



December 14, 2022

Derry Anderson

(b) (6)

Sent via email to: (b) (6)

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug issue, via regulation, changes to 21 CFR 868.5470, with proposed language providing that “hyperbaric chambers shall comply with the FDA’s recognized consensus standards for hyperbaric chambers, i.e. NFPA 99, Health Care Facilities Code (2021) and ASME PVHO-1, Safety Standard for Pressure Vessels for Human Occupancy (2019) and update the FDA’s recognized consensus standards for hyperbaric chambers, product code “CBF” (21 CFR 868.5470), to the most recent editions of NFPA 99, Health Care Facilities Code (2021) and ASME PVHO-1, Safety Standard for Pressure Vessels for Human Occupancy (2019) was received and processed under CFR 10.30 by this office on 12/13/2022.

It was assigned docket number FDA-2022-P-3201. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency’s decision on the substantive merits of the petition.

Sincerely,

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)