

Aventis Pasteur

Damian A. Braga
President US

October 30, 2002



Kathryn Zoon, Ph.D., Director
Office of the Center Director
Center for Biologics Evaluation and Research
c/o Document Control Center (HFM-99)
Woodmont Office Center, Suite 200 North
1401 Rockville Pike
Rockville, MD 20852-1448

Re: Docket No. 02N-0204

Bar Code Label Requirements for Human Drug Products
[67 FR 41360, June 18, 2002]

Dear Dr. Zoon:

I would like to take this opportunity to reaffirm the views of Aventis Pasteur, Inc. as they relate to the Center for Biologics Evaluation and Research's proposed rule entitled, "*Bar Code Label Requirements for Human Drug Products.*"

Please consider the following comments, relative to their application in the biological (vaccine) industry:

- Bar codes on vaccine labeling will have minimal beneficial impact on the reduction of medical errors, as most physicians do not have appropriate access to scanning equipment within their offices (where the vast majority of vaccines are administered).
- A requirement calling for vaccine bar code labeling could result in the disruption of Aventis Pasteur's vaccine production lines. This would occur if labels were required to list variable information (such as lot number and expiration date), which must be printed on-line.
- The key element for a bar code on the unit-of-use container should be the National Drug Code (NDC). Variable elements could, plausibly, be phased-in at a later date as technology and systems improve.
- The company requests a "phased-in" approach to comply with the proposed final rule issuing bar coding on container labels, based upon a 1 - 2 year timetable. During this time, the company would proceed with the implementation of a bar code with the National Drug Code (NDC), thereby avoiding any potential impact on vaccine supply. However, the addition of variable information on bar code labeling would require improved technology and integration of current production lines, and will require additional time.

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It is our contention that current space constraints and other technological hurdles regarding unit-of-use containers need to be overcome. This suggests the decision concerning a specific bar code symbology should be delegated to industry. Delegation to industry will ensure minimal impact on production lines.

Although we believe that there are benefits to bar coding unit-of-use containers, perhaps specifically with hospital-administered medicines, it is vital to consider the potential, comprehensive impact of bar coding on the fragile nature of the vaccine supply. This is increasingly important based upon recent shortages of a number of vaccines.

On behalf of Aventis Pasteur, Inc., I want to thank you for taking our concerns into consideration. Should you wish to discuss any of our comments or concerns further, please address inquiries directly to Kenneth P. Guito, Director, Regulatory Policy, by telephone at (570) 839-4212, facsimile at (570) 839-5529, or by e-mail at ken.guito@aventis.com.

Sincerely,

A handwritten signature in black ink, appearing to be "Ken Guito", with a large, stylized flourish at the end.

CC: Ken Guito
Wayne Pisano