

April 03, 2000

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Mr. Wayne H. Mitchell
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Comments about "The Marketing Exclusivity and Patent Provisions for Certain Antibiotic Drugs"

Mr. Mitchell:

The Marketing Exclusivity and Patent provisions rule seems to be an interesting regulation, but it will certainly have a major impact on many pharmaceutical companies today in the market.

We are a group of students from Florida International University (FIU) in Miami, and have some concerns referring to this regulation.

Firstable, the definition provided for antibiotic drugs in this proposal rule is very general and includes any derivative from micro-organisms such as salt and ester. How this definition has changed from the old definition for antibiotic drugs before adopted? And how this change is going to be implemented in the market of Antibiotic drugs?

The another concern refers to the Antibiotic drugs out in market which were introduced after November 21, 1997. How this regulations will be applied to those drugs?

We greatly appreciate your time and attention for our concerns.

Sincerely,

FIU Students
Business in Society Class

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