



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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October 9, 2002

Mr. Nicholas Tantillo
Senior Director, Regulatory Affairs
Barr Laboratories, Inc.
2 Quaker Road
P.O. Box 2900
Pomona, NY 10970-0519

Re: Docket No. 02P-0400/CP1

Dear Mr. Tantillo:

This letter confirms the substance of our October 4, 2002 telephone conversation. While we were on the phone, you verified that in the electronic version of *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book) Niaspan (Niacin Extended Release Tablet, 500 mg) is listed as a prescription drug product as opposed to a discontinued product. As a result, you agreed on behalf of Barr Laboratories, Inc., to withdraw the above referenced citizen petition. As we agreed, a copy of this letter has been filed in the docket with the instruction that this letter constitutes your formal withdrawal. Thank you.

Sincerely yours,

Aileen H. Ciampa
Office of Regulatory Policy (HFD-7)
Center for Drug Evaluation and Research

cc: HFA-305 (Docket No. 02P-0400/CP1)

02P-0400

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MEMORANDUM

TO: Dockets Management Branch [HFA-305]
FROM: Aileen H. Ciampa, Office of Regulatory Policy [HFD-7]
SUBJECT: Docket No. 02P-0400/CP1
DATE: 10/09/02

The attached letter to Mr. Nicholas Tantillo constitutes his formal withdrawal on behalf of Barr Laboratories, Inc., of the citizen petition he filed on September 5, 2002 (Docket No. 02P-0400/CP1). Please file it in the above referenced docket. If you have any questions, do not hesitate to contact me at x45622 or ciampaa@cder.fda.gov.

Attachment