CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

202344Orig1s000

STATISTICAL REVIEW(S)

STATISTICS FILING CHECKLIST FOR A NEW NDA/BLA

NDA Number: 202344 **Applicant:** EffRx Pharmaceuticals SA **Stamp Date:** 2/15/2011

Drug Name: Steovess™ 70-mg Effervescent tablets **NDA Type:** Standard

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			
2	ISS, ISE, and complete study reports are available (including original protocols, subsequent amendments, etc.)			X	Cross reference to N20-560
3	Safety and efficacy were investigated for gender, racial, and geriatric subgroups investigated (if applicable).			X	Cross reference to N20-560
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	Cross reference to N20-560

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	Cross reference to N20-560
Endpoints and methods of analysis are specified in the protocols/statistical analysis plans.			X	Cross reference to N20-560
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	Cross reference to N20-560
Appropriate references for novel statistical methodology (if present) are included.			X	Cross reference to N20-560
Safety data organized to permit analyses across clinical trials in the NDA/BLA.	X			
Investigation of effect of dropouts on statistical analyses as described by applicant appears adequate.			X	Cross reference to N20-560

Kate Dwyer, Ph.D. March 30, 2011

Reviewing Statistician Date

Mahboob Sobhan, Ph.D. March 30, 2011

Supervisor/Team Leader Date

File name: 5_Statistics Filing Checklist for a New NDA_BLA110207

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/s/

KATE L DWYER
03/30/2011

MAHBOOB SOBHAN
03/31/2011

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

STATISTICAL REVIEW AND EVALUATION

CLINICAL STUDIES

NDA/Serial Number:	202344
Drug Name:	Binosto (Alendronate Sodium) Effervescent tablets, 70 mg
Indication(s):	1) Treatment of osteoporosis in postmenopausal women 2) Treatment to increase bone mass in men with osteoporosis
Applicant:	EffRx Pharmaceuticals SA
Date(s):	Submission Date: 2/15/2011 PDUFA Due Date: 12/15/2011
Review Priority:	Standard
Biometrics Division:	Division of Biometrics III
Statistical Reviewer:	Kate Dwyer, Ph.D.
Concurring Reviewers:	Mahboob Sobhan, Ph.D.
Medical Division:	Division of Reproductive and Urologic Drug Products
Clinical Team:	Stephen Voss, M.D., Medical Reviewer Theresa Kehoe, M.D., Team Leader
Project Manager:	Karl Stiller

Keywords: NDA review, clinical studies

BACKGROUND

This submission is a 505(b) (2) in support of Binosto for the treatment of osteoporosis in postmenopausal women and to increase bone mass in men with osteoporosis. This NDA refers to NDA 20-560 for nonclinical safety data and clinical efficacy and safety data. The efficacy of Binosto 70 mg tablets is based on bioequivalence of Binosto 70 mg tablets to Fosamax 70 mg tablets evaluated in Study AE-1212-001-EM which is included in this NDA.

CONCLUSION

There was no new clinical efficacy data submitted in support of this submission. Therefore, no statistical review was necessary.

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/s/

KATE L DWYER
09/09/2011

MAHBOOB SOBHAN
09/12/2011