THE GOAL IS NOT TO STRESS YOU OUT!
THE GOAL

• Is to share information so that you are better able to create, produce, label and market your aromatherapy products, effectively, safely, and in accordance with the laws governing cosmetics.

• My personal goal is to ease your mind and to provide you with resources to support you and your business.
HOWEVER, YOU MAY WANT TO MEDITATE OR TAKE AN AROMATIC BATH AFTER THIS WEBINAR!
DEFINING COSMETICS

United States
Canada
Europe
UNITED STATES: FDA DEFINITION OF “COSMETICS”

Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)

The Federal Food, Drug and Cosmetic Act (FD&C Act) defines cosmetics by their intended use, as “articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body.....for cleansing, beautifying, promoting attractiveness, or altering the appearance” (FD&C Act, sec. 201 (i)).

Products include:

- Skin moisturizers
- Perfumes
- Lipsticks, fingernail polishes, eye and facial makeup preparations
- Cleansing shampoos
- Hair products: permanent waves, hair colors
- Deodorants
- As well as any substance intended for use as a component of a cosmetic product.
An Aromatherapy product is categorized according to its **intended use**.

- **Cosmetic:** see definition on previous slide.

- **Drug:** The FD&C Act defines drugs, in part, by their intended use, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals" [FD&C Act, sec. 201(g)(1)].
HOW IS A PRODUCT'S INTENDED USE ESTABLISHED?

• Claims stated on the product labeling, in advertising, on the Internet, or in other promotional materials. Certain claims may cause a product to be considered a drug, even if the product is marketed as if it were a cosmetic. Such claims establish the product as a drug because the intended use is to treat or prevent disease or otherwise affect the structure or functions of the human body. Some examples are claims that products will restore hair growth, reduce cellulite, treat varicose veins, increase or decrease the production of melanin (pigment) in the skin, or regenerate cells.
HOW IS A PRODUCT'S INTENDED USE ESTABLISHED?

- Consumer perception, which may be established through the product's reputation. This means asking why the consumer is buying it and what the consumer expects it to do.
- Ingredients that cause a product to be considered a drug because they have a well-known (to the public and industry) therapeutic use. An example is fluoride in toothpaste.

***Social Media: Twitter, Facebook etc.
REGULATIONS FOR SOAP

• Soap is a category that needs special explanation. That's because the regulatory definition of "soap" is different from the way in which people commonly use the word. Products that meet the definition of "soap" are exempt from the provisions of the FD&C Act because—even though Section 201(i)(1) of the act includes "articles...for cleansing" in the definition of a cosmetic—Section 201(i)(2) excludes soap from the definition of a cosmetic.
HEALTH CANADA

• Cosmetics are defined as "any substance or mixture of substances, manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth and includes deodorants and perfumes."

• This definition also includes cosmetics used by professional esthetic services, as well as bulk institutional products (e.g. hand soap in school restrooms).

• For Canada and Europe: Soap is included under cosmetic legislation.
A cosmetic is defined as "any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition."

For Canada and Europe: Soap is included under cosmetic legislation.
REVIEW:
WHO GOVERNS COSMETIC PRODUCTS?

• **United States**: The Food and Drug Administration (the FDA) regulates cosmetics under:
  • The Federal Food, Drug and Cosmetic Act (FD&C Act) and
  • The Fair Packaging and Labeling Act (FPLA)

• **Canada**: Health Canada - personal care products are regulated under the *Food and Drugs Act*.

• **Europe**: The cosmetics industry is governed by the European Union’s (EU) Cosmetic Directive which requires cosmetics to cause no damage to human health.
REGULATIONS ARE ABOUT SAFETY, AVOIDING CONTAMINATION, AND ACCURATE LABELING
• **United States**: The Food and Drug Administration (the FDA) regulates cosmetics under:
  - The Federal Food, Drug and Cosmetic Act (FD&C Act) and
  - The Fair Packaging and Labeling Act (FPLA)
THE FEDERAL FOOD, DRUG AND COSMETIC ACT (FD&C ACT)

- Law passed: 1938
- Gives the US Food and Drug Administration (the FDA) the directive to oversee the safety of food, drugs, and cosmetics.
  - **Specifically for Cosmetics:** This act requires that all cosmetic products and their individual ingredients are proven safe before going to market and that product labeling is not misleading.
THE FEDERAL TRADE COMMISSION

• Created in 1914.
• To Protect:
  • To prevent business practices that are anticompetitive or deceptive or unfair to consumers; to enhance informed consumer choice and public understanding of the competitive process; and to accomplish this without unduly burdening legitimate business activity.
  • The FTC works with the FDA to ensure proper labeling is used on cosmetics and drugs.
  • The Federal Trade Commission (FTC) regulates advertising, including infomercials most products sold to consumers. FDA works closely with FTC in this area.
FAIR PACKAGING AND LABELING ACT (FPLA)

• **Purpose of the Act:** The FPLA is designed to facilitate value comparisons and to prevent unfair or deceptive packaging and labeling of many household "consumer commodities."

• The Fair Packaging and Labeling Act (FPLA or Act), enacted in 1967, directs the Federal Trade Commission and the Food and Drug Administration to issue regulations requiring that all "consumer commodities" be labeled to disclose **net contents, identity of commodity, and name and place of business of the product's manufacturer, packer, or distributor.**
NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY (NIST)

• The NIST is a part of the US Dept of Commerce.
  • The Office of Weights and Measures promotes uniformity in U.S. weights and measures laws, regulations, and standards to achieve equity between buyers and sellers in the marketplace. This enhances consumer confidence, enables U.S. businesses to compete fairly at home and abroad, and strengthens the U.S. economy.
## WEIGHTS AND MEASUREMENTS

<table>
<thead>
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<tr>
<td>1 milligram</td>
<td>0.001 grams (g)</td>
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<tr>
<td>1 gram (g)</td>
<td>0.001 kilograms (kg)</td>
</tr>
<tr>
<td>1 gram (g)</td>
<td>0.03527392 ounces (oz)</td>
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<td>1 ounce</td>
<td>0.0625 pounds (lbs)</td>
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<td>0.45359237 kilograms (kg)</td>
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<tr>
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<td>2.2062262 pounds (lbs)</td>
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<td>14 pounds (lbs)</td>
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<tr>
<td>1 metric ton</td>
<td>1000 kilograms (kg)</td>
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## WEIGHS AND MEASUREMENTS

<table>
<thead>
<tr>
<th>Volume (liquid)</th>
<th>Equivalent</th>
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<tbody>
<tr>
<td>1 US tablespoon (tbsp.)</td>
<td>3 US teaspoons (tsp.)</td>
</tr>
<tr>
<td>1 US fluid ounce (fl oz, fl. oz.)</td>
<td>29.5735 mililiters (ml)</td>
</tr>
<tr>
<td>1 US cup</td>
<td>8 US Fluid ounces (fl oz)</td>
</tr>
<tr>
<td>1 liter (l)</td>
<td>33.8140227 US fluid ounces (fl oz)</td>
</tr>
<tr>
<td>1 liter (l)</td>
<td>1000 milliliters (ml)</td>
</tr>
<tr>
<td>1 US gallon (gal)</td>
<td>4 US quarts</td>
</tr>
<tr>
<td>1 US gallon (gal)</td>
<td>3.78541178 liters (l)</td>
</tr>
</tbody>
</table>
MISBRANDED

• A cosmetic may be deemed misbranded (Sec. 602) for reasons of:
  • False or misleading labeling.
  • Failure to state prominently and conspicuously any information required by or under authority of this act.
  • Misleading container presentation or fill.
• USDA regulates the term “organic” as it applies to agricultural products through its National Organic Program (NOP) regulation, 7 CFR Part 205.

• If a cosmetic, body care product, or personal care product contains or is made up of agricultural ingredients, and can meet the USDA/NOP organic production, handling, processing and labeling standards, it may be eligible to be certified under the NOP regulations.
USDA CONTINUED

• Any cosmetic, body care product, or personal care product that does not meet the production, handling, processing, labeling, and certification standards described above, may not state, imply, or convey in any way that the product is USDA-certified organic or meets the USDA organic standards.

• USDA has no authority over the production and labeling of cosmetics, body care products, and personal care products that are not made up of agricultural ingredients, or do not make any claims to meeting USDA organic standards.
USDA CONTINUED

• Cosmetics, body care products, and personal care products may be certified to other, private standards and be marketed to those private standards in the United States. These standards might include foreign organic standards, eco-labels, earth friendly, etc. USDA’s NOP does not regulate these labels at this time.
Has jurisdiction over any product that claims to kill or repel insects.

The EPA must approve such products. However there are exemptions.
ACTIVE INGREDIENTS EXEMPTED UNDER 25(B) OF THE FEDERAL INSECTICIDE, FUNGICIDE, & RODENTICIDE ACT

- Castor oil (U.S.P. or equivalent)*
- Cedar oil
- Cinnamon and cinnamon oil*
- Citric acid*
- Citronella and Citronella oil
- Cloves and clove oil*
- Corn gluten meal*
- Corn oil*
- Cottonseed oil*
- Dried Blood
- Eugenol
- Garlic and garlic oil*
- Geraniol*
- Geranium oil
- Lauryl sulfate
- Lemongrass oil
- Linseed oil
- Malic acid
- Mint and mint oil
- Peppermint and peppermint oil*
- 2-Phenethyl propionate (2-phenylethyl propionate)
- Potassium sorbate*
- Putrescent whole egg solids
- Rosemary and rosemary oil*
- Sesame (includes ground sesame plant) and sesame oil*
- Sodium chloride (common salt) *
- Sodium lauryl sulfate
- Soybean oil
- Thyme and thyme oil*
- White pepper
- Zinc metal strips (consisting solely of zinc metal and impurities)
GOOD MANUFACTURING PRACTICES

- GMPs are manufacturing guidelines which are used to ensure product quality control and an effective approach to risk management. These guidelines set out standards for product manufacturing, testing, storage, handling and distribution, to ensure that each step of manufacturing is acceptable for quality and safety of the product. (Health Canada)
GOOD MANUFACTURING PRACTICES

• GMP’s are: The quality assurance procedures and practices which ensure that products are consistently produced and controlled to the quality standards appropriate to their intended use.

   - Marie Gale
WELCOME DONNA MARIA OF INDIE BUSINESS NETWORK
LABELING
AROMATHERAPY PRODUCT LABELS
(COSMETIC LABELS)

• A label may consist of more than one panel. It may consist of a front panel, side panels and a back panel. Back and side panels are generally called information panels.

• The Principle Display Panel (PDP) - The part of a label that the consumer sees or examines when displayed for retail sale.
LABELS

• Required on all aromatherapy products:
  • Name of Product
  • Identity of the product (Brand)
  • Net quantity of the product (size or amount)
  • Place of business
  • Ingredient Deck (Listing): Not required on soap in the U.S.
    • Ingredients must be listed using the INCI name.
    • Ingredients are listed from what is in the product most to least.
THE PRINCIPLE DISPLAY PANEL (PDP)

The PDP is the part of the label that the consumer sees or examines when considering to purchase your product. The following must be listed prominently:

- **Name of Product:** e.g. Eucalyptus Body Cleanser

- **Identity of Product:** The Brand – e.g. Lunaroma

- **Net Quantity** of the Product: 8 fl oz / 236.59 ml
  - **The words “Net Weight” must be used for products they are sold by weight and the words “Net” or none at all for liquid measurements. Net Weight under 4 pounds, must also include number of ounces. E.g. Net Wt. 24 oz (1 lb. 8 oz)
OTHER INFORMATION THAT MUST BE ON YOUR LABEL

• Name and Location of Business

• Ingredients

• **If you package your product in an outer box with the product inside, the pertinent information must be on the outer box. Hang tags are permitted as well.**
INTERNATIONAL NOMENCLATURE OF COSMETIC INGREDIENTS (INCI)

- The INCI system was established in the early 1970's by the Personal Care Products Council (former CTFA, Cosmetic, Toiletry, and Fragrance Association) and the list is maintained by the Personal Care Products Council.

- INCI names are used in the United States, the European Union, China, Japan, and many other countries, for listing ingredients on cosmetic product labels. With few exceptions, the INCI labeling names in all countries are the same.
• Typically, is found on the back of container:
  • Sesamum indicum (Sesame) seed oil*, Daucus carota (Carrot) root*, Helianthus annuus (Sunflower) seed oil*, Persea Gratissima (Avocado) Oil*, Rosa canina (Rosehip) Fruit Oil*, Rosemary CO2 extract with Olea europaea (Olive) Fruit Oil, Essential oils of Daucus carota fruit oil*, Lavandula angustifolia flower oil, Helichrysum italicum oil*, and Rosmarinus officinalis (Rosemary) CO2 Herb Extract* in Olea Europaea (Olive) Fruit Oil*  *Certified Organic
EXAMPLES OF INCI

• Lemon Balm Oil Melissa Officinalis Leaf Oil
• Patchouli Oil Pogostemon Cablin Oil
• Grapeseed Oil Vitis Vinifera (Grape) Seed Oil
• Sesame Oil Sesamum Indicum (Sesame) Seed Oil
• Tea Tree Oil Melaleuca Alternifolia (Tea Tree) Leaf Oil

• Will be sent to you on the pdf file. 😊
FOR AROMATHERAPY PRODUCTS: 
SAFETY STATEMENTS

• **Safety Info:** Caution: If pregnant, nursing, suffering from any medical condition, or taking medication, consult a health care practitioner before use. Avoid eyes and mucous membranes. May irritate skin. For external use only. Keep out of reach of children.
CLAIMS

• Recall the definition of Cosmetics versus Drugs.

• **Cosmetics**: “articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body.....for cleansing, beautifying, promoting attractiveness, or altering the appearance” (FD&C Act, sec. 201 (i)).

• **Drug**: The FD&C Act defines drugs, in part, by their intended use, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals" [FD&C Act, sec. 201(g)(1)].
NO NO!

- Antibacterial
- Antiviral
- Antifungal
- Analgesic

- Soothes stomach upsets
- Relieves muscular tension
- Prevents coughs, colds, and flu
- Supports Immunity
LEFT: NO    RIGHT: YES

Muscle Gel

Muscle Gel
<table>
<thead>
<tr>
<th>Benefits</th>
<th>Features</th>
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</thead>
<tbody>
<tr>
<td>Calming</td>
<td>Restores skin vitality</td>
</tr>
<tr>
<td>Comforting</td>
<td>Skin-nourishing essential fatty acids</td>
</tr>
<tr>
<td>Energizing</td>
<td>Nourishes the skin.</td>
</tr>
<tr>
<td>Euphoric</td>
<td>Hydrating.</td>
</tr>
<tr>
<td>Refreshing</td>
<td>Moisturizing.</td>
</tr>
<tr>
<td>Clearing</td>
<td>Age-Defying</td>
</tr>
<tr>
<td>Warming</td>
<td>Replenishing</td>
</tr>
<tr>
<td>Balancing</td>
<td>Skin Balancing.</td>
</tr>
<tr>
<td>Fortifying</td>
<td></td>
</tr>
</tbody>
</table>
YES.

- Calming Tangerine
- Create an at-home spa treatment that sensualizes the senses, relaxes the body and calms the spirit. (Aura Cacia)
- Hydrates and softens skin.

- Energizing Eucalyptus
- A gentle cleanser for sensitive skin.
- An anti-aging restorative cream.
- Baby’s Soothing Massage Oil
YES.

- Love Balm
- Softens and Protects dry, chapped skin
- Relaxing bath soak.
- Skin Renewal Cream
- Lavender Balancing Bath Salts
- Stimulating
- Aphrodisia
- Breathing Space
- Meditation
- Strengthen
- Grounding
- Clears the Mind
- Memory Lane
FDA WARNING LETTERS

• If you ever receive a warning letter from the FDA, please know that you have time to make changes to your website, labels, etc.
• Better to be prepared and be responsible from the get go.
INDIE BUSINESS NETWORK
SERVING MAKERS AND HANDMADE ENTREPRENEURS

• Offering:
  • Affordable product liability insurance
  • Online marketing coaching and classes
  • Small business leadership training
  • Indie Beauty University self study classes
  • Secret Facebook Mastermind Group


• --> Use coupon code: Jade2015 for $25 off your first year membership dues! Expires on Saturday: January 10th (that’s this Saturday)
JOIN NAHA!

- Promote and disseminate aromatherapy education to the public.
- Encourage the development of high standards of education that promote well-trained professional aromatherapy practitioners.
- Promote and increase awareness of issues surrounding aromatic plant sustainability.
- Strengthen the network of support and communication between aromatherapy practitioners and business owners nationally and internationally.
- Foster high standards of ethics and integrity in the education and the practice of clinical/holistic aromatherapy.
- Promote cooperation between clinical/holistic aromatherapy practitioners and other health care providers.

www.naha.org
SPECIAL OFFERS: WWW.THEIDA.COM

• Special Offers: $150. for Butters, Balms, and Salves course (code: butters)

• $50. off Aroma101 Foundations Course and all independent modules (code: learn)

• $50. off Organic Body Care Products Course (code: learn) **Teaches GMP.

• $100. off Aromatic Scholars Program beginning January 31, 2015 – Email us at: info@theida.com

• Offers good through: January 31, 2014.
THANK YOU!

The East-West School for Herbal and Aromatic Studies

www.theida.com