U.S. FOOD & DRUG ADMINISTRATION

May 27, 2024

Dr. Hooman Noorchashm MD, PhD
(b) (6)

Sent via email to: (b) (6)

Re: Docket Number FDA-2022-P-3013

Dear Dr. Noorchashm:

This letter responds to your citizen petition, received November 28, 2022 ("Petition"). Your Petition requests that 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 safety defect in that company's GENESIS™ Sterilization Containers."

Requests for the agency to initiate enforcement actions, including by referring matters to other agencies for enforcement, are not within the scope of FDA's citizen petition procedures. *See* Title 21, Code of Federal Regulations (CFR), 10.30(k). Such matters are within the discretion of the agency. Therefore, we are denying your request that FDA initiate enforcement action against BD under 21 CFR 10.30(e). An agency denial of a request to take enforcement action does not constitute final administrative action. *See* 21 CFR 10.45.

While we are denying your Petition, we note that the allegations set forth in the Petition are substantially similar to allegations that were presented to FDA in or around August 2022. We take complaints seriously, and since that time, the agency has taken several steps to investigate the issues raised and assess potential regulatory violations and safety concerns. However, as a general policy, FDA does not comment on its compliance or enforcement approach regarding individual matters and therefore will not comment further.

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 we enforce.

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

Sincerely,

Ellen J. Flannery -S Digitally signed by Ellen J. Flannery -S
Date: 2024.05.27 14:07:31 -04'00'

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