



MAY 15 2006

Jeffrey P. Kushan
Sidley Austin Brown & Wood LLP
1501 K Street, NW
Washington, DC 20005

RE: Docket No. 2005P-0458

Dear Mr. Kushan:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on November 14, 2005. Your petition requests that the Agency refrain from approving Abbreviated New Drug Application (ANDA) No. 77-271, for a generic chlorhexidine gluconate 2% and isopropyl alcohol 70% product with tint, until the three-year period of market exclusivity for ChloroPrep with Tint has expired. Your petition also requests that FDA require ANDA 77-271 to rely on ChloroPrep with Tint as the reference listed drug and to provide certifications for the patents listed for CloraPrep with Tint.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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