



FILE COPY

September 26, 2001

William J. McNichol, Jr.
Reed Smith, LLP
2500 One Liberty Place
1650 Market Street
Philadelphia, PA 19103

Dear Mr. McNichol, Jr.:

Your petition, on behalf of Professional Detailing, Inc. requesting the Food and Drug Administration to stay approval of all new or pending ANDAs applications for generic products containing cefuroxime axetil that differs in crystalline structure and/or stereoisomeric mixture from the cefuroxime axetil in CEFTIN, was received by this office on 09/26/01. It was assigned docket number 01P-0428/PSA 1 and it was filed on 09/26/01. 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,

Jennie Butler
Dockets Management Branch

01P-0428

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