## The Camping Guidance

Guidance for Industry 180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day



U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER)

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## Multiple 30-Month Stays

- Not to be outdone by their generic counterparts, the brand industry also found ways to "leverage" Hatch-Waxman.
- They began to submit numerous patents on their products covering various parts of their formulation or other product components.

