



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

November 8, 2004

FILE COPY

Francis W. Busch
Prostrong, Inc.
20 Main Street
Oakville, Connecticut 06779

Dear Ms. Busch:

Your petition requesting the Food and Drug Administration to amend 21 CFR Sec. 333.250, regarding the labeling of anti-fungal drug products, was received by this office on 11/04/2004. It was assigned docket number 2004P-0490 and it was filed on 11/04/2004. 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,

Jennie Butler, Director
Division of Dockets Management
Office of Management Programs
Office of Management

2004P-0490

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