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2574 03 DEC -8 PM 12:

December 8, 2003

Division of Dockets Management
Food and Drug Administration (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 03P-0398: ANDA Suitability Petition for Oral Capsules Containing Hydrocodone Bitartrate 5 mg/Butalbital 50 mg/Caffeine 40 mg/ Acetaminophen 325 mg

REQUEST FOR DENIAL OF PETITION

Dear Sir or Madam:

We hereby request that the Food and Drug Administration ("FDA") deny the suitability petition filed under Docket No. 03P-0398. A client of our firm has been developing a new drug application for the specific combination covered by the petition. In formal discussions with the client, officials from FDA's Center for Drug Evaluation and Research advised that new clinical data will be required to establish the safety of the combination. Because investigations must be conducted to show the safety of the drug product at issue, FDA must deny the suitability petition filed by International Regulatory Business Consultants, L.L.C., 21 C.F.R. § 314.93(e)(1).

Our client has made significant investment to determine applicable approval requirements, and it has relied on FDA's formal advice by initiating clinical studies. It would be inconsistent with law and principles of fundamental fairness for FDA to apply a different, less exacting standard for approval of an essentially identical product.

For the foregoing reasons, we request that FDA deny the referenced petition.

03P-0398

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Please contact me should you have questions concerning this letter or our client's drug development activity.

Sincerely,

Christina M. Markus

cc: Ms. Jane A. Axelrad
Office of Regulatory Policy

Mr. Gary J. Buehler
Office of Generic Drugs