Biotechnology Industry Organization

November 7, 2012

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

**Re: Docket No. FDA-2011-N-0090: Proposed Rule: Unique Device Identification System**

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) thanks the Food and Drug Administration (FDA or Agency) for the opportunity to submit comments on the "Proposed Rule: Unique Device Identification System."

BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment.

We appreciate the Agency's efforts to create a Unique Device Identification (UDI) System that seeks to ensure the adequate identification of medical devices through distribution and use in order to achieve, amongst other goals, a reduction in medical errors, the ability to unambiguously identify any device and provide access to information, the rapid identification of devices with reported safety issues or which are subject to recall, and the faster correction of device problems and more accurate and rapid recall completion. BIO also recognizes FDA's partnership with industry and the broader healthcare community during the development of the proposed UDI system, including the Agency's intent to build upon international regulatory cooperation activities and existing, internationally recognized standards relating to unique identification and data exchange.

The scope and complexity of the proposal is significant as it requires manufacturers to implement and validate new information technology (IT) systems, procedures and processes. It impacts device operations related to labeling, manufacturing, design (direct part marking), IT, data management, quality systems, and funding processes. Due to the significant resource investment, it is important to recognize that it is only upon final, clear requirements that many activities can begin. For example, validation of the systems and processes associated with the data collection and transfer to supply the Global Unique Device Identification Database (GUID) is dependent upon a clear understanding of the final data elements. Validation of data process and collection systems prior to a clear understanding of the final requirements will result in repeat

1201 Maryland Avenue SW
Suite 900
Washington DC 20024
202.962.9200
202.488.6306
bio.org

validation and other activities. As the Agency finalizes the rule we respectfully request the Agency consider that expansions in scope have a direct impact on timeframes to implement the rule and further request that the Agency provide adequate implementation time periods for any expansions in scope.

BIO is also pleased to offer the following technical comments to the proposed rule:

- Combination Products: As written the UDI rule would subject all combination products to the UDI requirements. The rule states that a UDI is generally required for each device *constituent*, regardless of whether the combination product is required to have a UDI. FDA should *not* require UDIs for device constituents of combination products whose primary mode of action is that of a drug or biologic when the labeling bears an National Drug Code (NDC), NDC bar code, and Lot Number/Expiration Date. In this instance the label provides the necessary information to adequately identify the product to patients and practitioners. In addition, if FDA's Standard Numerical Identifiers Guidance for Industry is implemented it will provide an additional level of product identification.

- Internationally Recognized Date Format: BIO agrees that the rule, by requiring manufacturing and expiration dates on medical device labels to conform to a standard date format, would contribute to improved identification of medical devices, and better ensure the safe use of such devices. The use of a standard date format ensures dates are unambiguous and clearly understood. However, the proposed format of Month, Day, Year (*e.g.*, JAN 15, 2012) is divergent from both the internationally recognized standard, ISO 8601, which established a common format for Year-Month-Day (*e.g.,* 2012-01-15*)* or YEAR-MONTH (*e.g.,* 2012-01) and the internationally recognized standard for in vitro diagnostic medical device labeling, ISO 18113-2, which apples ISO 8601. We recommend that the rule be amended to conform to the international ISO standard for date format.

**CONCLUSION:**

BIO appreciates this opportunity to comment on the "Proposed Rule: Unique Device Identification System." We would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/S/

Ruth DeLuca
Manager, Science and Regulatory Affairs
Biotechnology Industry Organization (BIO)