



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

July 7, 2004

FILE COPY

Mr. Barry Sugarman
Nico Worldwide, LLC
1730 Michael Lane
Pacific Palisades, California 90272-2037

Dear Mr. Sugarman:

Your petition requesting the Food and Drug Administration to allow the submission and filing of an ANDA for Nicotine Base Bitartrate Solution 2 mg base per 240 mL oral solution and 4 mg base per 240 mL oral solution in bottles, was received by this office on 07/06/2004. It was assigned docket number 2004P-0282/CP 1 and it was filed on 07/07/2004. 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-0282

ACK1