Seminar on

ADULTERATION AND MISBRANDING

By

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Introduction

The Food, Drug and Cosmetic Act (FDCA) provides for the comprehensive regulation of all drugs introduced into interstate commerce.

The intent of the law is to protect consumers from adulterated or misbranded foods, drugs, cosmetics or devices.

Under the Act, no new drug may be marketed and sold unless it has been proved both safe and effective for its intended use and approved by the federal Food and Drug Administration (FDA).
At the turn of the century, investigative reports revealed widespread food and drug adulteration problems.

Most notably, the 1906 novel, “The jungle”, by Upton Sinclair, described atrocious adulteration problems in the meat industry.

Concern for the risks to the public health and safety associated with unsanitary and poorly labeled foods and drugs prompted congress in 1906 to pass the Pure Food and Drug Act.
Under the 1906 Act, drugs were defined simply as

“Medicines and preparations recognized in the United States Pharmacopoeia or the National Formulary for internal and external use and any substance to be used for the cure, mitigation or prevention of disease either in man or other animals.”

A drug was regarded as “adulterated” only under two conditions:

- When a drug is sold under or by a name recognized by the United States Pharmacopoeia and it differs from the standards of strength, quality and purity as established in those compendia.

- Its strength and purity falls below the professed standard or quality under which it was sold.
The law prohibited the adulteration and misbranding of food and drug in interstate commerce.

It fell short of providing the protection that the congress intended, and a Supreme Court statement revealed that the misbranding provision in the law did not prevent false or misleading claims.

Despite public awareness that the 1906 Act was inadequate, there was no new legislation until 1938.

A catalyst for the new law was the “sulfanilamide elixir” tragedy of 1937.
In late 1937, Elixir sulfanilamide that had been manufactured using diethylene glycol as a solvent was distributed and within two months approximately 107 deaths had resulted.

Following this disaster, the new federal Food, Drug and Cosmetic Act was passed and approved on June 25th, 1938.
Food, Drug and Cosmetic Act, 1938 (FDCA)

The law provides that no new drug could be marketed until proven safe for use under the conditions specified on the label and approved by the FDA.

The new law expanded the definitions of misbranding and adulteration used in the earlier Act, requiring that the labels must contain adequate “directions for use” and “warnings” about the habit forming drugs.
Definitions:

**Food:**

- Articles used as food or drink for man or other animals.
- Chewing gums
- Articles used as components of any such articles.
**Drug:**

- Articles recognized in the official Pharmacopoeias or any supplement to any of them.

- Articles used in the diagnosis, cure, mitigation, treatment or prevention of diseases in man or other animals.

- Articles (other than food) intended to affect the structure or any function of the body of man or any other animals.

- Articles used as components in any of the above articles.
Cosmetic

- Articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance.

- Articles intended for use as a component of any such articles.
Device: An instrument, apparatus, implement, machine, contrivance, implant, In vitro reagent or other related article, including any component, part or accessory which is

- Recognized in the official National Formulary, or the United States Pharmacopoeia or any supplement to them.

- Intended for use in the diagnosis of disease, or other conditions in the cure, mitigation, treatment, prevention of disease in man or other animals.
Intended to effect the structure or any function of the body of man or other animals and which does not achieve any of its principal intended purposes through chemical action and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.
Label:

A display of written, printed or graphic matter upon the immediate container or any article.

Its purpose is to:

- Inform the consumer about the product.
- Ingredients present, their quality and quantity.
- Directions for use.
- Warnings in case of habit forming drugs and for use by children.
- Manufacturer name and place.
- Manufactured and expiry dates.
Adulterated Food
Adulterated Food:

1. If any substance has been mixed and packed with, so as to reduce or lower or injuriously affect its quality and strength.

2. If any substance has been substituted wholly or in part for the article.

3. If any valuable constituent of the article has been wholly or in part abstracted.

4. If it be mixed, colored or powdered, coated, or stained in a manner whereby damage or inferiority is concealed.
5. If it contains any added poisonous or other added deleterious ingredient which may render such article injurious to health.

6. If it consists in whole or in part with filth, decomposed, or putrid animal or vegetable substance, or any portion of an animal unfit for food, whether manufactured or not, or if it is the product of the diseased animal, or one that has died than by slaughter.

7. If it is confectionary, and it bears or contains any alcohol or non-nutritive article.
Misbranded food:

1. If its labeling is false or misleading in any particular.

2. If it is offered for sale under the name of the another food.

3. If it is an imitation of another food, unless its label bears in type of uniform size and prominence, the word “imitation” and immediately thereafter, the name of the food imitated.

4. If it does not contain any statement, word or other information required by or under authority of this Act to appear on the label so as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.
5. If in package form it does not bear a label containing
   i. the name of the manufacturer, packer or distributor.
   ii. An accurate statement of the quantity of the contents
       in terms of weight, measure and numerical count.

6. If its container is so made, formed or filled as to be misleading.

7. If it purports to be a food for which a standard of quality has been prescribed by the department and its quality falls below such standard, unless it bears a statement of its true nature on its label.
8. If it is purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral or other dietary properties in order to fully inform purchasers as to its value for such uses.

9. If it bears or contains any artificial coloring agent, artificial flavoring agent or chemical preservative, unless it bears a label informing the fact.
Adulterated Drugs and Devices

1. It consists of in whole or in part of any filthy, putrid or decomposed substance; or if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth rendered injurious to health.

2. Its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health.
3. If it is a drug and the methods used in, or the facilities or controls used for its, manufacture, processing, packing, or holding do not confirm to, or are not operated or administered in conformity with, “Current Good Manufacturing Practices”.

4. If it is a drug and any substance has been mixed or packed therewith so as to reduce its quality or strength or to substitute wholly or in part for the drug.
5. It bears or contains **unapproved colors.**

6. If it is a drug recognized in an official compendium and its strength differs from its quality or purity falls below, the standards set forth in such compendium.

7. If it is not a drug recognized in an official compendium and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.
8. It is a device that has not been manufactured in compliance with the “Quality System Regulation.”

9. If it is a device and lacks required approval or has been banned by the FDA.
Misbranded drugs and devices:

1. If its labeling is false or misleading in any particular.

2. If in a package form unless it bears a label containing
   i. the name and place of business of the manufacturer, packer or distributor.
   ii. an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

3. If any work, or statement, or other information required by or under authority of this act to appear on the label or labeling is prominently placed thereon with such conspicuousness.
4. If it is for use by the man and contains any quantity of the Narcotic or hypnotic substance or any chemical derivative of such substance and designated as HABIT FORMING, unless its label bears the name, and quantity or proportion of such substance or derivative and with the statement,

“WARNING – MAY BE HABIT FORMING”.

5. If it is drug and is not solely designated by a name recognized in an official compendium unless it bears
   i. the common or usual name of drug
   ii. In case it is fabricated from two or more ingredients, the common or usual name of each active ingredient, including the quantity, kind and proportion of any alcohol.
6. Unless its labeling bears
   i. adequate directions for use.
   ii. adequate warnings against use in pathological conditions or by children.
   iii. where it may be dangerous to health, or against unsafe dosage or methods or duration of administration or application.

7. If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein.
8. If it has been found by the secretary to be a drug liable to deterioration, unless it is packaged in such manner and form, and its label bears a statement of such precautions.

9. If it is a drug and its container is so made, formed, or filed as to be misleading.

10. If it is imitation of another drug.

11. If it is offered for sale under the name of another drug.
Adulterated cosmetics:

1. If it bears or contains any poisonous or deleterious substance which may render it injurious to user under the conditions of use as are customary as usual.

2. If it contains in whole or in part of any filthy, putrid, or decomposed substance.

3. If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated by the filth.

4. If it is a hair dye and bears or contains a coal tar color other than the one which is permissible.
Misbranded Cosmetics:

1. If its labeling is false or misleading in any particular.

2. If in package form unless it bears a label contains
   i. the name and place of the manufacturer, packer or distributor.
   ii. an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

3. If it does not contain any statement, word or other information required by or under authority of this Act to appear on the label so as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.
4. If it contains a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations.

5. If its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 of the Poison Prevention Packaging Act, 1970.
Product Tampering

- Defined in the act as improper interference with the product for the purpose of making objectionable or unauthorized changes.

- The FDA regulations require that certain OTC drugs, cosmetics, and devices be manufactured in tamper-resistant packing.

- Violation of this regulation may be deemed to be adulteration and misbranding.
Current Good Manufacturing Practices

Is a set of regulations that establishes minimum requirements for the methods, facilities and controls used in the manufacture, processing, packaging or holding drug product.

Inspections are designed to:

- Confirm that the product and control procedures result in proper identity, strength, quality and purity of drugs.
- Identify deficiencies.
- Ensure correction of the deficiencies.
## Methods to determine adulteration of food

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<tr>
<th>Food</th>
<th>Authenticity problem</th>
<th>Technique</th>
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<td>Meat content and added water in meat products</td>
<td>Nitrogen factor</td>
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<td>Soluble coffee</td>
<td>Addition of vegetable matter, Addition of complex sugar</td>
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<td>Fruit juice</td>
<td>Addition of sugar syrup, Geographical origin</td>
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<td>Rice</td>
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Prohibited Acts:

- The **introduction or delivery** for introduction into interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded.

- The **practicing adulteration and misbranding** of any food, drug, device, or cosmetic in inter state commerce.

- The receipt in inter state commerce of any food, drug, device or cosmetic, that is adulterated or misbranded and delivery thereof to pay or otherwise.
➢ The **refusal to permit access to or copying of any records** as required or the failure to establish or maintain any record.

➢ Doing of any act which causes a drug to be a **counterfeit drug**, or the sale or dispensing, or the holding for sale or dispensing of a counterfeit drug.
Prevention of adulteration and misbranding

1. Strict enforcement of the law:

- Under section 302, the FDA can bring an injunctive action against the violators to cause it to cease its illegal activity.

- Under section 303, the FDA can institute criminal action against the violators, resulting in fines, imprisonment, or both.

- Section 303 allows the FDA to seize any adulterated or misbranded food, drug or cosmetic in interstate commerce.
2. Product Recalls:

Divided into three classes:

**Class I**: issued when there is probability that the product will cause serious, adverse health consequences or death.

**Class II**: occur when the product may cause temporary or medically reversible adverse health consequences, but the probability of serious adverse consequences is remote.

**Class III**: apply to products that are not likely to cause adverse health consequences.
Conclusion

The present medical armamentarium consists of large number of botanicals, drugs, foods, cosmetics and devices and volumes of complex and variety of these products are being added to the market everyday.

With the advent of more complex chemical and biological entities, coupled with more sophisticated biological entities, the potential for adulteration increases.

The primary means of controlling the incidence of adulteration is **stringent quality control through strict adherence to Current Good Manufacturing Practices.**
An important component of Current Good Manufacturing Practice relating directly to the prevention of distribution of adulterated products involves the development of appropriate specifications.

These specifications are the cornerstone for effectively testing finished dosage forms to assure that they are safe and meet the strength, quality, purity and identity characteristics they purport to possess.
References:

1. Federal statutes: 21 USC 351
2. Act of June 30th, 1906 Ch. 3915, 34 stat. 768.
5. Pharmacy practice and the Law by Richard Abood, chapter 2, Pg 44-72.
6. Federal regulations of medications, development, production and marketing from Jonnes and Barlett publishers.
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