DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 020551/S-017 **SUPPLEMENT APPROVAL**

Abbott Laboratories
Dept. PA71/Bld. AP30-1E
200 Abbott Park Road
Abbott Park, IL 60064-6157

Attention: Patrick L. Carney
Manager, Global Regulatory Affairs

Dear Mr. Carney:

Please refer to your Supplemental New Drug Application (sNDA) dated July 31, 2009, received August 3, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nimbex® (Cisatracurium Besylate) Injectable, 10 mg/5 mL (2 mg/mL), 200 mg/ 20 mL (10 mg/mL), 20 mg/10 mL (2 mg/mL).

Reference is also made to your submissions dated August 6, 2009, and February 4, March 2 and 19, and April 9, 2010.

This Prior Approval supplemental new drug application provides for revised carton and container labels that have been aligned with the company's standardized format for pharmaceutical products.

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 enclosed, agreed upon labeling text.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "Final Printed Carton and Container Labels for approved NDA 020551/S-017." Approval of this submission by FDA is not required before the labeling is used.

LETTERS TO HEALTH CARE PROFESSIONALS

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

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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, please call Allison Meyer, Sr. Regulatory Health Project Manager, at (301) 796-1258.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Director
Division of Anesthesia and Analgesia Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure
Carton and Container Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20551	SUPPL-17	ABBOTT LABORATORIES	NIMBEX INJ 2MG/ML 10MG/ML

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

/s/

BOB A RAPPAPORT
06/02/2010