

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

202832Orig1s000

STATISTICAL REVIEW(S)

STATISTICS FILING CHECKLIST FOR A NEW NDA/BLA

NDA Number: 202832

Applicant: Medefil Inc.

Stamp Date: Feb. 2, 2011

Drug Name: Sodium Chloride Injection, USP, 0.9% in plastic syringes
NDA/BLA Type: Original NDA

For diluting or dissolving drugs for intravenous.

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

	Content Parameter	Yes	No	NA	Comments
1	Index is sufficient to locate necessary reports, tables, data, etc.			x	No clinical information was submitted, as the Agency agreed previously. See the Agency's pre-meeting response to the 14-JUL-2008 per-NDA meeting in IND (b) (4). The response was issued on July 11, 2008
2	ISS, ISE, and complete study reports are available (including original protocols, subsequent amendments, etc.)			x	See comments in Item 1.
3	Safety and efficacy were investigated for gender, racial, and geriatric subgroups investigated (if applicable).			x	See comments in Item 1.
4	Data sets in EDR are accessible and do they conform to applicable guidances (e.g., existence of define.pdf file for data sets).			x	See comments in Item 1.

IS THE STATISTICAL SECTION OF THE APPLICATION FILEABLE? ___ Yes ___

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	See comments in Item 1.
Endpoints and methods of analysis are specified in the protocols/statistical analysis plans.			x	
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	See comments in Item 1.
Appropriate references for novel statistical methodology (if present) are included.			x	See comments in Item 1.
Safety data organized to permit analyses across clinical trials in the NDA/BLA.			x	See comments in Item 1.
Investigation of effect of dropouts on statistical analyses as described by applicant appears adequate.			x	See comments in Item 1.

File name: Statistics Filing Checklist for a NDA 202832

STATISTICS FILING CHECKLIST FOR A NEW NDA/BLA

Feng Zhou, M.S.	4/18/2011
Reviewing Statistician	Date
Joan Buenconsejo, Ph.D.	4/18/2011
Supervisor/Team Leader	Date

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/s/

FENG ZHOU
04/18/2011

JOAN K BUENCONSEJO
04/18/2011



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Translational Sciences
Office of Biostatistics

Statistical Review and Evaluation

CLINICAL STUDIES

NDA/Serial Number: NDA202832/S-00
Drug Name: 0.9% Sodium Chloride Injection, USP (b) (4) Syringe
Indication(s): Diluting or dissolving drugs for intravenous
Applicant: Medefil, Inc.
Date(s): 3/7/2011
Review Priority: 10-months
PDUFA 1/7/2012

Biometrics Division: Division of Biometrics II/Office of Biostatistics
Statistical Reviewer: Feng Zhou, M.S.
Concurring Reviewers: Joan Buenconsejo, Ph.D., Team Leader
Thomas Permutt, Ph.D., Division Director

Medical Division: Division of Pulmonary and Allergy Products
Xu Wang, M.D. (Medical Reviewer)
Clinical Team: Anthony Durmowicz, M.D. (Medical Team Leader)
Badrul Chowdhury, M.D., Ph.D. (Medical Division Director)
Project Manager: Eunice, Chung-Davies

Keywords: Clinical Studies

1. EXECUTIVE SUMMARY

1.1 Conclusions and Recommendations

Pursuant to 505(b)(2) of the Food, Drug and Cosmetic Act and in accordance with 21 C.F.R. Part 310.509, the sponsor, Medefil, Inc., submitted NDA 202832 for drug named (b) (4). (b) (4) is a sodium chloride injection, USP, 0.9%, supplied in a disposable, single-use plastic syringe, for diluting or dissolving drugs for intravenous, intramuscular or subcutaneous injection. The dosage forms of the product are 1mL, 2mL, 2.5mL, 3mL, and 5mL fill in 6mL syringe and 2mL, 5mL, and 10mL fill in 12 mL syringe for single use. As a basis for the 505(b)(2) submission route, the applicant cites Hospira's 0.9% Sodium Chloride Injection, USP, in fliptop plastic vial as the reference drug.

The Applicant discussed their product development plan with the Division of Gastroenterology Products in July 2008. The Agency concurred that no clinical studies would be required for the proposed product Chloride Injection, USP, 0.9% in plastic syringes [IND (b) (4), Draft response for pre-NDA meeting, Cristil Stark, M.S., Division of Gastroenterology Products, 07/11/2008]. The Center for Devices and Radiological Health (CDRH) determined previously that the syringe "is substantially equivalent to legally marketed predicate devices", and the Applicant "may market the device" [The Letter from Anthony D. Watson, BS, MS, MBA, Director, Division of Anesthesiology, General Hospitals, Infection Control, and Dental Devices, CDRH, FDA, 02/03/2011]. For this NDA submission, a CDRH inter-center consultation will be requested.

The NDA is a paper submission including only CMC data. There are no clinical section (Module 5) including clinical overview and summary in this NDA submission. The Applicant will be asked to provide a summary and update of safety information of the proposed product per regulation 21 CFR 314.50 (d)(5)(vi). Proposed labeling has been included in this submission. The content of the proposed labeling is similar to that of the reference product. An OSE labeling review consultation will be requested.

The NDA was submitted on January 31, 2011, and received on February 1, 2011. However, the submission was incomplete and was not accepted for filing since the appropriate user fee was not received at the time of the submission. The user fee for this application was waived on March 7, 2011. Therefore, the application has been accepted as of March 7, 2011. The PDUFA action date is January 7, 2012.

In this submission, no clinical information was submitted, as the Agency agreed previously. See the Agency's pre-meeting response to the 14-JUL-2008 per-NDA meeting in IND (b) (4). The response was issued on July 11, 2008. Therefore, there is no need for statistic review.

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/s/

FENG ZHOU
10/04/2011

JOAN K BUENCONSEJO
10/04/2011
I concur with Feng Zhou's review.