



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

August 28, 2000

David L. Dyer, Ph.D.  
Director  
Research and Development  
Woodward Laboratories, Inc.  
11132 Winners Circle, Building 100  
Los Alamitos, CA 90720

Dear Dr. Dyer:

Your petition requesting the Food and Drug Administration to find Benzalkonium Chloride (0.11-0.13%) is generally recognized as safe and effective as defined by the Tentative Final Monograph for Health-Care Antiseptic Drug Products for OTC Human Use was received by this office on 08/28/00. It was assigned docket number 75N-183H/CP 4 and it was filed on 08/28/00. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe  
Dockets Management Branch

75N-183H

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