Developing a Successful Natural Products Industry:
Quality, Claims, Cyber and Intellectual property

Presented by
Shari Claire Lewis, Esq.
Marc Ullman, Esq.

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Quality/Good Manufacturing Practices

• The Food and Drug Administration was given the authority to protect and promote public health under the U.S. Federal Food, Drug, and Cosmetic (FD&C) Act.

• The FD&C Act is a set of laws that were passed by the US Congress in 1938 to ensure the safety of food, drugs, and cosmetics.

• Herbs are generally regulated as food/dietary supplements
Quality/Good Manufacturing Practices

- FDA issues regulations to implement the FDCA
- GMPs are a set of regulations requiring that companies have procedures relating to the documentation of the proper design, monitoring, and control of manufacturing processes and facilities to ensure product has the identity, strength, quality, and purity which it is represented to possess.
- The “c” in cGMP means Current and requires the use of modern technologies, up-to-date systems, and innovative approaches to comply with the regulations but also achieve higher quality through continual improvement.
Quality/Good Manufacturing Practices

- Ensure product quality, purity, consistency and safety

- Consumers get accurately labeled and unadulterated (pure/safe) dietary supplements by requiring all consistent quality controls be in place at all facilities that manufacture, package or hold supplements
  - Important for consumer confidence which had been undermined in the US by poor quality/unreliable products
Quality/Good Manufacturing Practices

- Covers everything from the receipt and identification of raw materials, the exact manufacturing procedures used (nature of process and equipment) to the bottling and storage of finished product

- Critical component is record keeping
  - Get More Paper, Giant Mountains of Paper

- Registration and inspection of all domestic and foreign facilities

- USFDA memorandum of Understanding/Training
Quality/Food Safety Modernization Act

• January 4, 2001 - The most sweeping reform of US food safety laws in more than 70 years. Ensure the U.S. food supply is safe by focusing on preventing rather than responding to contamination

• Key components
  – Require all facilities to implement Hazard Analysis and Risk Based Preventative Control
    • Understand the inherent risks in food processing and handling and take affirmative steps to control/minimize them
  – Every facility holding food must have a written food safety plan
  – Supply chain control
    • Farm to table traceability
    • Foreign vendor verification and qualification
      – Can lead to equivalent of “global entry” at point of import

• USFDA registration and inspection of all domestic and foreign facilities

• FDA Memorandum of Understanding/training
Structure / Function Claims
Drug Claims

• Conventional Foods / Dietary Supplements
  – Intended to affect the structure or function of the body of man (Support Heart Health)

• Drug / Disease Claims (government approval)
  – intended to diagnosis, cure, mitigate, treat or prevent disease. (Prevent Cardio-Vascular Disease)

• Health Claims – (government approval)
  – describes a relationship between food or dietary supplement and reduced risk of disease (Calcium Reduces the Risk of Osteoporosis)
Substantiation / Evidence
Structure / Function Claims

• Dual Enforcement
  – FDA and US Federal Trade Commission
• What would experts in the relevant area of study generally consider to be adequate
• All forms of scientific research are considered
• Well-controlled human clinical studies are the best
  – Required for drugs
• Animal and in vitro studies also considered
• When a clinical trial is not possible epidemiologic evidence may be acceptable
Traditional Use Claims

- Claims based on historical or traditional use should be substantiated by scientific evidence.
- If a traditional claim is not supported by science, it may require a disclaimer that the claim has not been scientifically verified.
- Is the form of the product consistent with the traditional use?
  - Whole herb vs. extract
Intellectual Property
Definition of Intellectual Property

• Intellectual property (IP) refers to creations of the mind. Examples include music, literature, and other artistic works; discoveries and inventions; and words, phrases, symbols, and designs.

• IP Owners granted certain exclusive intellectual or industrial property rights, such as copyrights, patents, and industrial design rights; trademarks, trade dress, and in some jurisdictions trade secrets protections.

• Intellectual property rights are themselves a form of property, called intangible property
Forms of Intellectual Property

Copyright is a form of intellectual property that encompasses original works of authorship fixed in a tangible medium of expression.

A Trademark is any word, name, symbol, or device, or any combination thereof, used to identify and distinguish goods or services from those of another and to indicate the source of the goods or services, even if that source is unknown.
Internet Issues

Cybersquatting - registering, trafficking in, or using an Internet domain name with bad faith intent to profit from the goodwill of a trademark belonging to someone else. The cybersquatter then offers to sell the domain to the person or company who owns a trademark contained within the name at an inflated price.


- World Intellectual Property Association
  - Self-funding agency of the United Nations, with 191 member states. International IP dispute resolution services
  - In 2017 trademark owners filed an all-time high of 3,074 WIPO cases under the Uniform Domain Name Dispute Resolution Policy (UDRP).
Internet Issues

• Social Media – Establishing and maintaining control of your social media presence, such as on Facebook, Instagram, Twitter, Blogs, etc.

• Potential Issues:
  – False ID or Counterfeit
  – Unauthorized control of page or content
  – Misbranded content or passing off
  – Trolling, disparagement, anti-competitive action
  – Offensive, insensitive or discriminatory language
Privacy and Cybersecurity
Scary Statistics

• 90% of world data created in past 2 years
• 3.8 plus billion Internet users
• More data created in 2017 than in previous 5,000 years
• Greater cyber insecurity in disadvantaged countries*
  – More often targeted
  – May be used as conduit or soft opening
  – Greater impact on vital communications systems (even if generally less dependent on online network) leads to greater dysfunction and slower recovery

Data Breach in a Global Economy*

- 2017 data breach statistics:
  - Global cost increased 6.4%
  - Per capita cost increased 4.8%
  - Number of records lost increased 2.2%
- Data breach response most costly in U.S., Canada and Middle East; Least costly in India and Brazil
- Fast response to data breach leads to lower costs
- Hackers and criminal insiders cause most data breaches and cost more per record than human or computer error

* Ponemon Institute Report 2017
Every 21\textsuperscript{st} Century business is an e-business!

- 24\% data breaches occurred in Food and Beverage Industry*

- Agroterrorism – intentional contamination/spoilage of food supply and agricultural resource
  - Goal is anticompetitive, economic harm, political destabilization

- Global market – requires validation, security, dependability
  - Compliance with national or regional regulations

*Trustwave’s 2013 Global Security Report
Privacy

- The right/interest in controlling personal or confidential information about one’s self
  - What information is collected
  - How information is collected
  - Who can see/use information
  - How the information is used
  - Accuracy of information
  - Disposal and security of information

- Personal or private information is defined differently around the world
Proprietary Information

- Entities may not have a “privacy” interest
- Right to protect “proprietary” information
  - Business methods
  - Business plans
  - Formulas and recipes
  - Contract terms
  - Employee information
  - Intellectual property
Cybersecurity

Protection of private or proprietary information
  – Unauthorized access, intrusion or control
  – Attacks on integrity or accuracy
  – Policies and procedures designed to limit access, dissemination, misuse, disposal
  – Response and recovery to data breach incident
Small Island Developing States
Cybersecurity Laws*

- Legislation – 9 countries (31%)
- Draft Legislation – 4 countries (14%)
  - (at least 2 passed since UN published)
- No Legislation – 10 countries (34%)
- No data/unknown – 6 countries (21%)

SIDS Dock Member Legislation

- Both privacy and cybersecurity laws – 11 Members
- Solely privacy law – 1 Members
- Solely cybersecurity law – 5 Members
- No Legislation – 8 Members
- Some SIDS Dock Members may adopt or follow cybersecurity/privacy legislation of other nations
### World Models of Privacy Protection

**International Association of Privacy Professionals**

<table>
<thead>
<tr>
<th>World Models of Privacy Protection</th>
<th>Brief Description</th>
<th>Example Governing Body</th>
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<tbody>
<tr>
<td>Comprehensive Model</td>
<td>All-inclusive general law that governs personal information collection and usage in both the public and private sectors. An oversight body ensures compliance with the law.</td>
<td>European Union</td>
</tr>
<tr>
<td>Co-Regulatory Model</td>
<td>Specific industries develop rules for privacy protection. Enforced by the industry, overseen by a privacy agency.</td>
<td>Australia, Canada, New Zealand</td>
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<tr>
<td>Sectoral Model</td>
<td>Sector specific laws. Various regulatory bodies act as enforcement. State or regional enforcement</td>
<td>Japan, United States</td>
</tr>
<tr>
<td>Self-Regulatory Model</td>
<td>Industry associations create and enforce rules and regulations.</td>
<td>Payment Card Industry Data Security Standard, Online Privacy Alliance</td>
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## Potentially Relevant National Laws

<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>LAW</th>
<th>RESPONSIBLE AUTHORITY</th>
</tr>
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<tbody>
<tr>
<td><strong>China</strong></td>
<td><strong>The Cybersecurity Law of the People’s Republic of China</strong> (Eff. June 1, 2017)</td>
<td>Cyberspace Administration of China (CAC)</td>
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<tr>
<td></td>
<td>* Earlier laws include The Decision on Strengthening Online Information Protection; and The National Standard of Information Security Technology – Guidelines for Personal Information Protection with Information System for Public and Commercial Services. (Both rules are collectively referred to as the “General Data Protection Law”)</td>
<td></td>
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<td><strong>Australia</strong></td>
<td><strong>Data Breach Notification Law (DBN)</strong> (Eff. February 22, 2018)</td>
<td>The Office of the Australian Information Commissioner (OAIC)</td>
</tr>
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<td></td>
<td><strong>Privacy Act of 1988</strong></td>
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<tr>
<td><strong>New Zealand</strong></td>
<td><strong>Privacy Act 1993</strong></td>
<td>The Privacy Commissioner’s Office National Cyber Security Centre</td>
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<td><strong>Intelligence and Security Act 2017</strong></td>
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<td></td>
<td><strong>2015 NZ Cyber Security Strategy</strong></td>
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<tr>
<td><strong>Canada</strong></td>
<td><strong>The Personal Information Protection and Electronic Documents Act (PIPEDA)</strong></td>
<td>The Privacy Commissioner of Canada And provincial officials</td>
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<td></td>
<td><strong>Candada’s Anti-Spam Law (“CASL”)</strong></td>
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<tr>
<td></td>
<td><strong>Various Provincial Statutes and Regulations</strong></td>
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USA Privacy and Security

• Federal regulations by industry, e.g.
  – HIPPA (Private health information)
  – Gramm-Leach-Bliley Act (Private financial information)
  – Food and Drug Administration
  – Federal Trade Commission
  – Federal Bureau of Investigation, etc.

• State by state regulation, 50 states plus
  – Data breach legislation
  – Statutory or common law rules

• Private industry standards, e.g., PCI (credit card)
General Data Protection Regulation “GDPR”

- Effective May 25, 2018 (but regulations still not finalized)
- EU resident’s personal information (per EU definition)
- Applies to EU entities, non-EU entities:
  - EU subsidiary,
  - regularly provide goods or services to EU residents, or
  - “collect and process” data concerning EU residents
- Shift control from Data Collectors to Data Subjects and enhanced cybersecurity and accountability
GDPR “Privacy Principles”

1. Data processed “lawfully, fairly and transparently”
   - Legally permissible purpose
   - Opt-in, not opt-out

2. Data collection limited to what is “adequate, relevant and necessary…” for the purpose of collection

3. Data used for “specified, explicit and legitimate manner” and not further processed inconsistently with that purpose
GDPR “Privacy Principles”

4. Data accurate, up to date, and corrected without delay

5. Data’s “integrity” and “confidentiality” must be protected including appropriate “technical...or “organizational methods” (cybersecurity)

6. Non-anonymized data must be kept for only so long as needed for the purpose for which subject consented and disposed of in secure fashion.
GDPR Cybersecurity

- Collectors must “demonstrate” compliance with GDPR principles
  - what personal data is held
  - who has access
  - with whom it is shared
  - how is it protected
- Update privacy notices to provide full and clear disclosure, clear opt-in provisions and options to update subject’s preferences
- Analysis and upgrade the security of how data is collected, stored, and disposed
GDPR Cybersecurity - Data Breach

- Establish procedures to detect, report and investigate data breach
- Establish “rapid response plan”
- Provide notice to all affected subjects within 72 hours
- May be required to appoint “Designated Privacy Officer” under some circumstances
- Privacy by design in systems going forward
GDPR Enforcement

• Supervisory Authorities (SA) may:
  – Audit or demand supporting documentation (burden on data collector or processor)
  – Issue warnings, orders of remediation or erasure of data
  – Suspend transfer of data to non-EU country

• Fines
  – Violation of GDPR obligations – greater of 2% of annual global turnover or € 10 million
  – Violation of Data Subjects rights – greater of 4% of annual global turnover or € 20 million
SIDS Dock Opportunity – Privacy By Design

- Data protection and privacy integrated into technology
- Part of the culture and processes
- Technical and organizational measures at the planning stage
- Know who is responsible to do what
- Protect against intrusion, but plan for the inevitable
What Next?

- Practical steps at the planning stage
- Create cybersecurity/privacy protocol (revisit as technology evolves)
- Robust technical and physical security practices
- Complete vetting of vendors
- Employee handbooks, job guidelines and training
- Website Terms of Use/ Privacy Policies
- Non-disclosure (Confidentiality) Agreements
- Rapid Response Plan
- Document Retention and Destruction Policy
- Insurance
What Next?

TRAIN, TEST, ENFORCE, UPDATE, TEST ... OH MY!
We Are Here To Help!

Resource For Education And Action

Nancy A. Del Pizzo  
(201) 287-2472  
nancy.delpizzo@rivkin.com

Marc Ullman  
(516) 357-3240  
marc.ullman@rivkin.com

Steven Shapiro  
(212) 455-6542  
steven.shapiro@rivkin.com

Shari Claire Lewis  
(516) 357-3292  
Shari.lewis@rivkin.com