NDA 75-218 July 30, 1999

ESI Lederle
Attention: J. Barton Kalis
2 Esterbrook Lane
Cherry Hill, NJ 08003-4099

Dear Sir:

This is in reference to your abbreviated new drug application dated October 1, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Vecuronium Bromide for Injection, 10 mg/10 mL vial and 20 mg/20 mL vial.

Reference is also made to your amendments dated May 8, August 25, October 9 and November 12, 1998; and May 10, June 18, and July 28, 1999.

We have completed the review of this abbreviated application and based upon the information you have presented to date, we have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Therefore, the application is **tentatively approved**. This determination is based upon information available to the Agency at this time, (i.e., information in your application and the status of current good manufacturing practices (CGMPs) of the facilities used in the manufacture and testing of the drug product), and is subject to change on the basis of new information that may come to our attention. The listed reference drug product (RLD) upon which you have based your application, Norcuron for Injection of Organon Inc., is subject to a period of patent protection. Therefore, final approval of your application may not be made effective pursuant to 21 U.S.C. 355(j)(5)(B)(ii) of the Act until the period has expired, i.e., August 20, 1999.

Because the Agency is granting a tentative approval for this application, please submit an amendment at least 3-weeks prior to Norcuron’s patent expiry; i.e., August 20, 1999. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved, and should include updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. An amendment should be submitted even if none of these changes were made.

This submission should be designated clearly in your cover letter as a MINOR AMENDMENT. In addition to this amendment, the Agency may request at any time prior to the date of final approval that you submit an additional amendment containing the information described above.

Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your application, or may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this abbreviated application, as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (CGMPs) are subject to Agency review before final approval of the application will be made.

This drug product may not be marketed without final Agency approval under Section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under Section 501 of the Act. Also, until the Agency issues the final approval letter, your product will not be deemed approved for marketing under 21 U.S.C. 355 and will not be listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list, (the "Orange Book"), published by the Agency. Should you believe that there are grounds for issuing the final approval letter prior to August 20, 1999, you should amend your application accordingly.

At the time you submit any amendments, you should contact Kassandra Sherrod, Project Manager, at (301) 827–5849, for further instructions.

Sincerely yours,

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research