



GlaxoSmithKline

July 19, 2004

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Re: Docket No. 2003N-0324  
RIN 0910-AC35

Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products, Proposed rule, 69 *Federal Register* 21778 (April 22, 2004)

Dear Sir or Madam:

In the April 22, 2004 *Federal Register*,<sup>1</sup> the U.S. Food and Drug Administration ("FDA") published and invited comments on the above proposed rule. This rule is intended to bring FDA regulations into compliance with section 17 of the Best Pharmaceuticals for Children's Act ("the BPCA").<sup>2</sup>

As proposed, the rule requires the labeling of every human drug product approved under section 505 (21 U.S.C. § 355) of the Federal Food, Drug, and Cosmetic Act ("the FDC Act") to include: (1) A toll-free number maintained by FDA for the purpose of receiving voluntary reports of adverse events (or "side effects") regarding drugs, and (2) a statement that the number is to be used for reporting purposes only, not to seek or obtain medical advice. FDA would allow affected entities one year following the effective date of any final rule published in the *Federal Register* to be in compliance.

GlaxoSmithKline (GSK) is affected directly by the proposed rule for prescription products and for consumer/Over the Counter (OTC) products. The comments here submitted by GSK Consumer Healthcare relate specifically to the OTC products that fall under the scope of section 505 of the FDC Act.

GSK Consumer Healthcare supports the comments submitted separately by the Consumer Healthcare Products Association, especially that we infer from the tone and context of the BPCA that OTC drugs were not the intended target of this legislation. However, this notwithstanding, we offer the following additional comments:

<sup>1</sup> "Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products," 69 *Fed. Reg.* 21778 (April 22, 2004).

<sup>2</sup> Public Law No. 107-109.

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### **1. Number Placement in Labeling**

The proposal to position the FDA toll-free number in the “Warnings” section of labeling under “Stop use and ask a doctor if”, is not appropriate. The number itself does not constitute a “warning” and detracts from the information appropriately provided currently under this section (21CFR 201.66(5)(vii)). Instead, GSK Consumer Healthcare proposes that the number be positioned either in section 21CFR 201.66(7) or under 21CFR 201.66(9).

Additionally, BPCA requires the number on labeling (vs the label). We propose that it be made clear, therefore, that the number need appear only once within the labeling of a given product SKU (e.g. the insert or the carton, but not necessarily both).

### **2. Proposed Exemption**

OTC products carrying a toll free number for purposes of capturing adverse events (AEs) that are reported to MedWatch, should be exempt from carrying the additional FDA number. Adverse events would thus: a) be captured in one place, allowing timely trend analysis of a complete AE data set by the sponsor, b) would reduce confusion among consumers and c) reduce the call burden on FDA.

### **3. Process and Responsibility for Post-marketing Safety Reports**

Under current regulations (21 CFR 314.80 and 314.98), manufacturers of NDA and ANDA products are required to submit post-marketing safety reports for:

- (1) serious and unexpected adverse events from domestic and foreign sources and
- (2) spontaneously reported adverse events that occur domestically and that are
  - (i) serious and expected, (ii) non-serious and unexpected or, (iii) non-serious and expected.

The Proposed rule does not negate this responsibility, yet no guidance on how to access the information from FDA, or assess it in a timely manner is provided.

Additionally, the responsibilities for providing AE follow-up need to be addressed and defined in order that both manufacturers and the Agency are able to fulfill their obligations within regulation and to protect public health.

Respectfully submitted,



Sue James

Vice President Regulatory Affairs, Compliance & Quality  
GSK Consumer Healthcare R&D