



NDA 18-776/S-027

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 January 16, 2001, received January 23, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Norcuron (vecuronium bromide) for Injection.

We acknowledge receipt of your submission dated July 18 and October 10, 2001. Your submission of October 10, 2001, constituted a complete response to our July 20, 2001, action letter.

Reference is also made to the April 17, 2003, telephone conversation between you and Ms. Parinda Jani of this Division.

This supplemental new drug application provides for a revised **PRECAUTIONS** section of the package insert. A **Geriatric Use** subsection is added in accordance with 21CFR 201.57(f)(10).

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 and include the minor editorial revision indicated, to the draft package insert submitted October 10, 2001. These revisions are terms of the approval of this application.

As agreed to by you the following revisions will be made.

1. Revise the “**Drug Interactions:Thiopental**” subsection of the **PRECAUTIONS** section as follows.

Reconstituted Norcuron, which has an acid pH, should not be mixed with alkaline solutions (e.g., barbiturate solutions such as thiopental) in the same syringe or administered simultaneously during intravenous infusion through the same needle or through the same intravenous line (see DOSAGE AND ADMINISTRATION – Compatibility).

2. Revise the “**Compatibility**” subsection of the **DOSAGE AND ADMINISTRATION** section as follows.
 - a. Norcuron is also compatible in solution with: bacteriostatic water for injection (NOT FOR USE IN NEWBORNS). Use within 5 days of mixing with the above solution.
 - b. Reconstituted Norcuron, which has an acid pH, should not be mixed with alkaline solutions (e.g., barbiturate solutions such as thiopental) in the same syringe or administered simultaneously during intravenous infusion through the same needle or through the same intravenous line.
3. Revise the storage statement of the **HOW SUPPLIED** section as follows.

Store at 25⁰C (77⁰F). Excursions permitted to 15⁰C – 30⁰C (59⁰F - 86⁰F). See USP controlled room temperature.

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 18-776/027." 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.

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.

NDA 18-776/027

Page 3

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.
Acting 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
5/19/03 01:02:40 PM