DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR 23 2007

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Kip Vought
Director, Regulatory Affairs
Regulus Pharmaceutical Consulting, Inc.
4840 Pearl East Circle
Suite 201E
Boulder, Colorado 80301

Re: Docket No. 2006P-0445/CP1

Dear Mr. Vought:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated October 25, 2006. Your petition requests that the Agency determine whether Mivacron (mivacurium chloride injection), equivalent to 2 milligrams base/milliliter, the subject of new drug application (NDA) 20-098, was voluntarily withdrawn from sale for safety or effectiveness reasons.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2006P-0445

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