DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-398/S-014

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 July 11, 2003, received July 17, 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 August 20, September 16, 25, and 30, and October 6, 2003.

This supplemental new drug application provides for a change in manufacturing site.

We have completed our review of this application, as amended and it is approved, effective on the date of this letter.

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 15 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-014." Approval of this submission by FDA is not required before the labeling is used.

In addition we have the following comment.

Establish an acceptance criterion (specification) for the(b)(4)----------
(b)(4)--- impurity. Also, the (b)(4)----------meth----------
should be replaced by a ---------- ---eport the change in the annual report.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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, MD
Director
Division of Anesthetic, Critical Care, and
Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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

/s/

Bob Rappaport

10/17/03 03:13:28 PM