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Dockets Management Branch (HFA-305) 4 1 2 1 '98 JUL 24 P 3 :48  
Food and Drug Administration  
12420 Parklawn Dr., Rm. 1-23  
Rockville, MD 20857

July, 17, 1998

Dear FDA:

Kindly accept our comment on the Proposed Rules for Section 401 of FDAMA amended Federal Food, Drug and Cosmetics Act.

Our understanding of the spirit of the act is to provide health care practitioners with information on new uses for approved drugs in a timely manner. The act is written to eliminate much of the time between when the manufacturer begins to investigate a new use and when the manufacturer receives marketing approval. One aspect which apparently has been overlooked is the often lengthy publication process.

In the spirit of getting such information out as expeditiously as possible, please amend the following passage so that journal articles may be sent to FDA for their 60-day review once the publisher has approved the article, as opposed to once the publication has actually gone to press. This may seem trivial, but it could save six months or a year.

Kindly insert the words between the comas "...which was published, or has been accepted in its final form for publication, in a scientific or medical journal..." under Federal Register/Vol. 63, No. 109/ Monday, June 8, 1998/ Proposed Rules, Page 31156, Subpart B, §99.101, (2) (i).

Your consideration in this matter is appreciated.

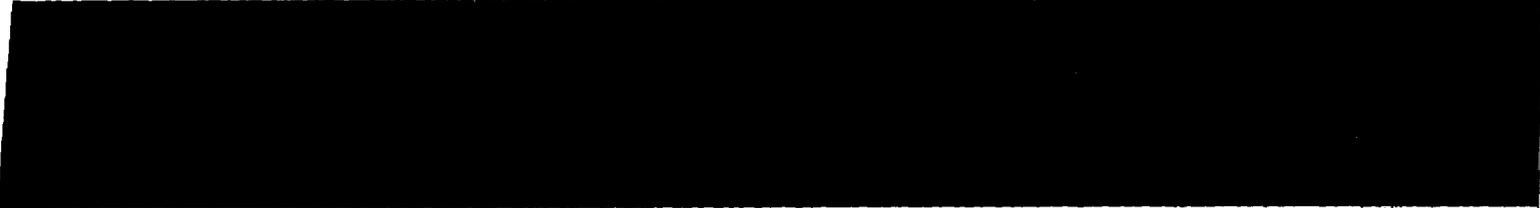
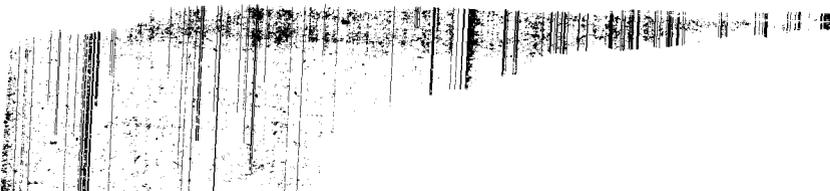
Yours truly,



Ernest T. Armstrong, MBA  
Member, ALLERGY LIMITED, LLC

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