

Wyeth Pharmaceuticals
500 Arcola Road
Collegeville, PA 19426

Wyeth

September 29, 2006

The Honorable Michael Ferguson
U.S. House of Representatives
214 Cannon House Office Building
Washington, DC 20515-3007

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Dear Representative Ferguson:

Wyeth Pharmaceuticals (Wyeth) appreciates the opportunity to respond to your letter of September 15, 2006, requesting information regarding Wyeth's role in ensuring the distribution of antidepressant Medication Guides in the United States.

Before addressing the specifics of your letter, it is important for you to know that Wyeth is committed to supporting the appropriate use of our prescription antidepressant medications. For physicians and patients dealing with the serious, chronic, medical condition of depression, we believe that antidepressant therapy continues to be an important component of treatment. With respect to use in pediatric populations, it should be noted that Wyeth's only antidepressant medications, Effexor XR (venlafaxine HCl Extended-Release Capsules) and Effexor (venlafaxine HCl Immediate-Release Tablets), are not (and have never been) approved for such use. Accordingly, Wyeth shares your views regarding the important role of Medication Guides in helping patients and their families make fully informed treatment decisions in consultation with their healthcare provider.

In this regard, Wyeth, in compliance with the Food and Drug Administration's (FDA) requirement, distributes Medication Guides affixed to unit-of-use packages¹ for its prescription antidepressants. Wyeth makes Medication Guides available by additional means, including physician samples and multiple on-line outlets. In addition, patients can call our medical communications toll-free phone number and request current prescribing information² and further product information. This letter further details Wyeth's efforts and answers the queries contained in your September 15 letter.

¹ As described by the FDA, unit-of-use packaging is a method of providing a medication in an original container, sealed and pre-labeled by the manufacturer.

² The contents of the Medication Guide are included at the end of the prescribing information, also referred to as the package insert.

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Following the FDA's Public Health Advisory on October 15, 2004, work began for dissemination of the Medication Guide entitled "About Using Antidepressants in Children and Teenagers." The preparations were conducted in close consultation between the FDA and a consortium of antidepressant manufacturers (branded and generic) that included Wyeth. The consortium, in order to expedite the distribution of the Medication Guide, contracted with a service provider to print and distribute tear-off pads to pharmacists and physicians throughout the United States. A replenishment option was also made available. Distribution to patients began in January 2005.

Concurrently, Wyeth also began implementing a manufacturing plan for the Effexor XR and Effexor product lines to achieve the FDA's ultimate goal of ensuring that Medication Guides be systematically provided to patients through unit-of-use packaging. In December 2005, Wyeth introduced its unit-of-use packaging with Medication Guides and prescribing information leaflets firmly affixed for all marketed strengths of Effexor XR and Effexor.³ In this regard, for retail pharmacy dispensing, Effexor XR and Effexor are now sold only in the following unit-of-use packages:

Effexor XR	Effexor
37.5 mg – bottles of 15, 30 or 90 capsules	25 mg – bottles of 30 or 60 tablets
75 mg – bottles of 15, 30 or 90 capsules	37.5 mg – bottles of 30 or 60 tablets
150 mg – bottles of 15, 30 or 90 capsules	50 mg – bottles of 30 or 60 tablets
	75 mg – bottles of 30 or 60 tablets
	100 mg – bottles of 20 or 60 tablets

Enclosed for your reference, please find a unit-of-use package for Effexor XR, which is representative of all Effexor XR and Effexor units that are currently stocked by retail pharmacies.

Wyeth's efforts in providing Medication Guides did not end with moving to unit-of-use retail pharmacy packaging. Following the FDA Advisory in late 2004, Wyeth also changed its physician sample packages. In February 2005, Wyeth began including an antidepressant Medication Guide in its sample packages for Effexor XR.⁴ Enclosed for your reference, please find an Effexor XR sample

³ The interim tear-off pad program sponsored by the consortium was discontinued in early 2006, when all antidepressant manufacturers were to have their own means of distributing the required Medication Guide. As such, current distribution of the Medication Guide may vary from manufacturer to manufacturer.

⁴ Wyeth does not provide physician samples of immediate-release Effexor.

package, which is representative of all Effexor XR sample units that are currently distributed to physicians, and ultimately patients.

Wyeth also recognized that, for whatever reason, there might exist a situation where the Medication Guide may not be available or is not provided with the prescribed product. For example, a Medication Guide may inadvertently become detached from the package, a patient or his or her family may misplace this information, or in some cases, generic manufacturers may not offer unit-of-use packaging as a means of ensuring distribution of Medication Guides. To help mitigate these circumstances, Wyeth makes the antidepressant Medication Guide available at various on-line locations, including Wyeth's corporate website (www.wyeth.com/products), the Effexor XR website (www.effexorxr.com), and the website for Wyeth's patient education and support program for depressed patients taking Effexor XR (www.timetotalk.com). Furthermore, patients and their families can also call the Wyeth Pharmaceuticals Medical Communications department at 800-934-5556 to request current prescribing information and further product information.

In conclusion, Wyeth is in compliance with the FDA requirements regarding the distribution of Medication Guides. We have taken numerous steps to help ensure that patients who are prescribed Effexor XR or Effexor (or their families or caregivers) receive a Medication Guide when they are dispensed their medication or have access to a Medication Guide at other times throughout the course of therapy. We appreciate the opportunity to respond to your concerns and your continuing commitment to your constituents. If you have questions or need additional information, please contact Leo Jardot in our Washington, DC office at 202-659-8320.

Sincerely,



D. Bruce Burlington, M.D.
Executive Vice President
Business Practices and Compliance