



ASBMT™

American Society for Blood and Marrow Transplantation

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Division of Dockets Management (HFA-305)
 Food and Drug Administration
 5630 Fishers Lane, Room 1061
 Rockville, MD 20852

Re: Docket No. 2005N-0403, OC 200734

Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs

Dear Sir or Madam:

On behalf of the Board of Directors of the American Society for Blood and Marrow Transplantation (ASBMT), I am writing about the proposed rule changes for labels and bar codes for human drugs and therapeutic agents, including biologics, under the National Drug Code (NDC).

It is our understanding that the proposed rule changes would require an identifying number for every therapeutic product. We think this is unworkable for hematopoietic progenitor cell (HPC) products and, in fact, could be harmful to transplant patients. There is a better, safer alternative. Therefore we are urging a rule exception for HPC products.

Among the reasons for the exemption are:

- HPC products have variable active and inactive contents. Each is uniquely tailored to a patient's needs – not mass produced like commercial drugs. Each HPC product is a lot unto itself and would require its own NDC number.
- Due to the biological nature of HPC products, which are typically infused within hours of collection, there is no reasonable opportunity for the collection facility or processing lab to attain an identifier number within minutes of collection 24 hours a day, seven days a week.
- The integrity of the HPC products can be compromised if delayed to obtain an identifier number. Particularly problematic would be products imported to the United States, which is very frequent.

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- A useful database of HPC product information would be impossible to create for searches before product use. The HPC product would necessarily be infused before the NDC number is populated in any federally maintained database.
- Adverse reactions that occur with a patient after infusion already are required to be reported to the FDA.
- Current cellular therapy processing and hospital laboratory computer systems are not designed to accommodate the reading and incorporation of NDC data. New computer programs would be needed by manufacturers and hospitals.
- The process of obtaining an NDC number for bar coding each product would impose an undue burden on the manufacturer with no positive benefit for patient safety.

In summary, the effect of the proposed changes in the NDC system would detract from, rather than enhance, current levels of patient safety in HPC transplants.

A far superior alternative already exists. The cellular therapy community has spent much time and effort in recent years to develop a system for accurate and complete identification and tracking of HPC and other therapeutic cell products. The ISBT 128 Standard was voluntarily created to identify and track cells from the time of collection through manufacturing, storage, transport and ultimately patient infusion.

More comprehensive than the proposed NDC scheme, the ISBT 128 labeling system offers more information for better tracking and tracing of products. The system is currently recognized by the major standard-setting organizations for cellular therapy, including ASBMT, EBMT, ISCT, NMDP, WMDA, FACT, AABB and other national and international organizations.

A mandatory step toward an inferior NDC system would be overly burdensome and, more important, adversely affect patient safety by opening the manufacturing processes to opportunities for error and by directing resources away from processes and initiatives that can add to patient safety.

If you have any questions about our recommendation for an exemption or need additional information, please don't hesitate to contact me through the ASBMT Executive Office at (847) 427-0224, or personally at (617) 632-4731.

Sincerely,



Robert Soiffer, MD
President