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THOMSON HEALTHCARE

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

Re: Comments on the FDA's Counterfeit Drug Initiative - Docket No. 2003N-0361

Thomson Healthcare Inc., the publisher of *Physicians' Desk Reference® (PDR)* and a leading supplier of drug information to the healthcare community, strongly supports the FDA's new initiative to more aggressively protect American consumers from counterfeit drugs. We applaud the agency's multi-pronged approach, especially the proposed rapid alert mechanism and the recommended increase in education and awareness efforts.

A proactive alarm system capable of alerting pharmacists to the discovery of counterfeits in the drug distribution pipeline is clearly an essential element in the overall anti-counterfeiting effort. Fortunately, such a system can be established easily and at virtually no incremental cost. Indeed, Thomson Healthcare's new paperless labeling system provides for precisely this capability, permitting the FDA to disseminate timely information about counterfeit drugs to all of the nation's pharmacies.

Developed to meet the user requirements of Pharmaceutical Manufacturers of America (PhRMA) Paperless Labeling Task Force, the *PDR On-Demand* system is designed to deliver electronic "FDA-approved labeling" to dedicated touch-screen devices installed at every dispensing site in the U.S. and its territories. Although the network's primary purpose is the delivery of daily updates to a comprehensive database of FDA-approved prescribing information, it is ideally suited to the rapid dissemination of any type of FDA alert, and provides immediate confirmation of the message's receipt at each site. A large-scale beta test of the network is due to begin shortly.

Once deployed nationwide, the system will be enhanced to enable visual identification of drugs from actual product photographs and will include packaging information needed for rapid authentication of questionable products. Further, PDR's extensive collection of images and drug identification data can provide an ideal foundation upon which to build a complete authentication database.

Please remember, however, that full-scale deployment of the *PDR On-Demand* system is contingent upon a regulatory change allowing pharmaceutical manufacturers to distribute up-to-date, electronic prescribing information in lieu of current paper-based package inserts. To reap its full benefits, we also urge the agency to move forward with the regulatory actions necessary to enable the use of paperless labeling.

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