

Wyeth

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November 29, 2005

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

**Re: Docket No. 2005D-0385): September 30, 2005 (70 FR 57300-57301)**

Dear Sir/Madam:

Wyeth Pharmaceuticals is submitting the following comments on the draft guidance for industry entitled *Using Electronic Means to Distribute Certain Product Information*.

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.

In general, Wyeth supports the option for distributing product information electronically, including voluntary recall communications for FDA regulated products and/or important safety information. This opportunity will facilitate the timely distribution of product safety information to the public by manufacturers and distributors. Our specific comments and recommendations are described below.

**Clarification of Part 11 Reference (p. 6, line 205)**

FDA encourages the use of electronic technology for dissemination of drug safety information subject to 21 CFR §§ 7.49 and 200.5, product recall notifications and communication of drug safety information not addressed in any FDA regulation. This draft document lists in detail FDA's current thinking on electronic communication but, unfortunately, is somewhat vague regarding applicability of the Part 11 electronic record requirements.

The guidance should be more specific by describing under what circumstances Part 11 requirements would apply. If FDA is encouraging the use of electronic communications for disseminating important product information, we recommend

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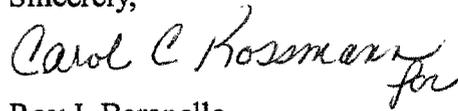
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that industry be given a clear understanding of the regulations and how they would apply under these circumstances. In particular, in order to avoid discouraging the use of electronic means for dissemination of product recall and drug safety information, we suggest that FDA should limit Part 11 applicability to only those specific circumstances where records are explicitly required by predicate rules and those circumstances should be clearly identified in the guidance.

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  
Assistant Vice President  
Regulatory Policy & Operations