U.S. FOOD & DRUG ADMINISTRATION

Date: April 21, 2023

Hooman Noorchashm MD, PhD
[redacted]

[redacted]

Re: Citizen Petition – Docket Number FDA-2022-P-2724

Dear Hooman Noorchashm,

This is an interim response to the petition dated 9/29/2022, filed by the Food and Drug Administration (FDA) on 11/01/2022. In the petition, you requested FDA immediately revoke the medical device classification of P4HB based products from Becton Dickinson and reclassify these to "Biologicals" – in order to ensure stringent clinical safety and efficacy testing of this material – most notably in cancer patients.

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 Andrew Yeatts, Ph.D. of our Office of Policy at Andrew.yeatts@fda.hhs.gov or (301) 796-4539.

Sincerely yours,

Ellen J. Flannery -S

Digitally signed by Ellen J. Flannery -S
Date: 2023.04.21 14:58:25 -04'00'

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