Wyeth Pharmaceuticals

Wyeth

1891 '03 APR -8 A9:14

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
Docket No. 03N-0016

Date: April 7, 2003

Re: Docket No. 03N-0016: Agency Information Collection Activities; Proposed Collection; MedWatch: The FDA Medical Products Reporting Program

Dear Sir/Madam:

Wyeth respectfully submits these comments to Docket No. 03N-0016 pertaining to the Agency's notice announcing opportunity for comment on the MedWatch form used for the collection and reporting of drug, biological and device adverse experience (AE) information (68FR 6752-6754, February 10, 2003).

Wyeth is one of the world's largest research-based pharmaceutical and healthcare products companies, and is a leading developer, manufacturer and marketer of prescriptions drugs and over the counter medications. As such, Wyeth is required to use the MedWatch form for reporting adverse experiences to the FDA.

FDA specifically requested comments on, among other things, ways to minimize the burden of the collection of information on MedWatch form users. To this end, Wyeth has two suggestions:

1. Harmonize the MedWatch form with the Council for International Organizations of Medical Sciences (CIOMS I) form in both data elements collected as well as format. The CIOMS I form is used for reporting AE information to international regulatory authorities worldwide. Although CIOMS I forms are currently accepted by FDA for AEs received from ex-US sources, FDA requires use of the MedWatch form for AEs originating in the US. The two forms do not capture the exact same data elements – most importantly, the MedWatch requires inclusion of the reporter's name and address. MedWatch forms containing this information cannot be used for ex-US reporting as inclusion of this information in reports to ex-US regulatory agencies violates certain countries' data privacy laws. For the same reason, the MedWatch form cannot be used to send ex-US investigators letters regarding serious, unexpected and related AEs from clinical trials. Therefore, companies with global reporting responsibilities are required to use two different forms for reporting AEs. This requirement is burdensome.

03N-0016

C2

Wyeth

Harmonizing the MedWatch with the CIOMS I form would alleviate this burden.

2. Focus Agency resources on developing the data elements that will be required in any future electronic submissions of AEs to FDA. If FDA will be taking the position that the preferred mechanism for data receipt is electronic submission of individual case safety reports, then it is a burden for industry to continue to make MedWatch form changes while supporting electronic submissions. It may be better use of both FDA's and industry's resources to focus on developing guidance on the data elements FDA intends to require in electronic submissions and to develop the capacity for electronic submissions to FDA.

We trust the Agency will find these comments useful.

Sincerely,

Roy J Baranello

Roy J. Baranello
Assistant Vice President
Worldwide Regulatory Affairs