

LAW OFFICES

KLEINFELD, KAPLAN AND BECKER

1140 NINETEENTH STREET, N.W.

WASHINGTON, D. C. 20036-6606

TELEPHONE (202) 223-5120

FACSIMILE (202) 223-5619

E-MAIL: kkb@kkblaw.com

THOMAS O. HENTELEFF
RICHARD S. MOREY
PETER O. SAFIR
KINSEY S. REAGAN
PETER R. MATHERS
BONNIE A. BEAVERS
DANIEL R. DWYER
GLENN E. DAVIS
PRESCOTT M. LASSMAN
STACY L. EHRLICH
JENNIFER A. DAVIDSON
STACEY L. VALERIO
ROBERT O. WINTERS

WEST COAST OFFICE:
ONE MARKET STREET
STEUART TOWER, SUITE 1450
SAN FRANCISCO, CA 94105-1313
TELEPHONE (415) 538-0014
FACSIMILE (415) 538-0016

VINCENT A. KLEINFELD
1907-1993

ALAN H. KAPLAN
1930-2001

OF COUNSEL:
HARVEY A. SUSSMAN

March 21, 2002

VIA MESSENGER

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
HFA-305, Room 1061
5630 Fishers Lane
Rockville, MD 20852

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Docket No. 02P-0078
Amendment to petition

Dear Sir or Madam:

The undersigned submits this amendment to Citizen Petition, No. 02P-0078. The above referenced petition was filed on February 21, 2002 to request that the Commissioner of Food and Drugs permit the filing of an Abbreviated New Drug Application (ANDA) for a new dosage form of a drug listed in FDA's publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (Orange Book). The Reference Listed Drug (RLD) product referenced in the petition was Novartis' Lioresal® (baclofen USP) 10 mg and 20 mg Tablets.

It has come to the attention of the undersigned that Lioresal is no longer marketed and will be moved to the "Discontinued" section of the Orange Book. Therefore, this petition is hereby amended to reference Ivax Pharmaceuticals, Inc.'s approved generic version of baclofen 10 mg and 20 mg tablets, USP. A copy of the most recent internet listing of the Orange Book, listing Ivax Pharms as an applicant of approved 10 mg and 20 mg baclofen tablets, is included in Attachment 1 to this amendment. A copy of the labeling for Baclofen Tablets, USP, manufactured by Ivax Corporation's U.S. generic subsidiary, Zenith Goldline Pharmaceuticals, Inc., is included in Attachment 2.

The draft labeling of the proposed product was included as an attachment to the original petition. The labeling is expected to be the same as that for the approved generic product, with the exception of

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the section denoting the manufacturer, and the change in dosage form to an orally disintegrating tablet.

All other information included in the original petition remains the same.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Richard S. Morey". The signature is written in a cursive style with a horizontal line extending from the end.

Richard S. Morey