



July 23, 1998

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Dockets Management Branch  
HFA-305  
Food and Drug Administration  
12420 Parklawn Dr.  
Room 1-23  
Rockville, Maryland 20857

To Whom It May Concern:

This is in response to the request for comments regarding the Federal Register Notice of June 8, 1998, "Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices" (63 FR 31143, Docket No. 98N-0222). The following represents the collective comments of Warner-Lambert Company, Morris Plains, NJ.

This Federal Register publication provides a Proposed Rule concerning the dissemination of information on unapproved uses for marketed drug products and serves to implement section 401 of the Food and Drug Administration Modernization Act of 1997 (FDAMA).

Section 99.205, titled "Application for exemption from the requirement to file a supplemental application" includes provisions for an exemption from the requirement to submit a supplemental application for a new use where it would be "economically prohibitive" to do so. Information requirements include submission of estimated market share during any exclusive marketing period, a projection of and justification for the price of the drug product and comparisons with sales of similar situated drug products.

Although the above information may be applicable for products that have a significant, but short patent life, we do not believe that such economic information should be required for products whose marketing exclusivity would have expired before any supplement could be submitted or approved. Exemption from the requirement to file a supplemental application based on economic reasons should apply to these products without the requirement to provide specific pricing or market share data. Essentially, the cost of conducting clinical trials for a product without exclusivity at the time of approval would invariably exceed the expected revenues simply because the product would be available as a generic. Thus, the economic information detailed in Section 99.205 would not be relevant to the agency's review of the exemption request.

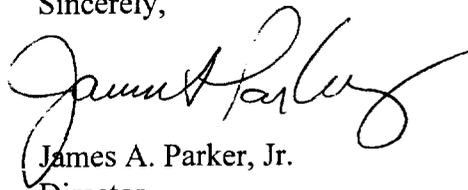
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Docket No. 98N-0222  
Dockets Management Branch  
July 23, 1998  
Page 2

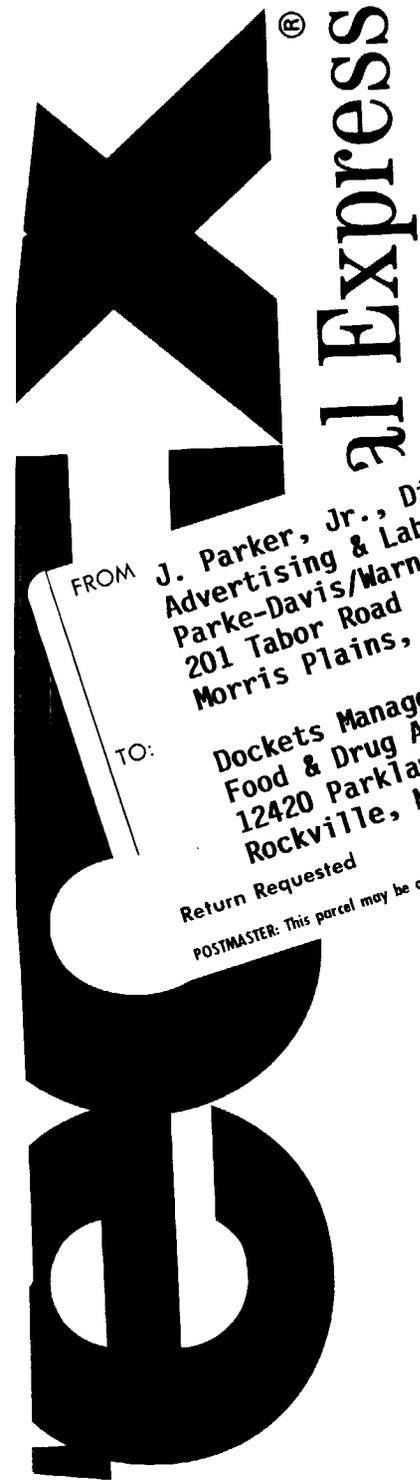
We believe the FDA should amend this particular section. Indications which could not be developed, submitted and approved as supplements prior to the expiration of marketing exclusivity should be exempt from the requirement of the supplemental NDA and any economic data to support this contention. FDA approval time estimates should be assumed to be the PDUFA goal for a standard review. Estimates for the time needed for development of the indication may be provided, economic data should not.

Sincerely,

A handwritten signature in black ink, appearing to read "James A. Parker, Jr.", written in a cursive style.

James A. Parker, Jr.  
Director  
Advertising and Labeling  
Parke-Davis  
Worldwide Regulatory Affairs

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FROM J. Parker, Jr., Director  
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Parke-Davis/Warner-Lambert Co  
201 Tabor Road  
Morris Plains, NJ 07950

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Food & Drug Administration  
12420 Parklawn Dr, Rm 1-23  
Rockville, Maryland 20857

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