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PHARMACEUTICALS

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November 30, 2000

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

Re: Docket No. 00N-1463
Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use

Dear Sir or Madam:

Reference is made to the Proposed Final Rule entitled, Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use. Submitted herewith, are comments from Procter & Gamble Pharmaceuticals regarding the proposed final rule. We appreciate the opportunity to respond to the Agency's request for comments.

Overall Comments

1. The proposed final rule contravenes the purpose of the prescription drug labeling which is intended to provide physicians with a clear and concise statement of data and information necessary for safe and effective use of the drug, not to direct physicians on how to practice medicine. The Proposed Final Rule requires extensive wording be added to the product package insert; wording that tells physicians how to practice medicine and significantly increases the length of the package insert. The addition of information beyond the intended scope of package insert jeopardizes the ease in which the product labeling may be used and interpreted by the healthcare professional.
2. The "Indication and Usage" section of antibiotic labeling states the specific organisms that the antibiotic is indicated to treat as approved by the FDA. The causative agent can be conclusively determined only by culturing. Also included in the "Indication and Usage" section of the majority of antibiotic package inserts is an additional statement indicating that appropriate culture and susceptibility testing should be performed before treatment to determine the causative agent and its susceptibility. Thus, the Proposed Final Rule wording would be redundant when included in the existing antibiotic label. In addition, since similar wording is currently present in antibiotic labeling and physicians confidently treat infections empirically despite the direction to culture and determine susceptibility, it is unlikely that more extensive, superfluous wording will change the practice of medicine.
3. Hospital acquired antibiotic resistant infections account for the highest incidence of antibiotic resistant infections, and hospitals are typically the point source for the spread of these infections into the

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community. Therefore, the proposed final rule would not appear to be the most effective mechanism for addressing this problem. A more direct approach would be for the FDA to work with public health agencies and state boards of health to establish more effective hospital infection control programs.

4. It is unclear in the analysis of impacts section whether the cost of the initial doctor visit, the culture and sensitivity tests, and follow-up visit were included in the analysis, as well as the likelihood of HMOs implementing this strategy and the affect that only partial compliance with the proposed labeling treatment direction would have on resistance. In addition, it does not appear that a plan has been developed to determine the success of this labeling change strategy to curb antibiotic resistance development.

Comments on Specific Sections of the Labeling

I. The direction to physicians in the "Indications and Usage" section to use local epidemiology and susceptibility patterns when determining the initial selection of the antibacterial agent is impractical since this information is not readily available to physicians, and when available, is infrequently used.

Thank you again for the opportunity to provide comments. If you have any questions, please feel free to contact me.

Sincerely,



Lenore Faulhaber, Ph.D., M.B.A.
U. S. Regulatory Affairs Manager

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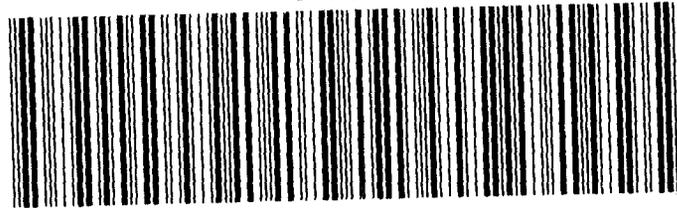
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