WILSON SONSINI

Citizen Petitions Are Crucial In Managing A Drug's Life Cycle

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BYLINED ARTICLES

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A citizen petition is a tool for petitioning the government which, properly applied, can be used to:

- 1. Advance the goal(s) of a pharmaceutical company;
- 2. Gain advantage(s) against a competitor (branded or generic); or
- 3. Alert the U.S. Food and Drug Administration of a potential public health hazard.

These objectives need not be mutually exclusive. Although we focus here on drugs—prescription and over-the-counter—citizen petitions have been used in other regulated categories such as dietary supplements.

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