DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	9/19/2018-9/26/2018* FEI NUMBER 1000624398

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Peter A. Lewis, President/CEO

FIRM NAME	STREET ADDRESS
Hyperbaric Technologies Inc.	PO Box 69, 1 Sam Stratton Rd
CITY, STATE, ZIP CODE, COUNTRY Amsterdam, NY 12010-5243	TYPE ESTABLISHMENT INSPECTED Mfr of Hyperbaric Chambers & Mountain Bags

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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Process validation activities and results have not been documented.

(a) Specifically, as it relates to the (b) (4) sealing process for Gamow nylon hyperbaric bags, process validation records were not maintained to identify (b) (4) sealing process parameters selected for (b) samples (set at (b) (4) limits) to show which settings were qualified to seal the bags and to report final performance results.

(b) In addition, process validation parameters and functional test results were not documented for (b) (4) sealing process using (b) samples, to show process settings using (b) (4) sealing tools #s: (b) (4) to seal 21", 27" & 32" hyperbaric chambers made of 100% urethane material and chambers manufactured with (b) (4) source.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jacqueline S Warner, Investigator	X Jacqueline S Warner Investigator Signed By: Jacqueline S. Warner -S Date Signed: 09-28-2018 10:02:11	9/28/2018

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OBSERVATION 2

Corrective and preventive action activities and/or results have not been documented.

(a) Specifically, your establishment implemented design changes to (b) (4) " hyperbaric chambers under design project (b) (4) to replace (b) (4) windows with (b) (4) windows as well as remove window slits (a self destruction safety feature) but a CAPA Report was not maintained to show a description of records revised, such as engineering drawings and Bill of Materials as well as show evidence these changes were found to be effective. NOTE: Batches release with the above modifications to customers displayed small tears near the seal of window.

(b) A CAPA report was not maintained to support design project (b) (4), to capture a change to hyperbaric chamber's body to replace the (b) (4) with (b) (4) with (b) (4) windows to show all documents required to be revised and if all changes were implemented and found to be effective.

OBSERVATION 3

The device history record does not demonstrate that the device was manufactured in accordance with the device master record.

(a) Specifically, all DHRs for 32" Hyperbaric chambers and Ultra light Gamow bags lacked evidence that relief valves were tested, as outlined per production SOPs: MFI# 15C38172 (2.2) to show (b) (4) and for MFI #15C37178 (3.2.2), a pressure of (b) (4)

(b) The DHRs for all products lacked evidence of leak test results to show pressure output was (b) (4) , as required by the DMR (MFI) for ultra lite bags and hyperbaric chambers.

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OBSERVATION 4

A device master record has not been maintained.

Specifically, a copy of SOP titled "WP-005 "-Testing Protocols appeared to be incomplete, as the following specifications were missing:

(a) Burst pressure must (b) (4)

(b) Cycling test, maximum cycles for standard chamber ((b) (4) cycles) versus (b) (4) cycles ((b) (4) cycles)

(c) Maximum temperature for static test , missing temperature of (b) (4) for (b) (4) and (b) (4) for (b) (4) chambers, as well as maximum lose of pressure not to exceed (b) (4)

(d) For peel test must (b) (4) .

OBSERVATION 5

Records of changes to documents were not maintained.

Specifically, as it relates to design change for hyperbaric chambers (21", 27" & 32" chambers) to switch to use (b) (4) material (b) (4) no evidence (record) was maintained to support the previous material (b) (4)) under material (b) (4) was discontinued for producing future batches of chambers under DMR, Rev #80.

*DATES OF INSPECTION

9/19/2018(Wed), 9/20/2018(Thu), 9/26/2018(Wed)

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

Observation 4: Promised to correct

Observation 5: Promised to correct

AMENDMENT 1

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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."