Cannabis Regulatory Process:

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FDA
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CDB Regulatory Proposal

A. Regulatory strategy

- 1. All submissions to FDA through NDIN Process.
- 2. No Self-Affirmed GRASS.
- 3. Enforcement: Any Company with a product currently in the market must expect a delayed NDI process of any NDIN.
- 4. IP Protection: Market exclusivity for 5 years for patented molecules or "Master file."
- 5. Federal re-emption to avoid conflicts with state authority.









