



November 8, 2010

Re: Docket No. FDA-2010-D-0426, Draft Guidance for Industry: Bar Code Label Requirements – Questions and Answers (Question 12 Update); Availability

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

To Whom it May Concern:

The Association of Immunization Managers (AIM) is a membership organization representing the sixty-four state, territorial and urban immunization program grantees designated by the Centers for Disease Control and Prevention (CDC) to receive federal immunization grants. We are writing to provide comments in response to the Food and Drug Administration (FDA) draft guidance for industry bar code label requirements.

AIM supports the changes proposed by the FDA to allow identification of vaccine products and vaccine vial and syringe labeling to move from the traditional linear bar code to a data matrix. This technology will allow vaccine manufacturers to include more information on the bar code label, such as the lot number and expiration date of the vaccine.

AIM has supported the use of enhanced bar coding on vaccines for years. In January, 2009, AIM participated in a meeting hosted by the American Academy of Pediatrics (AAP) to advocate and work for the implementation of bar codes. At that time, FDA regulations were identified as a barrier. We are thrilled that FDA has drafted this guidance to allow for two-dimensional, data matrix bar codes and strongly support its finalization as written.

The use of data matrix bar coding will improve the efficiency of vaccine ordering and inventory management. CDC is currently piloting a centralized vaccine ordering system which requires providers to report the lot number, expiration date and NDC code for vaccines in their inventory when ordering new vaccine. Having this information included on the vaccine bar code label will greatly reduce the reporting burden on the provider and transmission error which would result from manual entry.

Inclusion of lot number and vaccine expiration date in the bar code label will also increase the accuracy of vaccine data collection, improve the ability of public health agencies and providers to respond to vaccine recalls, and expedite response and reporting of potential vaccine adverse events. These improvements will continue the advancement of public health and medical information technology toward the goal of automated data exchange between electronic medical records, provider vaccine inventory and ordering, and immunization information systems.

In the final version of the guidance, AIM requests that FDA:

- specifically endorse the use of industry standards such as those developed by the GS1 Healthcare Standards organization;
- include language applying the rule to all vaccines, not just childhood vaccines, and
- provide clear guidance and support for manufacturers to adopt new, enhanced bar codes.

Thank you for the opportunity to comment. We hope the FDA will move forward with implementation of the proposed guidance for industry bar code label requirements.

Sincerely,

A handwritten signature in black ink that reads "Lorraine Duncan". The signature is written in a cursive style with a large, looped initial "L".

Lorraine Duncan, Chair

A handwritten signature in black ink that reads "Claire Hannan". The signature is written in a cursive style with a large, looped initial "C".

Claire Hannan, Executive Director