

sanofi pasteur

The vaccines business of sanofi-aventis Group

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March 28, 2006

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

Re: Docket No. 2005N-0510 Anti-Counterfeit Drug Initiative Workshop and Vendor Display [71 Federal Register 1759, January 11, 2006]

Dear Sir/Madam,

Sanofi Pasteur Inc. of Swiftwater, Pennsylvania thanks the Food and Drug Administration (FDA) for the opportunity to comment on the above-referenced workshop entitled, "Anti-Counterfeit Drug Initiative Workshop and Vendor Display." Headquartered in Lyon, France, sanofi pasteur is the vaccines business of sanofi-aventis Group. Sanofi-aventis is the world's third-largest pharmaceutical company.

Sanofi pasteur is a world leader in vaccines and produces more than one billion doses of vaccines every year to immunize 500 million people around the world. Sanofi pasteur, in close consultation with the US public health establishment, including the FDA, and Centers for Disease Control and Prevention (CDC), strives to alleviate the suffering and death of vaccine-preventable diseases.

We offer the following comments for your consideration concerning the FDA's solicitation of responses as they apply to the Biologics (Vaccine) industry.

Sanofi pasteur applauds the FDA's continued efforts to protect our nation's supply of drugs and biologics from counterfeit products. We consider the topic of drug counterfeiting to be very significant and we continue to work closely with FDA to assure safe and uninterrupted supply of our products. That having been said, with very few exceptions, counterfeiting of vaccines has not been a significant issue to date. Nonetheless, we do realize the benefits of track and trace technology with respect to supply chain management and integrity.

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A significant concern, however, regarding the adoption of RFID lies within product component issues, such as the possibility for interference with the biologic product itself, or with metals that make up the final container closure system. Many biologics are large-molecular entities in solution, and some are frequently combined with an adjuvant to make for a complex product that can be particularly sensitive to changes in surrounding environments. Although we are aware of some evaluations that have been initiated to determine effects of RFID on biologics (e.g., the CDRH/PQRI study), it must be acknowledged that no definitive information exists to date regarding this potential interaction. This alone is reason enough for biologics manufacturers to be cautious when considering perfunctory adoption of this specific identification and track and trace technology.

An additional concern is the use of RFID technology and resultant data. Distribution of vaccines differs significantly from other pharmaceuticals, especially with respect to the end user. In the U.S., the vast majority of vaccines are administered in a physician's office where many vaccines and other medicinal products can be stored in a common refrigerator. In this setting, knowledge of the technology and its use are limited, instrumentation and systems for reading RFID chips are not readily available, and the opportunity for interference with the technology due to the proximity of other RFID tags is a distinct possibility.

Sanofi pasteur is currently complying with the FDA bar code initiative and we are evaluating next generation barcoding technology (i.e., data matrix or 2-D bar codes), which goes beyond current requirements identified in the final FDA rule on this topic (21 CFR 201.25). Evaluation and ultimate adoption of these technologies adds complexity to the management of already vulnerable vaccine supply; however, as noted, we understand the benefits of appropriate product tracking technology. We also recognize the benefits RFID may offer to wholesalers with respect to distribution efficiencies, and we acknowledge the potential benefit that RFID implementation might provide the industry with respect to supply chain integrity. However, we believe the potential exists for disruption of critical vaccine supply if such a technology were imposed on our industry prior to a more thorough evaluation of all potential impacts and benefits.

For these reasons, we ask that FDA reconsider establishment of broad requirements for the implementation of RFID technology, and we urge the Agency to consider leaving the choice of track-and-trace technologies to the manufacturers who are most capable of taking a number of issues into consideration prior to implementing an appropriate track and trace system.

On behalf of sanofi pasteur, we appreciate the opportunity to comment and thank you for your consideration of these responses. Should you wish to discuss any of our comments or concerns further, please address inquiries directly to Denise Rieker, Deputy Director, Regulatory Policy and Intelligence, by telephone at (570) 895-3465, or me directly at 570-839-4212.

Sincerely,



Kenneth P. Guito

Sr. Director, Regulatory Policy and Intelligence

KPG/DR/kh

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