



November 1, 2022

Hooman Noorchashm MD, PhD

(b) (6)

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug immediately revoke the medical device classification of P4HB based products from Becton Dickinson and reclassify these to a “Biologicals” – in order to ensure stringent clinical safety and efficacy testing of this material – most notably in cancer patients was received and processed under CFR 10.30 by this office on 11/01/2022.

It was assigned docket number FDA-2022-P-2724. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency’s decision on the substantive merits of the petition.

Sincerely,

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)