

INTERNATIONAL REGULATORY BUSINESS CONSULTANTS, L.L.C.

Ira R. Berry, President

8736 '03 DEC -3 P1:32

November 21, 2003

Dockets Management Branch
Food and Drug Administration (HFA-305)
Department of Health and Human Services
12420 Parklawn Drive (Room 1-23)
Rockville, MD 20857

ATT: Ms. Emily Thomas

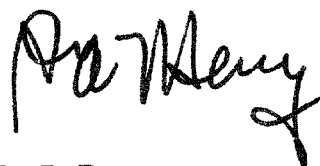
RE: SUITABILITY PETITION
Docket Number 2003P-0398/CP1

Dear Ms. Thomas:

As we discussed by telephone on November 17, 2003, please withdraw the application for the stated Suitability Petition – Oral Capsule Dosage Form Containing Hydrocodone Bitartrate 5 mg/Butalbital 50 mg/Caffeine 40 mg/Acetaminophen 325 mg.

Sincerely,

INTERNATIONAL REGULATORY BUSINESS CONSULTANTS, L.L.C.



Ira R. Berry

Certified Mail – Return Receipt Requested

2003P-0398

WDL1