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September 20, 2006

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The Honorable Michael Ferguson
United States House of Representatives
214 Cannon House Office Building
Washington, DC 20510

Dear Representative Ferguson:

In response to your letter of inquiry dated September 8, 2006, I want to thank you for the opportunity to clarify GlaxoSmithKline's role in distributing Medication Guides (MGs) with our antidepressant medications. GSK strives to ensure that all of our products are safe, effective and available to the appropriate patients they are intended to help. Like you, we believe that MGs play a vital role in treatment by ensuring that patients and their caregivers have access to scientifically sound information regarding their treatment options.

I understand the concerns expressed by you and your constituents. As you know, in October 2004 the FDA requested that an Antidepressant Medication Guide be included in labels for all antidepressant medications. GSK played a pivotal role in collaborating with more than 30 companies to coordinate and ensure that tear-off pads of Antidepressant Medication Guides were provided to pharmacies during the transition of antidepressant product packaging across companies. While we are proud of the role we played in providing for a smooth transition, GSK continues to demonstrate our commitment to providing patients who take our medications with relevant MGs.

The regulations governing the issuance and distribution of Medication Guides [21 CFR part 208.24(b)] states that:

" Each manufacturer who ships a container of drug product for which a Medication Guide is required under this part is responsible for ensuring that Medication Guides are available for distribution to patients by either:

- (1) Providing Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product; or
- (2) Providing the means to produce Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product."

GlaxoSmithKline operates in a manner which is fully compliant with these requirements. Following FDA approval of the Medication Guides, GSK generally provides the MGs as part of the Package

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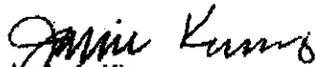
Insert with a statement on the actual container label that a MG is to be dispensed with the medication. The means by which the additional MGs are provided with the drug product vary depending on the presentation of the drug product, the number of pills per bottle, the number of bottles per container or the existence of a patient leaflet within the packaging. Regardless of these variables, GSK provides a sufficient number of MGs to permit the authorized dispenser to distribute a MG to each patient receiving a prescription for the drug product. Because actual distribution of the MG to each patient is the responsibility of the authorized dispenser (as per 21 CFR 208.24(e)), this function is beyond the control of GSK.

In our existing product portfolio, GSK provides MGs either as Extended Content Labels (ECL), as part of the packaging in the form of a tear-off leaflet, as a separate leaflet, or included in the Patient Package Insert. With the Extended Content Labels (ECL) format, a MG (or several MGs, depending on the number of pills in a bottle) is fixed onto the bottle. In addition, Medication Guides are provided on the company's website (www.gsk.com) along with the full prescribing information for all of GSK's products. Any dispenser who calls into the GlaxoSmithKline Response Center at 1-888-825-5249 is directed on how to obtain a copy of any of the MGs for relevant GSK products.

Based on this process and our overall commitment to improving patient health, GSK is confident that sufficient numbers of Medication Guides have been and are being provided to the authorized dispenser for distribution to patients receiving drug product with required Medication Guides.

Again, GlaxoSmithKline appreciates the opportunity to clarify our role in this important process. I hope you find this information useful and I trust you will contact me, or Phil Thévenet of my staff, if we may be of further assistance to you or the constituents of New Jersey's 7th District.

Sincerely,



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