Division of Dockets Management
HFA- 305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Dear Sir or Madame:

I am President of PediaMed Pharmaceuticals, a company located in Florence, Kentucky. We employ a workforce of 17 and have an additional sales force of 80 around the country. This letter is submitted as a comment on the "Draft Guidance On Marketed Unapproved Drugs" that appeared in the Federal Register on October 23, 2003. (68 Fed. Reg. 60,702), Docket Number 2003D-0478.

The pharmaceutical products that my company manufactures have a long history of safe and effective use. They are prescribed by supervising physicians and are routinely covered by medical insurance. It is important that FDA implement a regulatory scheme that does not reduce the availability or affordability of these important products. For this reason, I believe a prescription drug monograph (PDM), similar in structure to the current over-the-counter monograph system, should be a component of the FDA's draft guidance.

A PDM would increase the regulatory scrutiny of prescription drug products that are currently being marketed outside the FDA premarket approval system. It also would lower the drug costs for consumers by avoiding the short-term regulatory monopolies that can result under the current regulatory structure. Finally, it would be a more efficient use of FDA resources since a single monograph would obviate the need for FDA review of potentially thousands of similar premarket approval applications.

For these reasons, I urge the Food and Drug Administration (FDA) to issue a revised solicitation for comments on its draft guidance. The revised solicitation should broaden the proposed Compliance Policy Guide (CPG) to consider a PDM system that Congress has directed FDA to consider. By doing this, the public comments will assist FDA in assessing the relative merits of its currently proposed guidance with a broader approach that includes a PDM allowing certain prescription drugs to be marketed without FDA premarket approvals.

Thank you for the opportunity to submit comments on this important matter.

Sincerely,

Dr. Cameron Durrant

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