PURDUE

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

RE: DOCKET NO. 2003D-0478; DRAFT GUIDANCE "MARKETED UNAPPROVED DRUGS: COMPLIANCE POLICY GUIDE", 68 FED. REG. 60702, OCTOBER 23, 2003.

Dear Sir or Madam:

These comments refer to the draft Compliance Policy Guide (CPG) on Marketed Unapproved Drugs, referenced above.

Purdue Pharma, L.P. (Purdue) markets various drug products in compliance with FDA regulations. Purdue strongly favors the publication of compliance policy guidelines such as this draft CPG, as a useful guidance to understand and meet regulatory standards under the policies of the Food and Drug Administration. In general, the draft CPG serves this purpose by providing a concise review of the practices and policies of the Agency in the regulation of marketed new drugs. We have no critical comment concerning the main text of the CPG. The clear establishment of enforcement priorities based on a risk-based approach is sound, and in keeping with the practices of the Agency observed since the adoption of the new drug amendments of 1962.

However, in the CPG Appendix certain statements are made that are unnecessary and inappropriate for the purpose of the CPG. These statements are opinion only, and they should be deleted from the final CPG. These opinions are:

"The FDA believes that there are few, if any, drugs on the market that are actually entitled to grandfather status . . ."

"As mentioned above, the Agency believes it is very unlikely that any currently marketed drug is grandfathered or is otherwise not a new drug. However the Agency recognizes that it is at least theoretically possible that such a product exists."

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"some unapproved drugs were first marketed (or changed) after 1962. These drugs are on the market illegally."

These opinions are not useful or appropriate for the purposes of the CPG. The legal authorities that are cited do not support any universal finding that all non-NDA drugs are illegally marketed. The findings in the cited court rulings were limited to those particular products, under the particular facts and circumstances of each case. The Agency's opinion that these case decisions are applicable to all marketed non-NDA drug products does not change the statutory law, but the formal publication of these opinions may be harmful and wasteful to health care in foreseeable ways.

These opinions would arbitrarily negate key provisions of the Federal Food, Drug, and Cosmetic Act, intended by Congress to be meaningful exceptions to the definition of the term "new drug" [21 U.S.C. 321 (p) (1) and (2). The draft Appendix mentions the two "grandfather" clauses in the Act, only in the effort to negate these statutory provisions as inapplicable except possibly in theory. These draft opinions purport that (virtually) no prescription drugs can be shown to be safe and effective unless FDA approves them via the new drug approval process. By fiat this denies the express legislative intent to allow the marketing of "grandfathered" drugs, and would overreach the mandated authority of the Agency.

We believe that a number of drugs are marketed lawfully and safely under the "grandfather" exceptions to the new drug approval requirements of the Act. By asserting that all such products are illegal without any Agency review or specific findings of fact and law, these opinions if formally published would cause foreseeable harm to public health interests. FDA should agree that its opinions as published in a CPG do not have the force of law, and FDA has asserted that such opinions are not subject to court challenge since there is no actual case or controversy. One potential for harm is that pharmaceutical companies may be targeted in tort litigation. In this litigious time tort lawyers are likely to take the Agency's CPG comments at face value and initiate litigation against any products that are not NDA-approved, charging that usual and expected adverse events are injuries callously caused by the marketer of an unapproved drug. Even if FDA does not select a targeted drug for enforcement action under its CPG priorities, the Agency's opinion would be used to claim that the product is illegal. The drug marketer could still argue that the product is "grandfathered" and that it is generally recognized by qualified experts as safe and effective, but the FDA would not make this decision. It would ultimately be made by a lay jury, not having the qualifications to make balanced judgments on such relative issues as general recognition of safety and efficacy.

It is not in the public interest to formalize the opinion that there are no "grandfathered", or GRAS/GRAE products. Even without FDA action based upon valid findings, the drug industry could be required to withdraw what are essentially generic products, or use scarce resources to do major clinical research and develop a full NDA. Predictably, this would lead to increased costs and prices for all drug products in hitherto recognized categories of safe and effective drugs that have been marketed for decades with minimal cost to the health care system.

CONCLUSION

The noted opinions in the draft Appendix to the CPG are not necessary to adopt the otherwise useful guidelines that are proposed, to articulate priorities in the enforcement policies of the Agency. These opinions are highly doubtful, since a number of marketed drug products meet the statutorily mandated exceptions to the New Drug Approval process. FDA should not universally condemn all such drugs without any review of the facts and circumstances in which these drugs are marketed. The referenced opinions are not well founded and if adopted as part of this CPG, they predictably can lead to wasteful litigation, and restrict the availability of well-established GRAS/GRAE drug products. The result would be increased health care costs, and the redundant use of clinical resources to document the safety and effectiveness of proven, basically generic drugs.

Sincerely,

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Admitted to practice in Connecticut and New Mexico

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