



NOV 25 1997

**TRANSMITTED VIA FACSIMILE**

Barbara A. Thompson  
Assistant Director, Advertising Policy  
Regulatory Affairs  
GlaxoWellcome  
5 Moore Drive, P.O. Box 13398  
Research Triangle Park, NC 27709

**RE: NDA # 20-695**  
**Raxar (grepafloxacin hydrochloride) Tablets**  
**MACMIS ID # 6034**

Dear Ms. Thompson:

Reference is made to GlaxoWellcome's (Glaxo) November 6, 1997, press release regarding Raxar Tablets. The Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed this press release and finds it to be in violation of the Federal Food, Drug, and Cosmetic Act and the applicable regulations. Specifically, DDMAC objects to the following:

accumulates only at the infection site, e.g. the respiratory tract.

The press release is also misleading because it presents comparative *in vitro* data that implies clinical superiority for Raxar against respiratory bacteria over other anti-infective products without substantial evidence for support. Specifically, the press release states that the results of an *in vitro* study showed that Raxar provided activity against nearly 100% strains of *Streptococcus pneumoniae* that were resistant to penicillin and clarithromycin. In addition, the study states that no other antibiotic tested in the study had greater activity against penicillin-resistant *S pneumoniae* than grepafloxacin. The anti-infective products tested in this *in vitro* study included amoxicillin, clarithromycin, azithromycin, ciprofloxacin and levofloxacin.

However, the results of clinical studies used as the basis of approval for Raxar, in the treatment of respiratory infections, e.g. acute bacterial exacerbations of chronic

bronchitis and pneumonia, showed that Raxar demonstrated equivalence to the comparator drugs, e.g. amoxicillin and ciprofloxacin. Additionally, the approved product labeling (PI) for Raxar states that Raxar has been shown to be active, both *in vitro* and in clinical infections, against *S pneumoniae* (penicillin-susceptible strains). Raxar is not indicated to treat penicillin-resistant strains of *S pneumoniae*.

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study results. This disclaimer is not sufficient to correct the misleading impression that Raxar is superior to amoxicillin, clarithromycin, azithromycin, ciprofloxacin and levofloxacin in treating respiratory infections.

In order to address these objections, DDMAC recommends that Glaxo take the following actions:

1. Immediately discontinue the use of all promotional materials for Raxar that contain the same or similar violations.
2. Provide a written response to DDMAC of your intent to comply with the above request and a list of promotional materials, containing the misleading presentation(s), that will be discontinued.

*Glaxo's response should be received no later than December 9, 1997. If Glaxo has any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm 17B-20, 5600 Fishers Lane, Rockville, MD 20857.*

In all future correspondence regarding this particular matter, please refer to MACMIS ID # 6034 in addition to the NDA number.

Sincerely,

*Wb* Adn Spearmon, Pharm.D., M.P.A.  
Regulatory Review Officer  
Division of Drug Marketing,  
Advertising and Communications