



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable Mike Ferguson
House of Representatives
Washington, D.C. 20515-3007

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Dear Mr. Ferguson:

Thank you for your letter of August 31, 2006, concerning the distribution of FDA-approved Medication Guides when antidepressant medications are dispensed.

The Food and Drug Administration (FDA or the Agency) is committed to ensuring that prescribers, patients, and their families have the information needed to support the safe and effective use of antidepressant medications. Towards that end, in October of 2004, FDA requested the makers of FDA-approved antidepressants to revise their product labeling to address concerns about the products' use by children and teenagers. These revisions included development of a Medication Guide to accompany these products when dispensed, whether as a new prescription or a refill. The text of these guides was finalized in February of 2005 and added to the approved product labeling.

Your letter refers to the regulation at Title 21, *Code of Federal Regulations* (CFR), section 208.24, *Distributing and dispensing a Medication Guide*. Under this regulation, manufacturers who ship drug products for which Medication Guides are required must ensure that sufficient guides are available for distribution to patients. They may do so by providing Medication Guides in numbers that allow distributors, packers, or authorized dispensers to provide the guides to all patients who receive the drug product. Alternatively, manufacturers may provide the means for distributors, packers, or authorized dispensers to produce and provide Medication Guides to these patients. Importantly, the regulation requires each authorized dispenser of a prescription drug for which a Medication Guide is required to provide the guide to the patient, or to the patient's agent when the product is dispensed, unless exempt from this requirement under 21 CFR § 208.26.

In response to your first question, FDA believes that it has authority to enforce its regulations on Medication Guides. In short, as explained in the Medication Guide rulemaking (See 60 *Federal Register* [FR] 44210 and 63 FR 66382), under section 502(a) of the Federal Food, Drug, and Cosmetic (FD&C) Act, Title 21, United States Code (U.S.C.) section 352(a), a drug product is misbranded if its labeling is false or misleading in any particular. Pharmacists dispensing prescription drugs are not exempt from this provision section 503(b)(2) of the FD&C Act, 21 U.S.C. § 353(b)(2). Further, section 201(n) of the FD&C Act, 21 U.S.C. 321(n), describes the concept of "misleading" to encompass the failure of a product's labeling to reveal material facts with respect to consequences which may result from the use of the drug. Distribution of Medication Guides with antidepressant products helps to ensure that

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LET 6

patients, and their parents in the case of minors, receive the information necessary to use these products safely and effectively. The failure to provide a Medication Guide when these products are dispensed generally would cause the products to be misbranded in violation of the FD&C Act.

FDA has taken steps to help pharmacists understand that they must provide Medication Guides when dispensing antidepressant products. For instance, FDA's website at www.fda.gov/cder/offices/ods/medication_guides.htm provides pharmacists with a list of drug products, including antidepressants, that require Medication Guides. It also is noteworthy that many pharmacists use software programs that alert them to the need to dispense Medication Guides along with a medication.

Some pharmacists have advised FDA that manufacturers are not providing adequate quantities of Medication Guides, and that they want them transmitted electronically. In January of this year, we wrote to all manufacturers of approved antidepressant products, reminding them that they must assure that sufficient Medication Guides are available for distribution, whether by providing adequate numbers of these guides in hard copy or by providing the means to receive and produce them electronically. In support of the latter option, FDA has met several times over the past year with pharmacists to discuss electronic distribution of Medication Guides. There are a number of issues to be resolved, but in a letter dated August 28, 2006, FDA informed the National Council on Patient Information and Education and the National Association of Chain Drug Stores that the Agency is preparing a draft guidance regarding electronic Medication Guides.

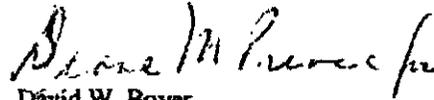
Turning to your second question, FDA has the authority to contact entities such as state regulatory authorities, national pharmacist trade associations, professional associations, and individual pharmacists, regarding Medication Guides and other important matters. But while the Agency shares your view that not a single patient should receive an antidepressant product without an accompanying Medication Guide, as a matter of practice and resources, it cannot enforce this requirement through inspection of the thousands of pharmacies nationwide. Instead, FDA focuses principally on manufacturers and wholesalers, to ensure that they produce and pass on an adequate supply of Medication Guides to these pharmacies. Regarding the pressing need to ensure that pharmacies actually dispense these guides, FDA generally defers to state boards of pharmacy. This is consistent with the Agency's historic practice, and reflects the state boards' ability to regulate day-to-day pharmacy practice.

Your letter mentions that your concern about the provision of Medication Guides stems from reports from your constituents. The Agency would be very interested in speaking with these constituents, if they are willing to do so. The information that these individuals or organizations provide will allow FDA to assess whether the problems encountered result from the limited availability of Medication Guides or factors that may be outside of FDA's jurisdiction. FDA considers this a serious issue and is taking steps on several fronts to ensure that all pharmacists have access to Medication Guides when they dispense antidepressant products.

Page 3 - The Honorable Mike Ferguson

Thank you for contacting us concerning this matter. If we can be of further assistance, please let us know.

Sincerely,

A handwritten signature in cursive script, appearing to read "David W. Boyer".

David W. Boyer
Assistant Commissioner
for Legislation