

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

207648Orig1s000

STATISTICAL REVIEW(S)

STATISTICS FILING CHECKLIST FOR A NEW NDA/BLA

NDA/BLA Number: 207-648	Applicant: Fresenius Kabi USA, LLC	Stamp Date: 26SEP2014
Drug Name: SMOFlipid 20% Lipid Injectable Emulsion	NDA/BLA Type: NDA; 505(b)(1)	Indication: <div style="background-color: gray; width: 100px; height: 80px; margin-top: 5px;">(b) (4)</div>

On **initial** overview of the NDA/BLA application for filing:

	Content Parameter for RTF	Yes	No	NA	Comments
1A	Paper Submission: Index is sufficient to locate necessary reports, tables, data, etc.			X	This was an electronic submission by the sponsor.
1B	Electronic Submission: Indexing and reference links within the electronic submission are sufficient to permit navigation through the submission, including access to reports, tables, data, etc.	X			This electronic submission was eCTD compliant and of satisfactory quality.
2	ISS, ISE, and complete study reports are available (including original protocols, subsequent amendments, etc.)	X			There were adequate and complete clinical study reports (CSRs) along with ISE and ISS reports submitted.
3	Safety and efficacy were investigated for gender, racial, and geriatric subgroups (if applicable).		X		No subgroup analyses for gender and race were presented.
4	Data sets in EDR are accessible and conform to applicable guidances (e.g., existence of define.pdf file for data sets).	X			Tabulation datasets were provided, and they were of satisfactory quality along with being compliant with CDISC/SDTM data standards. Appropriate data definition files in Define.XML format were included for these tabulation datasets. Legacy analysis datasets, with corresponding data definition files in Define.PDF format, were also submitted.

IS THE STATISTICAL SECTION OF THE APPLICATION FILEABLE? YES

If the NDA/BLA is not fileable from the statistical perspective, please state below the reasons and provide comments to be sent to the Applicant.

N/A

STATISTICS FILING CHECKLIST FOR A NEW NDA/BLA

Please identify and list any potential review issues to be forwarded to the Applicant for the 74-day letter.

Content Parameter (possible review concerns for 74-day letter)	Yes	No	NA	Comment
Designs utilized are appropriate for the indications requested.	X			There were no studies identified as pivotal studies in this submission.
Endpoints and methods of analysis are specified in the protocols/statistical analysis plans.	X			Descriptive analysis methods were specified in the protocols. Also there were Statistical Analysis Plans (SAPs) submitted.
Interim analyses (if present) were pre-specified in the protocol and appropriate adjustments in significance level made. DSMB meeting minutes and data are available.			X	There were no traditional interim analyses conducted.
Appropriate references for novel statistical methodology (if present) are included.			X	The statistical methodology was not novel per se hence no references were presented.
Safety data organized to permit analyses across clinical trials in the NDA/BLA.	X			Safety datasets were submitted for each study individually; however this data can be integrated. ISS datasets were also submitted.
Investigation of effect of dropouts on statistical analyses as described by applicant appears adequate.		X		No investigation of effects of dropouts appears to have been submitted,

Reviewer's comment:

The submitted study results should be considered descriptive or observational only as they do not rely on appropriate inferential statistics or trial designs that would be considered adequate to support specific endpoint testing. At the time of filing, we considered this application as 'No Action Indicated'. The statistical reviewer will, however, be available to the clinical review team, as needed, to address specific questions or concerns that would require statistical response.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

BEHRANG VALI
12/10/2014

MICHAEL E WELCH
12/11/2014