U.S. FOOD & DRUG ADMINISTRATION

June 8, 2023

Derry Anderson
[redacted]

Sent via email to: [redacted]

Re: Citizen Petition – Docket Number FDA-2022-P-3201

Dear Mr. Anderson:

This is an interim response to the petition dated December 13, 2022 and filed by the Food and Drug Administration (FDA) on the same day. In the petition, you requested that FDA:

1. 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
2. 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).

FDA has been unable to reach a decision on your petition because it raises issues requiring further review and analysis by agency officials. This interim response is provided in accordance with FDA regulations on citizen's petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

If you have any questions about this interim response, please contact Thomas Szivos of our Office of Policy at thomas.szivos@fda.hhs.gov or (240) 204-4599.

Sincerely yours,

Ellen J. Flannery -S

Digitally signed by Ellen J. Flannery -S
Date: 2023.06.08 12:48:35 -04'00'

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
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