



NDA 20-214/S-016

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 April 30, 2001, received May 1, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zemuron (rocuronium bromide) for Injection.

Reference is also made to your submissions dated May 9, 2002, and August 5, 2003. Your submission of August 5, 2003, constituted a complete response to our June 26, 2003, action letter.

This supplemental new drug application provides for a revised **DOSAGE AND ADMINISTRATION** section of the package insert.

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

The final printed labeling (FPL) must be identical to the draft package insert submitted August 5, 2003.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no 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 20-214/016." Approval of this submission by FDA is not required before the labeling is used.

In addition, all previous revisions as reflected in the most recently approved labeling must be included. To facilitate review of your submission, please provide a highlighted or marked-up copy that shows the changes that are being made.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

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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. Kim Compton, 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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