



JUL 7 2005

Food and Drug Administration  
Rockville MD 20857

Charles E. Dadswell  
Vice President, US Intellectual Property  
GlaxoSmithKline  
P.O. Box 13398  
Five Moore Drive  
Research Triangle Park, NC 27709

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Re: Docket No. 2005A-0015/API

Dear Mr. Dadswell:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your request for an advisory opinion dated January 10, 2005. You request that the Agency address whether patents of the following kinds should be listed in *Approved Drug Products With Therapeutic Equivalence Evaluations* (commonly known as the Orange Book):

- (1) Patents claiming drug delivery devices that are an integral and inseparable part of a drug product when:
  - a. The patents do not specifically claim the active ingredient(s) contained in the drug product; or
  - b. The patents fail to mention the active ingredient(s) contained in the drug product; and
- (2) Patents claiming the protective packaging or overwrapping for a drug product.

FDA has been unable to reach a decision on your request due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)) that are applicable to requests for advisory opinions (21 CFR 10.85(b)). We will respond to your request as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

2005A-0015

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