary supplements do not have component specifications.

This observation is inclusive of all lots of your dietary supplements, including your Bodyhealth Body Detox Dietary Supplement with Lot # (b) (4) manufactured on (b) (4) which does not have component specifications for identity, purity, strength, or composition.

OBSERVATION 2

You did not establish product specifications for the identity, purity, strength and composition of the finished dietary supplement.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Aaron J Fox, Investigator	X Aaron J Fox Investigator Signed By: 2001324349 Date Signed: 08-20-2021 12:05:27	8/20/2021

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	7/29/2021-8/20/2021* FEI NUMBER 3011105330

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Christopher D. Alexander, CEO

FIRM NAME	STREET ADDRESS
Bodyhealth.com, LLC	745 Main St
CITY, STATE, ZIP CODE, COUNTRY Dunedin, FL 34698-5018	TYPE ESTABLISHMENT INSPECTED Manufacturer

On 7/29/21 and 8/10/21, I found you did not establish product specifications for the identity, purity, strength, and composition for any lot of dietary supplement you manufactured, including your Bodyhealth Metal-Free Dietary Supplement and your Bodyhealth Body Detox Dietary Supplement.

This is inclusive of all lots of your dietary supplements, including your Bodyhealth Body Detox Dietary Supplements with Lot # (b) (4) which had no tests or examinations performed on this finished product before it was shipped to customers.

OBSERVATION 3

You did not qualify a supplier of a component by establishing the reliability of the supplier's certificate of analysis through confirmation of the results of their tests or examinations.

Specifically,

On 7/29/21 and 8/10/21, I found you did not qualify the suppliers for the components of your Bodyhealth Metal-Free Dietary Supplement or your Bodyhealth Body Detox Dietary Supplement by establishing the reliability of the supplier's certificate of analysis through confirmation of the results of their tests or examinations. You do not conduct testing of the components you receive prior to manufacturing your dietary supplements.

On (b) (4), you received (b) (4) with Batch # (b) (4) from your contract manufacturer, which was used in the manufacturing of your Bodyhealth Body Detox Dietary Supplement on (b) (4) with mix lot # (b) (4) This component was not challenged through any tests or examinations.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Aaron J Fox, Investigator X Aaron J Fox Investigator Signed By: 2001324349 Date Signed: 08-20-2021 12:05:27	8/20/2021

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	7/29/2021-8/20/2021* FEI NUMBER 3011105330

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Christopher D. Alexander, CEO	
FIRM NAME Bodyhealth.com, LLC	STREET ADDRESS 745 Main St
CITY, STATE, ZIP CODE, COUNTRY Dunedin, FL 34698-5018	TYPE ESTABLISHMENT INSPECTED Manufacturer

OBSERVATION 4

Your batch production records did not include documentation that quality control personnel approved and released, or rejected, a batch for distribution.

Specifically,

On 7/29/21 and 8/10/21, I found your production records did not include documentation that your dietary supplements were approved, released, or rejected, by quality control personnel prior to distribution, including your Bodyhealth Metal-Free Dietary Supplement and your Bodyhealth Body Detox Dietary Supplement.

This observation is inclusive of all lots of your dietary supplements, including your Bodyhealth Body Detox Dietary Supplement with Lot # (b) (4) manufactured on (b) (4)

OBSERVATION 5

You do not have quality control operations for packaging and labeling.

Specifically,

On 7/29/21 and 8/10/21, I observed you do not have quality control operations related to any of the finished product specifications for packaging and labeling of your dietary supplements.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Aaron J Fox, Investigator	X Aaron J Fox Investigator Signed By: 2001324349 Date Signed: 08-20-2021 12:05:27	8/20/2021

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	7/29/2021-8/20/2021* FEI NUMBER 3011105330

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Christopher D. Alexander, CEO

FIRM NAME	STREET ADDRESS
Bodyhealth.com, LLC	745 Main St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Dunedin, FL 34698-5018	Manufacturer

This observation is inclusive of all lots of your dietary supplements, including your Bodyhealth Body Detox Dietary Supplement with Lot # (b) (4) manufactured on (b) (4)

OBSERVATION 6

You have not identified personnel to be responsible for your quality control operations.

Specifically,

On 7/29/21 and 8/10/21, I found you did not identify personnel to be responsible for quality control operations.

OBSERVATION 7

Personnel engaged in manufacturing, packaging, labeling and holding dietary supplements do not have the education, training, or experience to perform the person's assigned functions.

Specifically,

I found the personnel engaged in manufacturing, packaging, labeling, and holding dietary supplements at your firm do not have the education, training, or experience to perform the person's assigned functions. Your personnel are performing critical dietary supplement activities but have no education in receiving, quarantining, and testing dietary supplement components as well as manufacturing, packaging, and labeling finished dietary supplements. On 7/29/21 and 8/10/21, I observed your personnel had not established a quarantine area for incoming dietary supplement components.

OBSERVATION 8

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Aaron J Fox, Investigator	X Aaron J Fox Investigator Signed By: 2001324349 Date Signed: 08-20-2021 12:05:27	8/20/2021

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	7/29/2021-8/20/2021*
	FEI NUMBER 3011105330

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Christopher D. Alexander, CEO

FIRM NAME	STREET ADDRESS
Bodyhealth.com, LLC	745 Main St
CITY, STATE, ZIP CODE, COUNTRY Dunedin, FL 34698-5018	TYPE ESTABLISHMENT INSPECTED Manufacturer

You did not make and keep documentation of calibrations for instruments or controls that you use in manufacturing or testing a component or dietary supplement.

Specifically,

On 7/29/21 and 8/10/21, I found you did not keep calibration records for your (b) (4) used to weigh out components in (b) (4) form used in your Bodyhealth Body Detox Dietary Supplement and your Bodyhealth Metal-Free Dietary Supplement. This is inclusive of all lots of your dietary supplement, including your Bodyhealth Body Detox Dietary Supplements with Lot # (b) (4)

***DATES OF INSPECTION**
7/29/2021(Thu), 8/10/2021(Tue), 8/20/2021(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Aaron J Fox, Investigator	X Aaron J Fox Investigator Signed By: 2001324349 Date Signed: 08-20-2021 12:05:27	8/20/2021

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."