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August 8, 2005

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

Re: **Docket No. 2005D-0202: June 7, 2005 (70 FR 33182)**

Dear Sir/Madam:

Wyeth Pharmaceuticals is submitting the following comments on the FDA's draft guidance for industry entitled, "Bar Code Label Requirements—Questions and Answers" (June 2005).

Wyeth is one of the largest research-based pharmaceutical and healthcare products companies and is a leading developer, manufacturer and marketer of prescription drugs, biopharmaceuticals, vaccines, and over the counter medications. Wyeth appreciates the opportunity to comment on the above-mentioned draft guidance; our comments are provided below:

Request for Clarification of 2-Year Implementation Date

Clarification is requested regarding Question 7: How is the 2-year implementation date intended to work? The response provided in the draft guidance states: "The 2-year implementation date is for drug products that received approval before April 26, 2004. This 2-year period is intended to provide the industry sufficient time to make the labeling changes necessary to comply with the rule by April 26, 2006...." (Lines 170-176)

However, for certain products it is likely that manufacturers could have inventory that was manufactured and packaged without bar codes well in advance of the 2-year implementation date. For example, some drug products are manufactured at irregular or lengthy intervals in campaigns, and inventory may still be on hand after the implementation date. Also, inventories may exist for drugs for rare diseases that address important medical needs, but which are manufactured infrequently due to the relatively small patient populations. It appears based on

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the preamble of the final rule (see italicized text below) the Agency intended that these remaining inventories could be shipped.

A 2-year implementation period will also enable firms to exhaust existing stock. If a drug has an expiration date that exceeds 2 years, and the drug was not subject to the bar code requirement at the time it was marketed, we will allow that drug to remain on the market without a bar code (69 FR 9147, Col. 1, par. 7).

Therefore, we recommend that the answer to Question 7 in the draft guidance be revised to clarify that the 2-year implementation date applies to product approved before April 26, 2004 and *packaged* on or after April 26, 2006. This would reduce the need for destruction or repackaging of product packaged prior to April 26, 2006 without a bar code, but that otherwise has sufficient expiration dating.

We are submitting the enclosed comments in duplicate. Again, Wyeth appreciates the opportunity to comment on the above-mentioned draft guidance, and trusts that the Agency will take these comments into consideration.

Sincerely,



Roy J. Baranello, Jr.
Assistant Vice President
Worldwide Regulatory Affairs