DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	2/3/2026-2/5/2026
	FEI NUMBER 2938401

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Derick J. Corrente, Director of Operations

FIRM NAME	STREET ADDRESS
B&B Medical Technologies, Inc.	1954 Kellogg Ave Ste 100
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Carlsbad, CA 92008-6581	Medical Device 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

A design and development file was not adequately maintained for each medical device type or medical device family.

Specifically, per you firm's Design Control Procedure (SOP-030, Rev. D), the DHF-11310_ Design and Development File for Hope Nebulize (class II medical Device) does not adequately include, or reference records generated to demonstrate conformity to the requirements for design and development and the records for design and development changes (i. e. DCO 2019-02 Labeling Change, DCO 2022-11_DMR Changes, DCO 2026-06_ Flow Rate Updates).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Sarah A Hassas, Investigator	X Sarah A Hassas Investigator Signed By: Sarah A. Hassas -S Date Signed: 02-05-2026 13:15:30	2/5/2026

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Annotations to Observations

Observation 1: Promised to correct

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Sarah A Hassas, Investigator	X Sarah A Hassas Investigator Signed By: Sarah A. Hassas -S Date Signed: 02-05-2026 13:15:30	DATE ISSUED 2/5/2026

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."