Contains Nonbinding Recommendations

Draft Guidance on Pomalidomide

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient: Pomalidomide

Dosage Form; Route: Capsules; Oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 4 mg
   Subjects: Normal healthy males, general population; female subjects should be excluded from the bioequivalence (BE) study
   Additional Comments: a. Pomalyst® is contraindicated for use in women who are or may become pregnant. b. Pomalyst® was approved with a Risk Evaluation and Mitigation Strategy (REMS), including elements to assure safe use (ETASU). All pertinent elements of the REMS must be incorporated into the protocol and informed consent.

2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 4 mg
   Subjects: Normal healthy males, general population; female subjects should be excluded from the BE study
   Additional Comments: Please see additional comments above.

Analytes to measure (in appropriate biological fluid): Pomalidomide in plasma, using an achiral assay
Bioequivalence based on (90% CI): Pomalidomide

Waiver request of in vivo testing: 1 mg, 2 mg, and 3 mg strengths based on (i) acceptable BE studies on the 4 mg strength, (ii) proportionally similar formulation across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods Web site, available to the public at the following location: http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).