

The National Marrow Donor Program<sup>®</sup> (NMDP) appreciates the opportunity to submit an additional comment on Federal Register Docket Number 2005N-0403.

The following comment is submitted from the perspective of facilitating hematopoietic stem cell (HSC) transplants under the C.W. Bill Young Cell Transplantation Program (42 U.S.C. § 274k):

From this perspective, the NMDP believes that the administrative burden to both the FDA and to foreign establishments arising out of a requirement that each foreign establishment submit identifying information for each individual importer (*see* proposed 21 C.F.R. § 1271.25(a)(5)) would far outweigh any benefit to the FDA in obtaining the full proposed scope of that information.

Based upon the proposed definition of “importer” (21 C.F.R. § 1271.3(mm)), it appears that the domestic transplant center (hospital) housing the patient awaiting HSC transplant would be the designated importer for the purposes of the proposed regulations. In practice, the regulated foreign establishment may transport unrelated cellular therapy product (*i.e.*, Peripheral Blood Stem Cells (PBSC) and Donor Lymphocytes (DLI)) to some subset of more than 120 NMDP Network Transplant Centers located in the United States, depending upon the location of the patient in need of transplant. As proposed, the foreign establishment would be required under the new regulations to provide a list of contact information for approximately 120 NMDP Network Transplant Centers, notwithstanding the fact that the foreign establishment will likely transport regulated cells to only a very small percentage of the listed “importers.” It is relevant to note that the list of Transplant Centers will change from time to time as well, creating additional administrative burden.

The NMDP suggests that FDA consider including a mechanism that would allow a foreign establishment to name the NMDP as the importer of regulated products for transplants facilitated by the NMDP. As a practical matter, the NMDP believes that this would better allow the FDA to quickly identify the final recipient of regulated product on a case-by-case basis through contact with the NMDP, while minimizing the amount of peripheral, and potentially irrelevant, information submitted to the FDA.