Aventis Pasteur

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

12 June 2003

Re: Docket No. 02N-0204; Bar Code Label Requirement for Human Drug Products and Blood; Proposed Rule [68 Federal Register 12500, March 14, 2003]

Dear Sir/Madam,

Aventis Pasteur Inc. of Swiftwater, Pennsylvania thanks the Food and Drug Administration (FDA) for the opportunity to further comment on the above-referenced proposed rule entitled "Bar Code Label Requirement For Human Drug Products and Blood" in order to develop a regulation on bar code labeling for human drug products, including biologic products. Aventis Pasteur Inc. is part of the Aventis Pasteur family of companies, which consists of the parent firm Aventis Pasteur SA, headquartered in Lyon, France, Aventis Pasteur Inc., and other subsidiaries (collectively Aventis Pasteur). In turn, Aventis Pasteur SA is a subsidiary of Aventis SA.

Aventis Pasteur is a world leader in vaccines and produces more than one billion doses of vaccines every year to immunize 400 million people around the world. Aventis Pasteur provides the broadest range of human vaccines and biologicals commercially available from any single US vaccine company. It is a leading supplier of vaccines to protect against influenza, diphtheria, tetanus, pertussis, polio, Japanese encephalitis, yellow fever, *Haemophilus influenzae* type b disease, meningitis, rabies, and typhoid fever. Aventis 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 solicited responses as they apply to the biologics (vaccine) industry:

1. *Whether we should require bar codes on prescription drug samples, and the costs and benefits associated with such bar codes.*

   This does not apply to vaccines.

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2. *The risks and benefits of including vaccines in a bar code rule.*

   In order to minimize medication errors, we believe that there is a potential benefit to including the National Drug Code (NDC) in a bar code symbology for hospital-administered medicinals. However, we believe that the inclusion of bar codes on vaccine labeling will have minimal beneficial impact as the vast majority of vaccines are administered in a physician's office, a setting where scanning equipment and systems are not readily available.

   Due to space constraints on unit-of-use container labels, exemptions of certain text requirements should be considered by FDA in order to alleviate already crowded primary container labels. In line with this concern, specifying a linear bar code symbology could potentially impact the ability to physically place a bar code on certain unit-of-use container labels. We therefore urge the FDA to leave the decision as to the type of bar code symbology up to industry. Aventis Pasteur supports the vaccine manufacturer's (Industry Forum Subcommittee of the Vaccine Identification Standards Committee) recommendation for the preference of two-dimensional bar code symbology (i.e., Data Matrix).

3. *What terms we should use to describe OTC drugs that should be subject to this bar code requirement.*

   This does not apply to vaccines.

4. *Information on the costs and benefits associated with putting lot number and expiration date in the bar code.*

   Aventis Pasteur supports the FDA position of not mandating the inclusion of lot number and expiration date in the bar code symbology. We have significant concern that including lot number and expiration date will increase the potential for disrupting vaccine production lines due to the need for on-line printing of this variable data. This disruption could in turn lead to shortages of certain vaccines in the market. Additionally, no evidence has been presented to indicate that inclusion of lot number and expiration date will in fact minimize or eliminate medical errors. Couple this with the previously noted fact that the majority of vaccines are administered in a physician practice setting, and we believe there is no added benefit to including this variable data at this time.

5. *Whether the rule should refer instead to linear bar codes without mentioning any particular standard or refer to UCC/EAN and HIBCC standards.*

   The regulation should allow the use of both two-dimensional and linear codes to be in compliance with UCC/EAN data format standards. Manufacturers and labelers should not be restricted to only linear symbology standards. The relative code sizes and space limitations require the flexibility to use Data Matrix, RSS or other codes as required, and as space permits. For instance, we prefer the use of the Data Matrix symbology due to its reduced size and quality design. This symbology is imbedded with error detection and correction capabilities to ensure absolute read accuracy.

6. *Additional information regarding bar code scanning technology and the ability of bar code scanners to read different symbologies.*

   Through consultations with suppliers and venders, we understand that there are universal scanning devices available and in use that are capable of reading both two-dimensional and linear codes. The standard data structures within a majority of symbologies (e.g., Data Matrix, RSS) will permit the use of the same scanning equipment.

7. *Whether the rule should adopt a different format (whether that format is a symbology, standard, or other technology).*

   We recommend that the rule identify the key data required such as the NDC number, which contains the essential components (i.e. manufacturer, product, and dosage) in order to support the initiative to reduce medical errors. However, we again request that the type of bar code symbology be left up to industry, and we reiterate our alignment with the vaccine manufacturer's (Industry Forum Subcommittee of the Vaccine Identification Standards Committee) recommendation for the preference of the two-dimensional bar code symbology (i.e., Data Matrix).

8. *Whether any specific product or class of products should be exempt from a bar code requirement and the reasons why an exemption is considered to be necessary. In addition, how could we create a waiver provision that would minimize the potential for misusing the waiver?*

   We recommend that exemptions be made for vaccine unit-of-use container labels when a manufacturer demonstrates an inability to apply a bar code due to space limitations.

9. *Whether the implementation period for a final rule can and should be shortened from 3 years to some other specified time period.*

   We support the proposal for a 3-year phase-in period in order to comply with the final ruling.

10. *Whether we should require the use of ISBT 128 for blood products, a specific symbology that is consistent with that required for drugs in proposed §201.25, or machine-readable symbols" as approved by the Director of CBER.*

    This does not apply to vaccines.

11. *How the proposed rule might affect hospitals where patients receive blood or blood components, particularly with respect to a hospital's decision to purchase a machine reader (e.g., scanner) that can properly identify the intended recipient of the blood or blood component, the machine readable information encoded on the blood or blood component label and perhaps the linear bar codes appearing on drugs and OTC drugs that are dispensed pursuant to an order and commonly used in the hospital.*

    Through consultations with suppliers and venders, we understand that there are universal scanning devices available and in use that are capable of reading both two-dimensional and linear codes. The standard data structures within a majority of symbologies (e.g., Data Matrix, RSS) will permit the use of the same scanning equipment, which will also apply to blood or blood components and OTC drugs.

12. *Whether any of the alternatives discussed in the economic analysis have merit.*

    As noted previously in our response, the majority of vaccines are administered in the physician's office where scanning equipment and machine-readable technologies are not readily available. It is our belief that the rate of technology acceptance in the vaccine healthcare sector will not be as expeditious as it may be in other healthcare settings. This we believe is due in large part to the considerable capital required to purchase computer hardware and software, as well as bar code reading equipment. We would recommend that FDA therefore consider a concurrent mandate for physicians to actively use the bar codes applied to the unit-of-use labeling.

On behalf of Aventis Pasteur Inc., we appreciate the opportunity to comment on this proposed rule regarding a Bar Code Label Requirement For Human Drug Products and Blood 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 Kenneth P. Guito, Director, Regulatory Policy and Intelligence, by telephone at (570) 839-4212, or by email at ken.guito@aventis.com.

Sincerely,

Kenneth P. Guito

Luc Kuykens, MD, MPH, DTM
Vice President, Regulatory Affairs, North America
and Authorized Official

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