CHPA

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November 7, 2012

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

Re: Docket No. FDA-2011-N-0090, Unique Device Identification System; FDA, Proposed Rule; 77 Fed. Reg. 40736 (July 10, 2012)

Dear Sir or Madam:

The Consumer Healthcare Products Association (CHPA) welcomes the opportunity to comment on the above captioned proposed rule issued by the Food and Drug Administration in the July 10, 2012 Federal Register for Unique Device Identifiers (UDI). CHPA is the 131-year-old trade association representing manufacturers and distributors of nonprescription, or over-the-counter (OTC) medicines and dietary supplements. In addition, many CHPA members manufacture class I or class II devices which are sold at retail without a prescription. For this reason, CHPA has an interest in the subject matter of the proposed rule.

CHPA supports FDA's goals of reducing medical errors, simplifying device use information into data systems, identifying devices with adverse events, facilitating recall efficiency, and focusing communication. CHPA agrees with FDA's proposal for an exemption from UDI labeling and data reporting for class I devices which are lower risk and not subject to a prescription, and for class I devices from production identifiers. CHPA agrees with FDA's proposal for an exception from the UDI labeling requirements for nonprescription devices sold at retail. The imposition of these requirements to class I and nonprescription devices at retail would, rather than advancing FDA's goals, add unfocused and unnecessary complexity to a market-based system where nonprescription devices include universal product codes (UPCs) for each stock-keeping unit (SKU). Further, the law under which this requirement would be implemented envisions its application to devices that are implantable, life-saving, and life-sustaining. Neither Class I nor nonprescription devices at retail would fall within that scope.

Instead, nonprescription devices at retail already meet existing, broadly-accepted identification standards at the SKU level. In the preamble to the proposed rule, the agency correctly noted that a guiding principle of device identification should be use of systems which are broadly compatible and accepted for use in commerce. The agency points out

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that the private sector has already implemented device identification systems and, where possible, the rule should not require significant alteration of those systems. Today, nonprescription devices are widely sold in diverse retail settings, and include a machine-readable UPC number in the form of a bar code for each SKU to allow retailers, distributors, and manufacturers to track distribution to the store level of specific SKUs. UPC numbers also appear in plain-text numeric form. The UPC system works within a Global Trade Identification Number system; works across manufacturers, distributors, and retailers; and already works through virtually an entire industry of scanner suppliers, database subscription services, and other vendors using UPC bar codes. Disruption of that system would come at great cost, would risk disruptions in supply as products were relabeled, and would come without a description of a clear public health benefit. We therefore support the proposed rule's exemption for nonprescription devices that are sold at retail establishments, and support the continued ability to use an existing system.

Since we read proposed section 21 USC 801.50 as similarly providing an exemption from permanent marking of the UDI on the device itself, we support this exemption on the same basis. We would note that, in those instances where a nonprescription device is separated from its original container, these devices continued to be of lower risk and, in many instances, include a trade name on the device itself (e.g., a toothbrush).

Respectfully submitted,

David C. Spangler
Senior Vice President, Policy, and
General Counsel & Secretary

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