Food Drug and Cosmetic Act
1938
The Need for a new Act

• Weakness of the 1906 Act
  – *Lack of standards for food products*

• Developments in Science and technology
  – *Canning / Chemical analysis*

• Expansion of cosmetics industry

• *Sulfanilamide* and other Tragedies
Food Tragedies

(Outside scope of 1906 Act)

- Koremlu Cream
  - Contained Thallium acetate

- Slenderizing compounds
  - Pharmocological agents

- Radiothor
  - "Radium containing water"
  - Consumers died of radiation exposure
  - Label true and no therapeutic claims
Food Tragedies

• Elixir of Sulfanilamide
  – *Tested only for flavor, not safety*
  – *Contained unlisted ingredient* "diethylene glycol"
  – 100 deaths
  – *Only basis for FDA jurisdiction was* "misbranding b/c of term "elixir"
  – *Failure to test for safety or to list ingredients was not a violation* of 1906 Act
Differences between the 1906 and 1938 Act

• Prohibited interstate traffic in food "which may be injurious to health"
  – *1906 Act prohibited only if "added substance"

• Prohibits addition of poisons except if "unavoidable"

• Authorized "*Emergency Permit Control*" if required to protect public
Differences between the 1906 and 1938 Act

• Authorized *labeling of artificial colors*, flavors and preservatives
• Labeling of "special dietary foods"
• Set controls for containers that might affect food safety
• *Increased penalties* for violations (100,000/day/violation)
Differences between the 1906 and 1938 Act

- Authorized *factory inspections*
- Prohibited use of *"deceptive containers"*
- Prohibited use of *"uncertified coal tar dyes"* as color additives except in hair dyes
- Authorized “*injunctive relief*”
- *Standards of identity*, quality and fill
Food Standards

• Harvey Wiley published **200 standards** in Bureau of Chemistry circulars
  – “to help states combat adulteration and help courts determine when a product was adulterated”

• Food Standards =
  – *Standards applied to articles used as food and components of food intended for consumption by humans or other animals, whether or not in edible form*
Types of Food Standards

• Standards of *identity*
  – *What is it*

• Standards of *quality*
  – *How good is it*

• Standards of *fill*
  – *Is container properly filled*

• Standards of *grade*
  – *What is the level of quality*
Mandatory vs. Voluntary Standards

- When is a standard mandatory?
- Under FDCA, standards of *identity*, *fill*, *quality* and *grade* are mandatory for any product in *interstate commerce*
- ISO-9000  Quality Standards
  - *International prescriptive quality standards*
  - *International Standards Organization*
"Poisonous"

• 1906 Act defined *adulteration* in terms of poisonous or deleterious
  – *Presence of poison = adulterated*

• 1938 Act:
  – "...the majority of things consumed by the human family contain, under analysis, some kind of poison....it depends on the combination and chemical relation to the body that determine whether or not substance is dangerous to the human system."
## Food, Drug and Cosmetics Act of 1938

<table>
<thead>
<tr>
<th>Chapter One</th>
<th>Short title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chapter Two</td>
<td>Definitions and terms</td>
</tr>
<tr>
<td>Chapter Three</td>
<td>Prohibited Acts and Penalties, adulteration and misbranding, Injunctive relief, Strict liability standard (intent), due process, enforcement through Justice Department</td>
</tr>
<tr>
<td>Chapter Four</td>
<td>Authorizes the regulation of foods, standards of Identity Emergency Permit Controls</td>
</tr>
<tr>
<td>Chapter Five</td>
<td>Drugs and Devices</td>
</tr>
<tr>
<td>Chapter Six</td>
<td>Cosmetics</td>
</tr>
<tr>
<td>Chapter Seven</td>
<td>Administrative provisions and tools, rulemaking, regulation promulgation, Inspections</td>
</tr>
<tr>
<td>Chapter Eight</td>
<td>Imports and Exports</td>
</tr>
<tr>
<td>Chapter Nine</td>
<td>Repeal of 1906 Act, Exemptions (meats, biologics, etc)</td>
</tr>
</tbody>
</table>
### Definition of Food

<table>
<thead>
<tr>
<th>1938 Act</th>
<th>1906 Act</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Articles used for food or drink for man or other animals;</td>
<td>“all articles used for food, drink, confectionery or condiment by man or other animal, whether simple, mixed or compound.”</td>
</tr>
<tr>
<td>(2) chewing gum;</td>
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</tr>
<tr>
<td>(3) Articles used for components of any such article.</td>
<td></td>
</tr>
</tbody>
</table>
Adulteration Criteria:

- Contains any poisonous or deleterious substance *which may render it injurious* to users, when used as directed
- Contains any “filthy, putrid or decomposed substances”
- Prepared, packaged or held under unsanitary conditions and became contaminated or render injurious
- Has a poisonous or deleterious container or
- Contains an *unapproved food or color additive*
Unavoidable Contaminants

- Under FDCA any food containing any _avoidable, added, poisonous_ or _deleterious_ substance that is unsafe is adulterated.
- _Unsafe_ = any poisonous or deleterious substance added to food, except those which cannot be avoided by good manufacturing practices
- FDCA authorizes FDA to set “tolerances” for unavoidable contaminants to protect public health
Under 1906 Act:

- Any substance mixed with so as to lower or *injuriously affect its quality*
- Any *substituted substance* wholly or in part
- Any *valuable component extracted*
- Treated so as to *conceal damage or inferiority*
- Contains any *added ingredient* which may *render it injurious to health*
- Any putrid, diseased substance or unfit for food
Misbranding under the 1938 Act:

- If label is "false or misleading in any particular"
- Is an imitation of another food (unless clearly labeled as an imitation)
- Does not meet FDA regulations regarding standard of identity, quantity or fill
The “Later Acts”

• 1947 - Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)
  – Registration of “economic poisons”
• 1957 - Poultry Inspection Act
• **1958 - Food Additives Amendment**
• 1960 - Color Additives Amendment
• 1966 – Fair Packaging and Labeling Act
  – Labeling to provide consumer with information regarding quantity and contents for value comparisons
The “Later” Acts

- 1967 - Wholesome Meat Act
  - *Amended Meat Inspection Act to include “intrastate” commerce*

- 1976 - Vitamin and Mineral Amendments
  - *Minimum levels of potency (>xp = Drug)*
  - *Defined “special dietary uses”*

- 1977 - Saccharin Study and Labeling Act
  - *Moratorium on saccharin ban to determine risk to certain segments of the population*
  - *Real reason ($)*

The “Later” Acts

- 1990 - Nutritional Labeling and Information Act
  - Mandatory nutritional information in uniform format
  - Authorized use of “health claims”

- 1994 – Dietary Supplement Health and Education Act
  - Defined and established scheme for regulation of Dietary Supplements

- 1997 - FDA Modernization Act
  - Streamline and improve regulatory program of FDA
Food Additives

- Prior to 1958 no mechanism for evaluation and approval of chemicals *added* to foods
- FDA could only evaluate product “already on the market”
- 1954 only 200 of 1400 chemicals tested
- Need process for *pre-market approval* of substances to be added to foods
Food Additive

• “any substance, the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component of food or otherwise affecting the character thereof….if such substance is not generally recognized as safe based on evaluation or common use.
Exemptions from Premarket Approval:

- Approved Food Additives
- *Generally Recognized As Safe* (GRAS)
- Prior Sanctioned Substances
- Indirect Additives
  - Noncarcinogenic substances in food contact *articles* that result in concentrations <0.5 ppb
- Unavoidable Contaminants
  - Substances which *cannot be avoided by GMPs*
Food Labeling

Next