**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-214/S-021

Organon, Inc.
375 Mt. Pleasant Ave.
West Orange, NJ 07052

Attention: Dori Glassner
Associate Director, Regulatory Affairs

Dear Ms. Glassner:

Please refer to your supplemental new drug application dated February 12, 2004, received February 20, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zemuron (rocuronium bromide) for Injection.

We acknowledge receipt of your submissions dated April 27 and June 3, 2004.

This "Changes Being Effected in 30 days" supplemental new drug application provides for addition of barcodes to the 5 mL and 10 mL trade vials, as well as the 5 mL professional sample vials.

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

If a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to appropriate NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Ms. Allison Meyer, Regulatory Health Project Manager, at (301) 827-7410.

Sincerely,

*{See appended electronic signature page}*

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

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/s/

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Bob Rappaport

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