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VIA ELECTRONIC SUBMISSION ON REGULATIONS.GOV
(Docket No. FDA-2013-S-0610)

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, Maryland 20852

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RE: Recognized consensus standards for hyperbaric chambers should be made mandatory via regulation; update NFPA 99 and ASME PVHO-1 to most recent revision date.

The undersigned (the "Petitioner") submits this Petition, in accordance with 21 C.F.R. §§ 10.25 and 10.30 and the Food, Drug and Cosmetic Act ("FDCA").

A. Action Requested

Petitioner requests that the Commissioner of the Food and Drug Administration (hereinafter referred to as "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).**

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).

B. Statement of Grounds

Hyperbaric chambers are Class 2 devices under Title 21, Code of Federal Regulations, Part 868.5470. The FDA has approved two recognized consensus standards for hyperbaric chambers (product code "CBF"): (1) NFPA 99, Standard for Health Care Facilities, Chapter 20 – Hyperbaric Facilities (2005) ; and (2) ASME PVHO-1, *Safety Standard for Pressure Vessels for Human Occupancy* (2007). Unless a recognized consensus standard has been incorporated by reference into a regulation, the use of consensus standards is not mandatory for medical device premarket submissions. 21 CFR 868.5470 does not provide that the recognized consensus standards are mandatory. Petitioner requests that the recognized consensus standards should be, by regulation, made mandatory.

Recognized Consensus Standards

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Product Classification Product Code: *Cbf*

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Date of Entry	Specialty Task Group Area	Recognition Number	Standards Developing Organization	Standard Designation Number and Date	Title of Standard
01/30/2014	Anesthesiology	1-78	ASME	PVHO-1-2007	Safety Standard for Pressure Vessels for Human Occupancy
03/31/2006	Anesthesiology	1-67	NFPA	99:2005	Standard for Health Care Facilities Chapter 20 - Hyperbaric Facilities

Hyperbaric chambers, to be legally marketed in the United States, require the submission of an application for clearance under section 510(k) of the Act, 21 U.S.C. § 360(k). A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device (section 513(i)(1)(A) FD&C Act). Submitters must compare their device to one or more similar legally marketed devices and make and support their substantial equivalence claims. A legally marketed device is a device that was legally marketed prior to May 28, 1976 (preamendments device), or a device which has been reclassified from Class III to Class II or I, a device which has been found SE through the 510(k) process, or a device that was granted marketing authorization via the De Novo classification process under section 513(f)(2) of the FD&C Act that is not exempt from premarket notification requirements. The legally marketed device(s) to which equivalence is drawn is commonly known as the "predicate."

A 510(k) clearance signifies the FDA's conclusion that a medical device is "safe and effective." A 510(k) clearance, however necessary, is ***not sufficient***. The recognized consensus standards for hyperbaric chambers that the FDA considers voluntary for 510(k) purposes, are almost universally ***mandatory requirements outside of the FDA***. NFPA 99 and ASME PVHO-1 code provisions are enforced by state and local fire code officials, building officials, and pressure vessel inspectors (collectively "AHJs"). Confusion currently exists among some AHJs as to the significance of 510(k) clearance.

All states have adopted one or more of the following codes: (1) International Fire Code (IFC); (2) International Building Code (IBC); and/or (3) NFPA 101 (adopted in all states). Within

each of these codes, the mandatory obligation to adhere to hyperbaric chamber requirements in NFPA 99 is found, via incorporation.

For example, Section 609.1 of the IFC (2015, 2018, and 2021 editions) provides that:

> "Hyperbaric facilities ***shall*** be inspected, tested and maintained in accordance with NFPA 99."

Note: the 2015 edition of the IFC of the above provision is codified in Section 611.1

A similar incorporation reference is found in Section 425.1 of the IBC (2015, 2018, and 2021 editions):

> "Hyperbaric facilities ***shall*** meet the requirements contained in Chapter 14 of NFPA 99."

Likewise, NFPA 101 Sec. 8.7.5, (2012, 2015, 2018, and 2021 editions) provides that:

> *"**All occupancies*** containing hyperbaric facilities ***shall*** comply with NFPA 99 unless otherwise modified by other provisions of this *Code."*

Within NFPA 99, Sec. 14.2.2.1 provides the mandatory requirement for adherence to ASME PVHO-1.

> "Chambers for human occupancy and their supporting systems ***shall be designed and fabricated to meet ASME PVHO-1, Safety Standard for Pressure Vessels for Human Occupancy***, by personnel qualified to fabricate vessels under such codes."

Some states, in addition to adopting one or more versions of the IFC, IBC, and NFPA 101, have directly adopted ASME PVHO-1. For example, in the state of Georgia, pursuant to Ga. Comp. R. & Regs. r. 120-3-26-.02, et. seq., "…the 2019 ASME PVHO-1 Pressure Vessels for Human Occupancy and 2019 ASME PVHO-2 In-Service Guidelines" have "…statewide application as being the state minimum fire safety codes and standards for boilers and pressure vessels …." Just because a particular device has FDA 510(k) clearance is of no value if that chamber is not designed and fabricated to meet the requirements of ASME PVHO-1.

The result of the current disjointed scheme is that obtaining an FDA 510(k) clearance, other than compliance with the FDCA, is of little actual value in ensuring that a particular device is, in fact, safe. The two codes and standards organizations, the National Fire Protection Association and the American Society for Mechanical Engineers have determined that their standards, found in NFPA 99 and PVHO-1, are the ***minimum*** requirements to ensure safety of hyperbaric chambers for human occupancy. A hyperbaric chamber that submits a "code case" to the ASME, and is subsequently approved, receives a "U-stamp" on the device from ASME. This stamp signifies compliance with the standard. Many hyperbaric chambers do, in fact, have the "stamp." Virtually all low-pressure hyperbaric chambers, however, do not- even though they fall within the relevant

scope provisions of both NFPA 99 (0 to 100 psi…found in Sec. 1.1.12) and ASME PVHO-1 (pressure vessels exceeding 2 psi).

It makes little sense for the FDA to issue a 510(k) clearance for a device that does not meet the requirements of NFPA 99 and ASME PVHO-1. There are several reasons why the current FDA 510(k) clearance process for hyperbaric chambers is untenable. First, a hyperbaric chamber that does not comply with the requirements of NFPA 99 and ASME PVHO-1 should not be considered safe. Second, the current practice creates confusion among manufacturers, AHJs, practitioners, and the public about whether a device is indeed safe for use. Third, whether intentionally or through ignorance, there are manufacturers that are insisting that, because their chamber has FDA clearance, that they are indeed safe, despite knowing that their chamber is not compliant with NFPA 99 and ASME PVHO-1. These controversies can be easily resolved if the FDA mandates, as a condition of 510(k) clearance, adherence to the same standards that these chambers are subject to in the marketplace when they are placed into use.

Making it a mandatory requirement, via regulation, that hyperbaric chambers must comply with NFPA 99 and ASME PVHO-1, prior to issuance of a 510(k), serves both the public, manufacturers, and enforcement authorities. It would also significantly streamline the 510(k) process for manufacturers. Rather than the current "Declaration of Conformity," the applicant can simply include certification from ASME showing that the chamber is designed and fabricated in accordance with the standard. Such a requirement adds no additional burden to the applicant.

C. Environmental Impact

Petitioner claims a categorical exclusion under 21 C.F.R. § 25.31.

D. Economic Impact

As provided in 21 C.F.R. § 10.30(b), economic impact information will be provided if requested by FDA.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioner which are unfavorable to the Petition.

F. Conclusion

Petitioner strongly urges the FDA to mandate the requirement, via regulation, to provide that hyperbaric chambers shall meet the requirements of NFPA 99, Health Care Facilities Code (2021) and ASME PVHO-1, *Safety Standards for Pressure Vessels for Human Occupancy* (2019). Petitioner also requests that the FDA update the versions of both codes to the most recently adopted versions.

Respectfully submitted,

Derry Anderson

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