Prepared for

SIDSDOCK
SMALL ISLAND DEVELOPING STATES
ISLAND ENERGY FOR ISLAND LIFE

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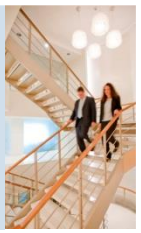

Developing a Successful Natural Products Industry: Quality, Claims, Cyber and Intellectual property

Presented by

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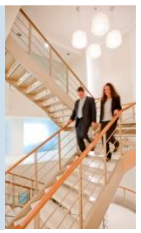
July 21, 2018

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



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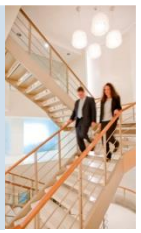
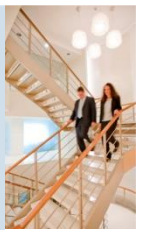
Quality/Good Manufacturing Practices

- 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.



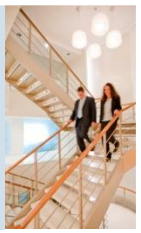
Quality/Good Manufacturing Practices

- 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



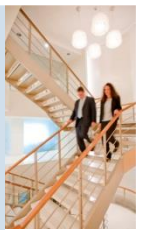
Quality/Good Manufacturing Practices

- Covers everything from the receipt and identification of 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



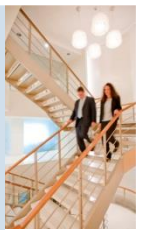
Quality/Food Safety Modernization Act

- 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

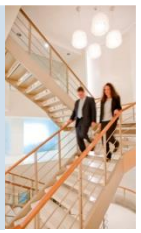


Structure / Function Claims
Drug Claims

- 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)

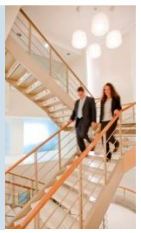


Substantiation / Evidence Structure / Function Claims

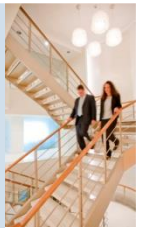


- Dual Enforcement
  - FDA and US Federal Trade Commission
- What would experts in the relevant area of study generally consider to be adequate
- All forms of scientific research are considered
- Well-controlled human clinical studies are the best
  - Required for drugs
- Animal and in vitro studies 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

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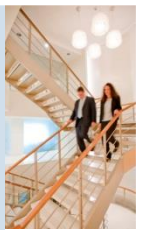
Definition of Intellectual Property

- 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



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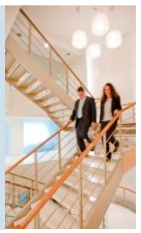
Forms of Intellectual Property

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.



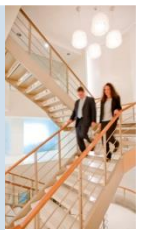
Internet Issues

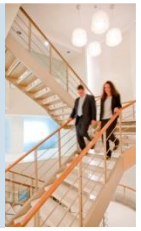
Cybersquatting - registering, trafficking in, or using an Internet domain name with bad faith intent to profit from the goodwill of a trademark belonging to someone else. The cybersquatter then offers to sell the domain to the person or company who owns a trademark contained within the name at an inflated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

- U.S. Anticybersquatting Consumer Protection Act (ACPA) of 1999.
- 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

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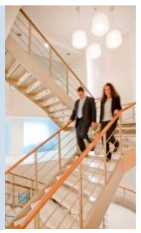
Scary Statistics

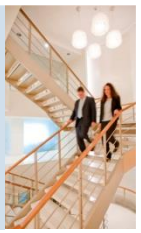
- 90% of world data created in past 2 years
- 3.8 plus billion Internet users
- More data created in 2017 than in previous **5,000** years
- Greater cyber insecurity in disadvantaged countries*
  - More often targeted
  - May be used as conduit or soft opening
  - Greater impact on vital communications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

** (Ellada Gamreklidze (2014) Cyber security in developing countries, a digital divide issue, The Journal of International Communication, 20:2, 200-217, DOI: 10.1080/13216597.2014.954593)*



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

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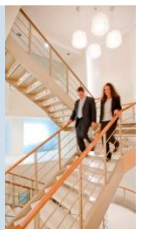
Every 21st Century business is an e-business!

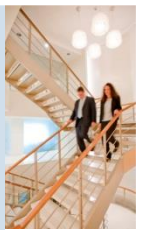
- 24% data breaches occurred in Food and Beverage Industry*
- Agroterrorism – intentional contamination/spoilage of food supply and agricultural resource
  - Goal is anticompetitive, economic harm, political destabilization
- Global market – requires validation, security, dependability
  - Compliance with national or regional regulations



**Trustwave's 2013 Global Security Report*

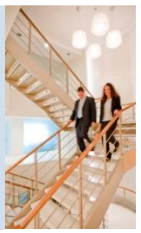
Privacy

- 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

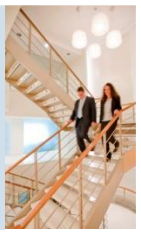
- Entities may not have a “privacy” interest
- Right to protect “proprietary” information
  - Business methods
  - Business plans
  - Formulas and recipes
  - Contract terms
  - Employee information
  - Intellectual property



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



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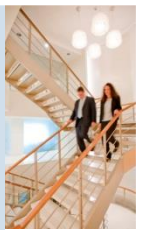
Small Island Developing States Cybersecurity Laws*

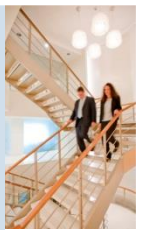
- Legislation – 9 countries (31%)
- Draft Legislation – 4 countries (14%)
  - (at least 2 passed since UN published)
- No Legislation – 10 countries (34%)
- No data/unknown – 6 countries (21%)



*"Data Protection and Privacy Legislation Worldwide" http://unctad.org/en/Pages/DTL/STI_and_ICTs/ICT4D-Legislation/eCom-Data-Protection-Laws.aspx

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



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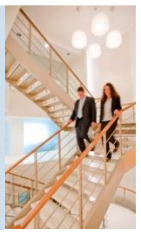
World Models of Privacy Protection

International Association of Privacy Professionals

World Models of Privacy Protection	Brief Description	Example Governing Body
Comprehensive Model	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.	European Union
Co-Regulatory Model	Specific industries develop rules for privacy protection. Enforced by the industry, overseen by a privacy agency.	Australia, Canada, New Zealand
Sectoral Model	Sector specific laws. Various regulatory bodies act as enforcement. State or regional enforcement	Japan, United States
Self-Regulatory Model	Industry associations create and enforce rules and regulations.	Payment Card Industry Data Security Standard, Online Privacy Alliance



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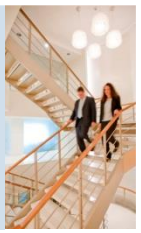
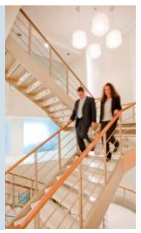
Potentially Relevant National Laws

COUNTRY	LAW	RESPONSIBLE AUTHORITY
China	**The Cybersecurity Law of the People's Republic of China** (Eff. June 1, 2017) * 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")	Cyberspace Administration of China (CAC)
Australia	**Data Breach Notification Law (DBN)** (Eff. February 22, 2018) **Privacy Act of 1988**	The Office of the Australian Information Commissioner (OAIC)
New Zealand	**Privacy Act 1993** **Intelligence and Security Act 2017** **2015 NZ Cyber Security Strategy**	The Privacy Commissioner's Office National Cyber Security Centre
Canada	**The Personal Information Protection and Electronic Documents Act (PIPEDA)** **Candada's Anti-Spam Law ("CASL")** **Various Provincial Statutes and Regulations**	The Privacy Commissioner of Canada And provincial officials



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)



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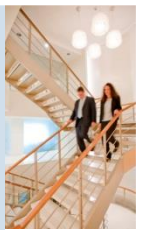
General Data Protection Regulation "GDPR"

- 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



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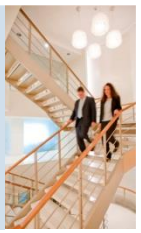
GDPR "Privacy Principles"

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



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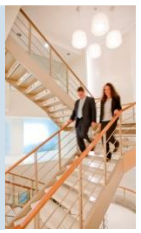
GDPR "Privacy Principles"

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

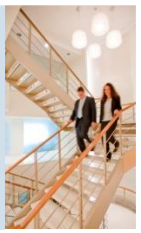
5. Data's "integrity" and "confidentiality" must be protected including appropriate "technical…or "organizational methods" (cybersecurity)

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



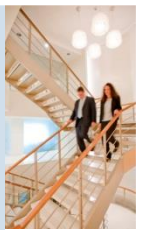
GDPR Cybersecurity

- 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

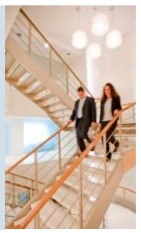
- Establish procedures to detect, report and investigate data breach
- Establish “rapid response plan”
- Provide notice to all affected subjects **within 72 hours**
- May be required to appoint “Designated Privacy Officer” under some circumstances
- Privacy by design in systems going forward



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

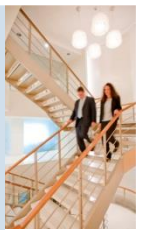
SIDS Dock Opportunity – Privacy By Design



- 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



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What Next?

TRAIN, TEST, ENFORCE, UPDATE, TEST … OH MY!

We Are Here To Help!

Resource For Education And Action

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