CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

204078Orig1s000

STATISTICAL REVIEW(S)

STATISTICS FILING CHECKLIST FOR NDA 204-078

NDA Number: 204-078 **Applicant: Eclat** **Stamp Date: July 31, 2012**

Drug Name: Neostigmine **NDA/BLA Type: 505(b)(2)**

On **initial** overview of the sNDA (resubmission): **Studies 3005012 and 3005013**

	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**			
3	Safety and efficacy were investigated for gender, racial, and geriatric subgroups investigated (if applicable).		**X**		See comment 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 comment 2

IS THE STATISTICAL SECTION OF THE APPLICATION FILEABLE? Yes

Comments:

1. According to the regulations for NDA submissions, 21 CFR 314.50(d)(5)(v), the efficacy data should be summarized by gender, age, and racial subgroups. The applicant summarized efficacy and safety by age and gender but did not provide any information regarding racial subgroups. The medical officer reviewing this application suggests that the information does not likely exist.. However, this is a marketed unapproved drug for which no apparent concerns have arisen regarding efficacy and safety within racial subgroups. The lack of information regarding racial subgroups will not be considered a filing issue and will be discussed in the clinical review.

2. Efficacy and safety are supported by literature. There were no clinical studies conducted by the applicant.

STATISTICS FILING CHECKLIST FOR NDA 204-078

Content Parameter (possible review concerns for 74-day letter)	Yes	No	NA	Comment
Designs utilized are appropriate for the indications requested.			X	
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	
Appropriate references for novel statistical methodology (if present) are included.			X	
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	

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

/s/

DAVID M PETULLO
10/10/2012

DIONNE L PRICE
10/10/2012
concur