

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513) 322-0700 Fax: (513) 679-2772		DATE(S) OF INSPECTION 2/25/2026-2/27/2026 FEI NUMBER 3005182235			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Tracee Wesolowski, Director of Quality Compliance					
FIRM NAME Compass Health Brands Corp.		STREET ADDRESS 18901 Snow Rd Bldg 6			
CITY, STATE, ZIP CODE, COUNTRY Brookpark, OH 44142-1465		TYPE ESTABLISHMENT INSPECTED manufacturer, repacker/relabeler			
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. <i>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.</i>					
DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 The inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements were not adequately established and implemented. Specifically, incoming inspections are not consistently performed in accordance with the established AQL sampling plan, as described in procedures #SP-28-01, "<u>Receiving Inspection</u>", and #WI-SP-28-01, "<u>Inspection and AQL Sampling Plan</u>". For example, * <u>Hydratherm Deluxe</u>: Sampling Plan: (b)(4). Sample size = (b)(4) were sampled (out of (b)(4)) * <u>O2 Concentrators</u>: Sampling Plan: (b)(4) Sample size = (b)(4) were sampled (out of (b)(4))					
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%;"> EMPLOYEE(S) SIGNATURE Laureen M Geniusz, Investigator </td> <td style="width: 40%; text-align: right; vertical-align: bottom;"> DATE ISSUED 2/27/2026 Laureen M Geniusz Investigator Signed By: Laureen M. Geniusz - S Date Signed: 02-27-2026 11:50:38 X _____ </td> </tr> </table>		EMPLOYEE(S) SIGNATURE Laureen M Geniusz, Investigator	DATE ISSUED 2/27/2026 Laureen M Geniusz Investigator Signed By: Laureen M. Geniusz - S Date Signed: 02-27-2026 11:50:38 X _____
EMPLOYEE(S) SIGNATURE Laureen M Geniusz, Investigator	DATE ISSUED 2/27/2026 Laureen M Geniusz Investigator Signed By: Laureen M. Geniusz - S Date Signed: 02-27-2026 11:50:38 X _____				

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION				
DISTRICT ADDRESS AND PHONE NUMBER 550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax: (513) 679-2772		DATE(S) OF INSPECTION 2/25/2026-2/27/2026 FEI NUMBER 3005182235		
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Tracee Wesolowski, Director of Quality Compliance				
FIRM NAME Compass Health Brands Corp.		STREET ADDRESS 18901 Snow Rd Bldg 6		
CITY, STATE, ZIP CODE, COUNTRY Brookpark, OH 44142-1465		TYPE ESTABLISHMENT INSPECTED manufacturer, repacker/relabeler		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Laureen M Geniusz, Investigator		DATE ISSUED 2/27/2026	
	Laureen M Geniusz Investigator Signed By: Laureen M. Geniusz - S Date Signed: 02-27-2026 11:50:36 X _____			
FORM FDA 483 (09/08)		PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS	PAGE 2 of 3 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513) 322-0700 Fax: (513) 679-2772		DATE(S) OF INSPECTION 2/25/2026-2/27/2026 FEI NUMBER 3005182235	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Tracee Wesolowski, Director of Quality Compliance			
FIRM NAME Compass Health Brands Corp.		STREET ADDRESS 18901 Snow Rd Bldg 6	
CITY, STATE, ZIP CODE, COUNTRY Brookpark, OH 44142-1465		TYPE ESTABLISHMENT INSPECTED manufacturer, repacker/relabeler	
Annotations to Observations Observation 1: Promised to correct			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Laureen M Geniusz, Investigator		DATE ISSUED 2/27/2026 Laureen M Geniusz Investigator Signed By: Laureen M. Geniusz - 8 Date Signed: 02-27-2026 11:50:38 X _____

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."