

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 15301

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TO: Walter Sloboda /BD-233	DIVISION DNDP
SUBJECT: Anorectic Study Reviews	
SUMMARY Attached is a draft outline of material to be checked by physicians reviewing anorectic studies. Let me also list the areas not included, on the assumption that you, your program, and perhaps tech aides will check them. Please correct me if the assumption is wrong. Number of subjects in study and in treatment groups. Randomization procedures. Stratification. Comparability of treatment and control groups and subgroups. Verification of completeness of data sheets, together with some assessment of importance of incompleteness. Verification that certain "standard" items are recorded. By "standard" I mean such things as data of entry into study, dates of follow-up visits, dosages employed. Checks for internal consistency. Examples might be: cross-checking patient number randomization against date of entry into study; checking intrasubject consistency (e.g., does subjects weight begin at 202 and go to 150 1 week later); examining age and weight distribution; checking "ideal weight" figures against height, age, sex, and frame recorded. Of course we rely on your analyses of firm's statistical model and techniques. Presentation of conclusions validly supported by the data in quantitative form, e.g., for each study, percent of excess weight lost because of active drug over applicable time intervals. Quantitative précis of study along these lines: study with 44 subjects, 21 active day, 23 placebo, 33 pts completed study..... Should any of these areas be amplified? or rephrased? Other areas you expect to analyze?	
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