

NDA 214610

## **COMPLETE RESPONSE**

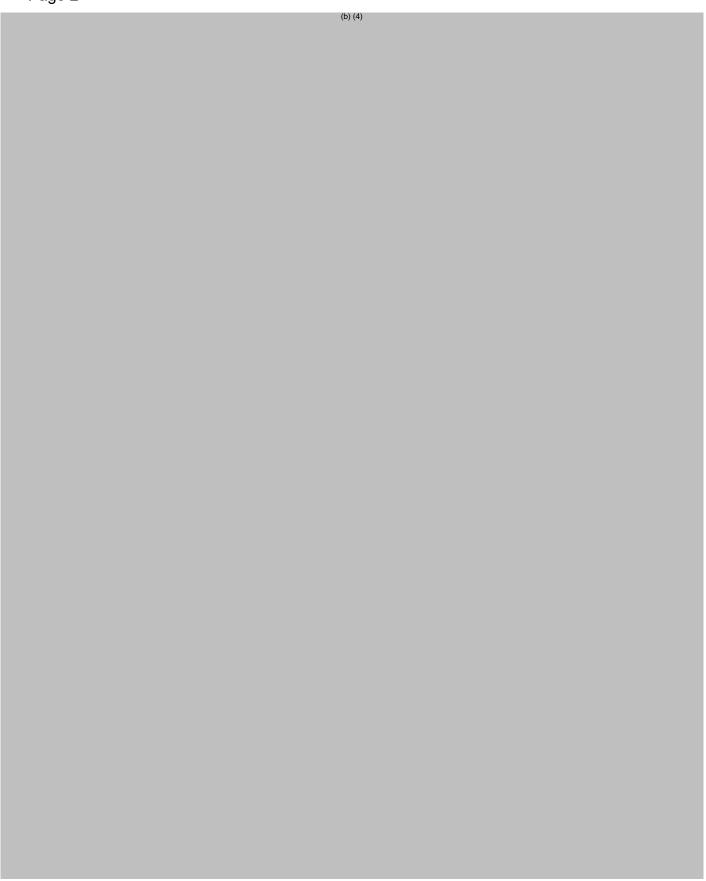
Fresenius Kabi USA, LLC Attention: Jennifer Gross, M.S. Senior Regulatory Affairs Associate Three Corporate Drive Lake Zurich, IL 60047

Dear Jennifer Gross:

Please refer to y	our new drug ap	pplication (ND	<b>A</b> )	(b) (4)		
			for	(b) (	4)	
	(amino acids wi	th electrolytes	, dextrose, a	and lipid i	njectable en	ıulsion).
We acknowledg complete respor	e receipt of your nse to our	amendment d	lated , action lett		, which cons	stituted a
	e receipt of your oal date by three	•	ment dated	(b) (4)	, which	
not reviewed for	vledge receipt of this action. You ence as part of y	may incorpora	ate applicab		, w is of the am	
that we cannot a	eted our review o approve this appl action below and	lication in its p	resent form	. We have	e described	our

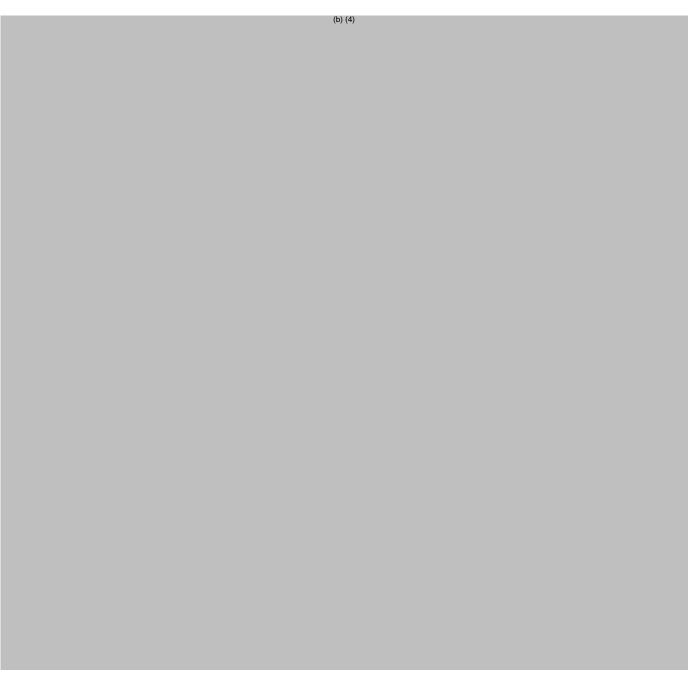
## **NONCLINICAL**

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	(b) (4)

# **PRODUCT QUALITY**



(b) (4)

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### PRESCRIBING INFORMATION

We reserve comment on the proposed labeling until the application is otherwise adequate. We encourage you to review the labeling review resources on the Prescription Drug Labeling Resources<sup>5</sup> and Pregnancy and Lactation Labeling Final Rule<sup>6</sup> websites, including regulations and related guidance documents and the Selected Requirements for Prescribing Information (SRPI) – a checklist of important format items from labeling regulations and guidances

<sup>&</sup>lt;sup>5</sup> https://www.fda.gov/drugs/laws-acts-and-rules/prescription-drug-labeling-resources

<sup>&</sup>lt;sup>6</sup> https://www.fda.gov/drugs/labeling-information-drug-products/pregnancy-and-lactation-labeling-drugs-final-rule

### **CARTON AND CONTAINER LABELING**

We reserve comment on the proposed labeling until the application is otherwise adequate.

#### **PROPRIETARY NAME**

Please refer to correspondence dated,	, which addresses the proposed
proprietary names, (b) (4)	. These names were found
conditionally acceptable pending appro-	val of the application in the current review cycle.
Please resubmit the proposed proprieta	ary names when you respond to all of the
application deficiencies that have been	identified in this letter.

### **SAFETY UPDATE**

When you respond to the above deficiencies, include a safety update as described at 21 CFR 314.50(d)(5)(vi)(b). The safety update should include data from all nonclinical and clinical studies/trials of the drug under consideration regardless of indication, dosage form, or dose level.

- (1) Describe in detail any significant changes or findings in the safety profile.
- (2) When assembling the sections describing discontinuations due to adverse events, serious adverse events, and common adverse events, incorporate new safety data as follows:
  - Present new safety data from the studies/clinical trials for the proposed indication using the same format as in the original submission.
  - Present tabulations of the new safety data combined with the original application data.
  - Include tables that compare frequencies of adverse events in the original application with the retabulated frequencies described in the bullet above.
  - For indications other than the proposed indication, provide separate tables for the frequencies of adverse events occurring in clinical trials.
- (3) Present a retabulation of the reasons for premature trial discontinuation by incorporating the dropouts from the newly completed trials. Describe any new trends or patterns identified.
- (4) Provide case report forms and narrative summaries for each subject who died during a clinical trial or who did not complete a trial because of an adverse event. In addition, provide narrative summaries for serious adverse events.

- (5) Describe any information that suggests a substantial change in the incidence of common, but less serious, adverse events between the new data and the original application data.
- (6) Provide updated exposure information for the clinical studies/trials (e.g., number of subjects, person time).
- (7) Provide a summary of worldwide experience on the safety of this drug. Include an updated estimate of use for drug marketed in other countries.
- (8) Provide English translations of current approved foreign labeling not previously submitted.

### **OTHER**

Within one year after the date of this letter, you are required to resubmit or take other actions available under 21 CFR 314.110 If you do not take one of these actions, we may consider your lack of response a request to withdraw the application under 21 CFR 314.65. You may also request an extension of time in which to resubmit the application.

A resubmission must fully address all the deficiencies listed in this letter and should be clearly marked with "RESUBMISSION" in large font, bolded type at the beginning of the cover letter of the submission. The cover letter should clearly state that you consider this resubmission a complete response to the deficiencies outlined in this letter. A partial response to this letter will not be processed as a resubmission and will not start a new review cycle.

You may request a meeting or teleconference with us to discuss what steps you need to take before the application may be approved. If you wish to have such a meeting, submit your meeting request as described in the draft guidance for industry *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products*.

The product may not be legally marketed until you have been notified in writing that this application is approved.

f you have any questions, contact	(4) (4)
	Sincerely,
	{See appended electronic signature page}
	(b) (4)

Center for Drug Evaluation and Research

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This is a representation of an electronic record that was signed
electronically. Following this are manifestations of any and all
electronic signatures for this electronic record.

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/s/

(b) (4)

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