



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

November 30, 2004

FILE COPY

Michael L. Groesbeck
Vice President, Infection Prevention
Cardinal Health
1500 Waukegan Road, Bldg. WM
McGaw Park, IL 60085

Dear Mr. Groesbeck:

Your petition requesting the Food and Drug Administration to file an ANDA for a preoperative prep containing a chlorhexidine gluconate (CHG) / isopropyl alcohol (IPA) solution with tint, was received by this office on 11/30/2004. It was assigned docket number 2004P-0528/CP 1 and it was filed on 11/30/2004. 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. Gaffe
Division of Dockets Management
Office of Management Programs
Office of Management

2004P-0528

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