U.S. FOOD & DRUG ADMINISTRATION

May 25, 2023

Dr. Hooman Noorchashm MD, PhD
[redacted]

[redacted]

Re: Citizen Petition – Docket Number FDA-2022-P-3013

Dear Dr. Noorchashm:

This is an interim response to the petition dated November 27, 2022, filed by the Food and Drug Administration (FDA) on November 28, 2022. In the petition, you requested FDA refer Becton Dickinson and Company ("BD") to the Department of Justice for alleged violations of the False Claims Act based on BD's alleged "deliberate concealment of a bacterial ingress and contamination breach defect" in BD's "510(k) cleared GENESIS™ line of Rigid Sterilization Containers."

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: 2023.05.25 18:48:15 -04'00'

Ellen J. Flannery, J.D.
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