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October 25, 2006

Division of Dockets Management:
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Citizen Petition

Dear Sir or Madam:

The undersigned submits this petition on behalf of a client in quadruplicate pursuant to 21 CFR 10.30 and in accordance with the regulations at 21 CFR 314.161, requesting the commissioner of the Food and Drug Administration to provide a determination whether a previously listed drug Mivacron (mivacurium chloride injection) has been withdrawn for safety or effectiveness for the reasons as outlined below. If not, it is requested that the FDA accept an ANDA for a generic version of the drug.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration (FDA) determine whether Mivacron - EQ 2 mg base/mL (NDA 20-098), held by Abbott Laboratories, Inc. has been voluntarily withdrawn from sale for safety or efficacy reasons. If not, it is requested of the FDA to accept an ANDA for a generic version of the drug and expedite the review of the application.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products that are eligible for submission as abbreviated new drug applications (ANDAs). The list, referred to as the *Orange Book*, contains all FDA-approved drug products. Mivacron, 2 mg base/mL was approved by the FDA on January 22, 1992 and was considered to be a "listed drug product" in the *Orange Book*. It should also be noted that FDA has also approved Mivacron In Dextrose 5% in Plastic Container (EQ 50 mg base/mL) on the same date and colisted it in the *Orange Book*.

An electronic query of the *Orange Book* made on October 20, 2006, does not show a listing for either Mivacron product. However, a query of discontinued drugs lists both products as being discontinued. It is believed that the NDA holder has either never marketed the product or discontinued sale of the Mivacron products solely for marketing reasons. The FDA has previously determined "for purposes of 21 CFR 314.161 and 314.162 that never marketing an approved product is equivalent to withdrawing the drug from sale (65 FR 38561).

Under FDA regulations, drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drug product's application for reasons of safety or effectiveness, or if the FDA

determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161(a)(1)).

As stated above at the time of submission of this petition, the Mivacron products appear in the discontinued section of the *Orange Book* and, therefore, either have been discontinued from sale or never marketed. Therefore, it is requested that the FDA determine whether the appearance of the Mivacron products in the discontinued section of the *Orange Book* represents a discontinuation for marketing reasons or safety or effectiveness reasons.

If the Mivacron products are withdrawn for marketing reasons, it is requested that the FDA accept applications for generic versions of the drug using Mivacron as the RLD. The withdrawal of Mivacron from the market leaves the absence of a short duration neuromuscular blocking agent that can be administered in small doses and have a short time to maximal blockade. Alternative neuromuscular agents are available on the market; however, our client's market research shows that there remains a demand for mivacurium. Hence, our client intends to submit an ANDA application for their mivacurium product. It is also requested to expedite the review of the ANDA as there is currently no mivacurium chloride injection product available in the US market. A request for expedited review has already been requested via a fax to the Office of Generic Drugs, but is also requested formally in this citizen petition.

Should Mivacron or a generic version of the drug become available on the market, and listed in the *Orange Book*, after the submission of this petition and prior to FDA response, this petition will be considered moot. Regulus will at that time take appropriate action to request withdrawal of the petition.

C. Environmental Impact

A claim for categorical exclusion of the requirement for submission of an environmental, assessment is made pursuant to 21 CFR 25.31.

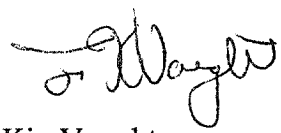
D. Economic impact

Pursuant to 21 CFR 10.30(p), economic impact information is to be submitted only when requested by the Commissioner. This information will promptly be submitted, if so requested.

E. Certification

The undersigned certifies that to the best of his knowledge and belief, this petition includes all information and views, on which the petitioner relies, and that includes representative data and information known to the petitioner, which are unfavorable to the petition.

Respectfully submitted,



Kip Vought
Director, Regulatory Affairs