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THOMSON HEALTHCARE

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

Re: Comments on Proposed Rule Requiring a Bar Code Label for Human Drug Products and Blood — FDA Docket No. 02N-0204

Thomson Healthcare Inc., the publisher of *Physicians' Desk Reference® (PDR)* and a leading supplier of drug information to the healthcare community, strongly endorses the inclusion of bar codes containing the National Drug Code (NDC) number on all drug packages. Indeed, our paperless labeling system provides for precisely this methodology, permitting users to retrieve the latest product labeling simply by scanning the bar-coded NDC number on the drug package.

We agree that routine use of bar code technology can significantly reduce medication errors and, when used in conjunction with decision-support systems such as our paperless labeling system, can yield major improvements in patient safety. We applaud this initiative, which promises to advance the use of information technology throughout the industry. To reap its full benefits, however, we also urge the agency to move forward with the regulatory actions necessary to enable the use of paperless labeling. Only when the latest FDA-approved prescribing information is instantly available at every dispensing site can the full potential of bar coding be realized.

With regard to the content of the bar code, Thomson Healthcare does not advocate a redefinition of the NDC number. We have been supplying providers and payers with electronic drug databases for more than two decades, and find that the current NDC system is sufficient for identification of the precise form and strength of each product, as well as for retrieval of appropriate labeling and safety information. Because the current NDC nomenclature is deeply embedded in today's Health Information Services (HIS) systems, a change in the NDC nomenclature would be disruptive to providers and payers and could potentially undermine patient safety. To achieve the most expeditious implementation of bar-code-based systems at the least cost to industry stakeholders, we would recommend retention of the current NDC system, albeit with strict enforcement of

rules governing reuse of old numbers, i.e., permanence—the NDC should be associated with the same packaged product indefinitely.

We thank FDA for this opportunity to comment on the agency's bar code initiative and strongly support the agency's efforts to seek new ways to maximize patient benefit while minimizing risk. Lastly, we'd like to explore the many ways in which our expertise and infrastructure can be harnessed to facilitate immediate deployment of information technology to accomplish the agency's patient safety initiatives, including proposed bar code regulations and the paperless labeling system.

Sincerely,

Mukesh Mehta, RPh
Vice President

MM/lm