DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-398/S-015

Sabex 2002, Inc.
C/O Roundtable Healthcare Partners
272 E. Deerpath Street
Suite 350
Lake Forest, IL 60045

Attention: George S. Zorich
U.S. Authorized Agent

Dear Mr. Zorich:

Please refer to your supplemental new drug application dated November 7, 2003, received November 10, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Regonol (pyridostigmine bromide) injection USP.

We acknowledge receipt of your submissions dated March 15 and May 13, 2004.

Your submission of May 13, 2004, constituted a complete response to our March 10, 2004, action letter.

This supplemental new drug application proposes the addition of new packaging components and a change in the (b)(4) along with updates to the labeling.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and submitted labeling (immediate container and carton labels submitted May 13, 2004).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 17-398/S-015." Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Kimberly Compton, Regulatory Project Manager, at (301) 827-7432.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director,
Division of Anesthetic, Critical Care, and
Addiction Drug Products
Office of New Drugs
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Rigoberto Roca
9/21/04 06:35:31 PM
for Bob Rappaport, M.D.