July 21, 2023

Lynn R. Webster/Michael C. Barnes
Center for U.S. Policy
1455 Pennsylvania Ave, NW
Suite 400
Washington, DC 20004

Sent via email to: obackhaus@sequelhl.com

Re: Docket Number FDA-2023-P-1702

Dear Petitioner:

This letter responds to your petition, dated April 28, 2023, that requests FDA "(1) deem Bamboo's NarxCare software a misbranded device; (2) issue a Warning Letter to Bamboo; (3) commence mandatory recall procedures with respect to the NarxCare software; and (4) take any other prompt action the agency deems appropriate to prevent serious, adverse health consequences or death." FDA sent an acknowledgement letter on May 1, 2023.

We have carefully reviewed your petition and have interpreted your requests, enumerated above, to be requests for FDA to investigate Bamboo Health, communicate to Bamboo Health that NarxCare software is not in compliance with the law, order a recall of the device, and initiate enforcement actions/related regulatory activities, as appropriate. Requests for the agency to initiate enforcement actions and related regulatory activity are not within the scope of FDA's citizen petition procedures. *See* 21 CFR 10.30(k).

FDA has interpreted 21 CFR 10.30(k) as covering not only situations where enforcement action is requested, but where related regulatory activities, such as investigations prior to the issuance of a Warning Letter or a recall, are required to determine whether subsequent enforcement actions may be taken. *See* 21 CFR § 10.3(a). Such matters are within the discretion of the agency.[1]

Therefore, we are denying your petition. An agency denial of a petition does not constitute final administrative action. *See* 21 CFR 10.45.

We appreciate the information that you provided. Such information is often helpful for us to identify problems with marketed products and possible violations of the laws and regulations that

[1] *See* Heckler v. Chaney, 470 U.S. 821, 835 (1985) ("The [FD&C] Act's enforcement provisions thus commit complete discretion to the Secretary to decide how and when they should be exercised."). *See also* 21st Century Cures Act § 3060(a), 21 U.S.C. § 360j(o)(4) ("Nothing in this subsection shall be construed as limiting the authority of the Secretary to . . . exercise enforcement discretion as to any device subject to regulation under this chapter.").

we enforce. We take complaints seriously, and we will evaluate this matter to determine whether follow-up action is appropriate. Decisions with respect to initiating enforcement actions are generally made on a case-by-case basis.

Sincerely,

Ellen J. Flannery -S

Digitally signed by Ellen J. Flannery -S
Date: 2023.07.21 13:41:00 -04'00'

Ellen J. Flannery, JD
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov