Reviewers' Guide

1. SDTM VALIDATION CRITERIA

[Instruction to be removed:
When the FDA processes study data received in the Study Data Tabulation Model (SDTM), format validation criteria is applied. The sponsor should be aware of errors that may be generated during the load of the data and specify any issues that the FDA may encounter.

The sponsor can search the FDA website for information on the SDTM validation specifications and include a list of errors that are present. If the sponsor has a pre-formatted error listing it can be inserted directly into the Reviewer's Guide. The following is intended as a guide and identifies the minimum content to be represented for FDA reviewers]

Table 1. Sample Error Explanations

Domain	***Error Message***	***Explanation***
EX	High Severity: This subject is not found in the EX domain	Subjects assigned to an AMCD but who are missing exposure data did not take study medication.
VS, LB, EG, DA	No Baseline result	Not an error: The subjects without Baseline result flags are Screen Failures
LB	Missing units on value	Not an error: Qualitative tests in LB have no standardized numeric results or units
CM	Start date expected when end date provided	Not an error: Start date is unknown

2. NOTES FOR THE TABULATION DATASETS

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2.1 DEMOGRPHICS (DM)

Two subjects in the Demographics (DM) domain were randomized but did not receive study drug. These subjects were assigned a treatment arm, but do no have any records in the Exposure (EX) domain. This will cause a HIGH severity error. A list of the subjects and treatment arms are in Table 3–1.

Table 3-1. Subjects Randomized and Did not receive Drug

3.