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October 14, 2003

OVERNIGHT COURIER 10/14/03

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

Amendment to Docket No. 2003P-0464/CP1
ANDA Suitability Petition
Clonazepam Oral Solution, 1 mg / 5 mL
Clarification of Reference Listed Drug Product

Dear Sir or Madam:

The undersigned submits this amendment in quadruplicate to the above-referenced Docket to clarify that the reference listed drug (RLD) product upon with the petition is based is Klonopin (Clonazepam) Tablets, 1 mg. This is the RLD, as designated by the Agency in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, 23rd edition. The 0.5 mg and 2 mg products are mentioned for supporting purposes and to demonstrate that the proposed oral product can be utilized to provide for all approved doses cited in the approved labeling of the RLD.

Respectfully submitted,

Robert Pollock pk

Robert W. Pollock, Vice President
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RWP/pk

cc: M. Shimer (Office of Generic Drugs)
L. Lachman

G13P3287

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