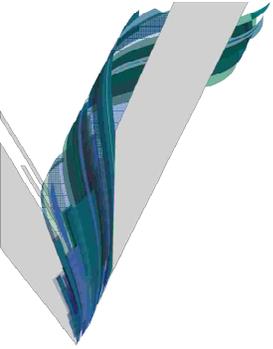


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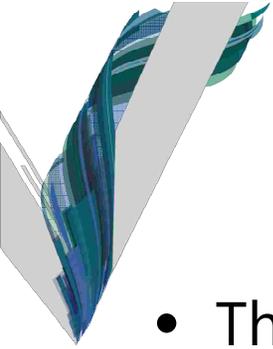
Supply Side West: Navigating the Business of the Nutraceutical Industry

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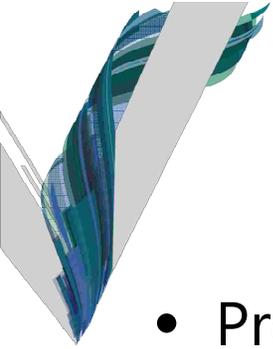


Legal/Regulatory Concerns: Merger & Acquisitions



Preparing for Due Diligence - Buy Side

- Think about the types of documents you want to request:
 - A preliminary review of publicly available information (e.g., what claims are made on the website) can give you an idea of what types of support for those claims you will want to request.
- What is a priority?
 - It can often take awhile to get documents...
 - What are the documents that are most important for purchasing decisions?



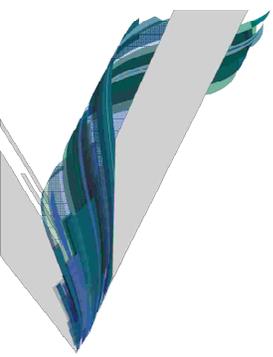
Prepare for Due Diligence – Sell Side

- Prepare documents for sharing with other side.
- Think about how to share documents securely (e.g., data rooms).
- Attorney/Client Privilege issues.



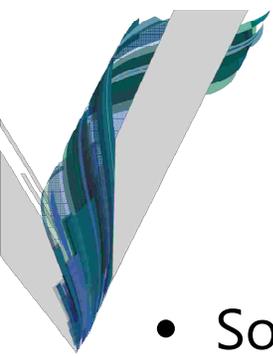
Food and Drug Administration

- Facility registrations
- GMP SOPs
- Product labelling
- Documents related to ingredient issues (e.g., GRAS or NDI status)
- FDA Inspection related issues:
 - Pre-FDA inspection third-party audit reports (if applicable)
 - FDA inspection
 - Form 483s and responses
- Warning Letters or Untitled Letters and responses
- Records of any FDA import issues and resolution
- Recalls
- Any other FDA related documents (e.g., FDA lawsuits, detention)



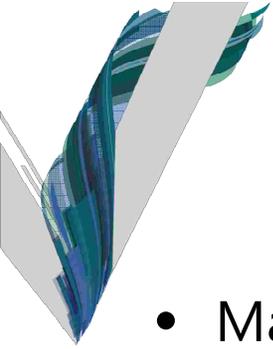
Other Federal and State Regulatory Issues

- USDA National Organic Program documents:
 - Do organic claims appear in labeling or advertising?
 - Organic certification documents.
- California Proposition 65:
 - Are current ingredients/materials on the Proposition 65 list?
 - Is there potential for future issues (i.e., possibility for heavy metals without testing in place)?
 - Have they had any past Proposition 65 lawsuits/settlements?



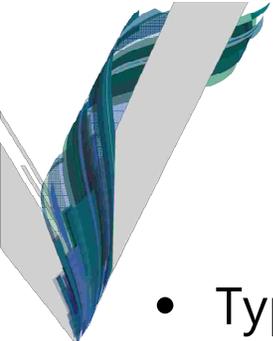
Advertising and Marketing

- Sources:
 - Websites and Social Media
 - Any print advertisements
 - Review YouTube Channel
- Key Questions:
 - What types of documents do you have to request/provide based on claims (i.e., if there are “gluten free” claims, you want to provide/request gluten testing)?
 - Are the current claims made for the products permissible (e.g., drug claims)?
 - Do the claims or marketing create other liabilities (e.g., IP infringement, comparative claims to competitors, etc....)?
 - If claims will need to be changed, how much will the change affect revenue?



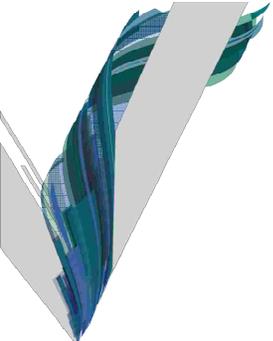
False/Misleading Advertising Challenges

- Many different possible sources of challenges to advertising or marketing:
 - Better Business Bureaus Advertising Self-Regulatory Council: NAD/ERSP self-regulatory advertising challenges
 - Competitor/Lanham Act challenges
 - FTC Civil Investigative Demands, Complaint, or Consent Decrees related to misleading or unfair advertising practices
 - Consumer Class Action Lawsuits
 - California Consumer Legal Remedies Act (CLRA) demand letters and complaints
 - State Attorney General actions
 - County District Attorney (mostly in California) actions



Past and Current Litigation

- Types of Litigation:
 - General contracts
 - Products liability
 - IP
 - Advertising
 - Etc....
- Buy Side: important to request documents related to both filed and threatened (e.g., CLRA demand letter) litigation, and how/if they were resolved
 - Think about how past litigation settlements have been implemented (e.g., Did they agree to discontinue a claim in a settlement, but are still using the claim?).
- Sell Side: when possible, think about providing information regarding the resolution of threatened or filed litigation
 - The risk posed by an ongoing litigation is much different than a litigation that has been settled or dismissed.



FTC Competition – Agency Review

- Mergers and acquisitions that exceed certain size thresholds may require notification to the FTC and DOJ before closing (often referred to as an “HSR filing” in reference to the Hart-Scott-Rodino Act of 1976 which established the notification process).
- For 2017, an HSR filing is required if the value of a transaction exceeds \$80.8 million, other thresholds relating to the size of the parties are met, and no exemptions apply. Note that the dollar thresholds increase slightly on a yearly basis.
- If an HSR filing is required, the parties cannot close the transaction prior to expiration of the HSR waiting period, which is typically 30 days. The FTC or DOJ can extend this waiting period by issuing a request for additional information and/or challenging the deal.
- Even if a transaction does not require an HSR filing, the FTC and DOJ can still investigate and challenge deals (before or after they are consummated) that they deem anticompetitive, so it is always smart to consult with antitrust counsel when contemplating any transaction with competitive implications.



FTC Competition - Mergers/Acquisitions Likely to Attract Agency Attention

- Section 7 of the Clayton Act prohibits mergers and acquisitions when the effect “may be substantially to lessen competition or tend to create a monopoly,” and the FTC and DOJ have broad jurisdiction to investigate and/or challenge any transaction that they believe meets this standard.
- In practice, horizontal mergers (deals between horizontal competitors) that create or enhance market power are most likely to attract attention from the agencies.
 - For example, a merger between two competitors resulting in large market share in a market where there are few other competitors is more likely to garner agency interest than a deal between two small competitors that does not result in large market share.
- Vertical mergers (between, for example, a buyer and a seller) and potential competition mergers (in which one competitor buys a company that is planning to enter its market) are also sometimes investigated and/or challenged if they are viewed as harming competition in a given market.
 - An example of competitive harm in the context of a vertical merger would be if the merger makes it difficult for competitors to gain access to an important component product or channel of distribution.
 - An example of competitive harm in the context of a potential competition merger would be the elimination of a future competitor and the increased competition that would have resulted from the firm’s entry.