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REGULATORY ACTIONS AGAINST MISBRANDING AND ADULTRATION

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ABSTRACT

In today's competitive environment the reduction of the time taken to reach the market is critical to a product's and hence the company's success. The proper conduct of its Regulatory Affairs activities is therefore of considerable economic importance for the company. Inadequate reporting of data may prevent a timely positive evaluation of marketing application. Even worse1 failures to fully report all the available data or the release of product bearing incorrect labeling, may easily result in the need for a product recall. Either occurrence may lead to the loss of several millions of units of sales, not to mention the resulting reduction in confidence of the investors, health professionals and patients. A good Regulatory Affairs professional will have a 'right first time' approach and will play a very important part in coordinating scientific endeavor with regulatory demands throughout the life of the product, helping to maximize the cost-effective use of the company's resources. The attitudes and actions of the Regulatory Affairs professionals will condition the perceptions of the government officials to the company for better, or worse Officials respond much better to a company whose representatives are scientifically accurate and knowledgeable than to one in which these qualities are absent. The importance of the Regulatory Affairs function is such that senior Regulatory Affairs professionals are increasingly being appointed to boardroom positions, where they can advise upon and further influence the strategic decisions of their companies.

Keywords: Regulatory Actions, Misbranding, Adultration.

INTRODUCTION

The Regulatory Affairs professional's job is to keep track of the ever-changing legislation in all the regions in which the company wishes to distribute its products. They also advise on the legal and scientific restraints and requirements, and collect, collate, and evaluate the scientific data that their research and development colleagues are generating. They are responsible for the presentation of registration documents to regulatory agencies, and carry out all the subsequent negotiations necessary to obtain and maintain marketing authorization for the products concerned [1]. They give strategic and technical advice at the highest level in their companies, right from the beginning of the development of a product, making an important contribution both commercially and scientifically to the success of a development program and the company as a whole [2].

It may take anything up to 15 years to develop and launch a new pharmaceutical product and problems may arise in the process of scientific development and because of a changing regulatory environment. Regulatory Affairs professionals help the company avoid problems caused by badly kept records, in appropriate scientific thinking or poor presentation of data. Regulatory affairs professionals are the link between pharmaceutical industries and worldwide regulatory agencies [3]. They are required to be well versed in the laws, regulations, guidelines and guidance of the regulatory agencies. There is a growing need to incorporate the current requirements of pharmaceutical industries in the standard curriculum of pharmacy colleges to prepare the students with the latest developments to serve the industries.

As the pharmaceutical industries throughout the world are moving ahead towards becoming more and more competitive, these are realizing that the real battle of survival lies in executing the work by understanding the guidelines related to various activities carried out to give an assurance that the process is under regulation [4]. Pharmaceutical Industry, being one of the highly regulated industries in immense need of people than ever before who are capable of handling issues related to regulatory affairs in a comprehensive manner [5].

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METHODOLOGY

Regulatory Action against Misbranding and Adulteration

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).

Pure Food and Drug Act, 1906

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. "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.

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.

A) 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:

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.

B) 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.

C) Misbranded food
1. If it's labeling is false or misleading in any particular.
2. If it is offered for sale under the name of the 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. 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.
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.

D) 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 that has not been manufactured in compliance with the "**Quality System Regulation."**
9. If it is device and lacks required approval or has been **banned by the FDA.**

E) Misbranded drugs and devices:
1. If it's 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 content 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 it's 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.

F) 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.

G) Misbranded Cosmetics

1. If it's 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.

H) 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.

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 interstate commerce.
- The receipt in interstate 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

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

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.

Food, Drug and Cosmetic Act, 1938

The United States Federal Food, Drug, and Cosmetic Act (abbreviated as FFDCA, FDCA, or FD&C), is a set of laws passed by Congress in 1938 giving authority to the U.S. Food and Drug Administration (FDA) to oversee the safety of food, drugs, and cosmetics. A principal author of this law was Royal S. Copeland, a three-term U.S. Senator from New York. In 1968, the Electronic Product Radiation Control provisions were added to the FD&C. Also in that year the FDA formed the Drug Efficacy Study Implementation (DESI) to incorporate into FD&C regulations the recommendations from a National Academy of Sciences investigation of effectiveness of previously marketed drugs. The act has been amended many times, most recently to add requirements about bioterrorism preparations.

The introduction of this act was influenced by the death of more than 100 patients due to a sulfanilamide medication where diethylene glycol was used to dissolve the drug and make a liquid form. See Elixir Sulfanilamide disaster. It replaced the earlier Pure Food and Drug Act of 1906.

Historical significance: The **Pure Food and Drug Act** of 1906 was a key piece of Progressive Era legislation, signed by President Theodore Roosevelt on the same day as the Federal Meat Inspection Act. Enforcement of the Pure Food and Drug Act was assigned to the Bureau of Chemistry in the U.S. Department of Agriculture which was renamed the U.S. Food and Drug Administration (FDA) in 1930. The Meat Inspection Act was assigned to what is now known as

the Food Safety and Inspection Service that remains in the U.S. Department of Agriculture. The first federal law regulating foods and drugs, the 1906 Act's reach was limited to foods and drugs moving in interstate commerce. Although the law drew upon many precedents, provisions, and legal experiments pioneered in individual states, the federal law defined "misbranding" and "adulteration" for the first time and prescribed penalties for each. The law recognized the U.S. Pharmacopeia and the National Formulary as standards authorities for drugs, but made no similar provision for federal food standards. The law was principally a "truth in labeling" law designed to raise standards in the food and drug industries and protect the reputations and pocketbooks of honest businessmen.

Particular drugs deemed dangerous;

Under the law, drug labels, for example, had to list any of 10 ingredients that were deemed "addictive" and/or "dangerous" on the product label if they were present, and could not list them if they were not present. Alcohol, morphine and opium, and cannabis were all included on the list of these "addictive" and/or "dangerous" drugs. The law also established a federal cadre of food and drug inspectors that one Southern opponent of the legislation criticized as "a Trojan horse with a bellyful of inspectors." Penalties under the law were modest, but an underappreciated provision of the Act proved more powerful than monetary penalties. Goods found in violation of the law were subject to seizure and destruction at the expense of the manufacturer. That, combined with a legal requirement that all convictions be published (Notices of Judgment), proved to be important tools in the enforcement of the statute and had a deterrent effect upon would-be violators.

Deficiencies in this original statute, which had become noticeable by the 1920s, led to the replacement of the 1906 statute with the Federal Food, Drug, and Cosmetic Act, which, was enacted in 1938 and signed by President Franklin Roosevelt.

The 1938 Food, Drug, and Cosmetic Act, along with its numerous amendments, remains the statutory basis for federal regulation of all foods, drugs, biological products, cosmetics, medical devices, tobacco, and radiation-emitting devices by the U.S. FDA.

Product Tampering

On occasion, a telephone call may be received or an individual may come into the office concerning possible tampering of a food product, over-the-counter drug or cosmetic.

Most reports have proven to be false, with the claimants seeking attention and/or profit. Another common trend is “copy cat” reports on the heels of a widely publicized tampering incident, e.g. syringe in a can of soft drink. A “red flag” indicating a possible false report is when the environmental public health specialist is contacted about the incident by an attorney or news reporter, rather than by the alleged victim.

Tampering, threat of tampering and false reporting of tampering of food products, over-the-counter drugs, or cosmetics is a federal crime. Whenever a report of possible or actual tampering is received, referral must be made to the U.S. Food & Drug Administration (FDA) via the DHSS/BERL central office.

Authority

1. FDA is authorized to investigate reports of tampering:
A. Federal Anti-Tampering Act (FATA), Title 18, USC, Section 1365; and
B. Federal Food, Drug and Cosmetic Act.
2. The lead agency is FDA’s Office of Criminal Investigations (FDA/OCI).
A. FDA/OCI will coordinate notifications with appropriate law enforcement agencies, including the Federal Bureau of Investigation (FBI).

The goal of the FDA/OCI investigation is to:

1. Determine if tampering has occurred;
2. Determine the seriousness of the problem;
3. Determine the quantity of the affected products on the market;
4. If possible, determine the source of the tampering;
5. Quickly remove any contaminated products from consumers or commerce; and
6. Seek to identify and initiate criminal prosecution of those persons responsible for criminal activity associated with the tampering/threat incident.

In some cases, the FDA/OCI may decide not to follow up on reports of tampering because of resource limitations.

They will then consult with the FDA district office to determine proper follow-up, which may include referral to state or local agencies, which may include DHSS/BERL. Any information on matters under investigation by federal agencies must not be released without prior discussion and concurrence of the FDA/OCI.

Method: Reports of tampering may be received directly from the victim, perpetrator, news reporter or attorney; or by referral from the FDA. Timely communication with FDA is important for purposes of coordination and investigation.

When information is received directly from the field:

1. Information from the initial contact should be recorded:

A. Name, address, telephone number of the victim;
B. Product information of the item involved;
(I) Product brand;
(II) Flavor, variety, etc.
(III) Size of container; and
(IV) Lot number, production code, UPC and/or other descriptive identifiers.
C. Problem with the product:
(I) off quality (off-color, off-odor, etc); and/or
(II) Foreign objects.
D. If there has been resulting injury/illness:

(I) has physician and/or medical center been consulted?
(II) Have the police been contacted?
(III) Has victim volunteered that an attorney has been contacted?
(IV) Has victim volunteered that news media has been contacted?
E. If product or product container can be secured, arrange to assume custody of the product/container:
(I) Do not forward to DHSS Laboratory Services unless instructed; and
(II) Notify FDA/OCI for disposition of product/container.
8. Attempt to answer the following concerns as quickly as feasible:
A. Has tampering occurred, or can the condition of the product be explained by other means?
B. Is death, injury, or illness associated with the report and if so, does it appear to be isolated, or widespread?
C. Does the incident appear to be isolated or widespread?
D. Is it likely that other similarly affected products remain in distribution and if so, what is the extent and magnitude of the distribution?
E. If not isolated, could the product tampering have occurred at the production facility or in the distribution chain?
F. Does the report seem plausible; does the victim's story stay consistent?
Upon request or invitation from FDA to DHSS/BERL, personnel may inspect retail stores, distribution points and/or manufacturers relative to a tampering incident investigation.
1. The request or invitation shall be from FDA to DHSS/BERL central office.
A. In most cases, the request of invitation will be routed to appropriate DHSS/BERL regional personnel
B. Depending on circumstances, central office and regional personnel may be involved with the field work associated with the incident;
C. DHSS/BERL personnel should concentrate their efforts on identifying possible avenues that products could become contaminated; and
D. Matters concerning security at these sites, e.g. employee and visitor logs, employees with potential grudges, labor disputes, etc., should be left to the law enforcement agencies.
2. Retail Store Inspection
a. For an isolated incident, visit the retail store where the suspect product was obtained.
To help determine if the tampering occurred after stocking of the shelves or before arrival to the store:
i. Examine other containers of the same lot number for visible signs of tampering;
ii. Inspect what is on the store shelves; and
iii. Inspect what is in the stock room.
b. Obtain the relevant information about the distribution source of the product;
i. If in Missouri, arrange for a visit to the facility for further inspection; or
ii. If out of state, inform DHSS/BERL Central Office, who will notify FDA.
c. For known tampering that presents an immediate health threat, e.g. cyanide in Tylenol, visits to retail outlets known to have the product should be made immediately.
i. The products suspected of being involved shall be placed under embargo and secured.
ii. DHSS/BERL will inform FDA/OCI of the quantity of product placed under embargo, the current location, and the site where the product was found.
iii. The regulatory agency for the affected area will be informed, either by FDA, or DHSS/BERL, for an inspection of the facility.
c. For known tampering that presents an immediate health threat, e.g. cyanide in Tylenol, visits to retail outlets known to have the product should be made immediately.
i. The products suspected of being involved shall be placed under embargo and secured.
ii. DHSS/BERL will inform FDA/OCI of the quantity of product placed under embargo, the current location, and the site where the product was found.
3. Distribution Point
a. Determine if the product was received from another distributor or directly from the manufacturer;
b. Determine if product with the implicated lot number is on hand;
i. If so, the amount should be noted;
ii. Try to learn the amount of suspect product received and any variations from the amount consigned to the facility;
iii. Try to ascertain if the accounts are wholesale, retail or both, and if they handle any cash and carry orders;
iv. The distribution area covered by the facility is also needed. If possible, a listing of accounts likely to have received shipments of the product with the implicated lot number should be made; and
v. Stock rotation practices should be noted.
a) Determine if returns are accepted and how they are handled; and
b) If returns of implicated products are made, are they segregated so they will not inadvertently be re-distributed?
c) Note if there are any practices or opportunities that would allow for tampering of the product.
4. Manufacturer
a. Inspection of a manufacturing facility can be time-consuming and exhausting. The objective is to determine if contamination of the product could have occurred at the facility. Thus, inordinate time should not be given to other sanitation aspects of the facility, e.g. don't document rodent activity by the loading dock if the tampering concern is glass shards in packages of cookies. The rodent activity
Should be noted, but not pursued until the next routine inspection of the facility. With the implicated product in mind:
b. Obtain the names, titles, addresses, and telephone numbers of company representatives;
c. If there are any contract packagers, obtain the name, location and products handled;

d. List other facilities that may produce the product;
e. Determine the production dates of the lot number of the affected product;
i. Describe the lot numbering system and any plant identification numbers and expiration dates placed on product containers and cases;
ii. Find the lot size and history of production beginning with date of receiving raw material and the dates and description of processing steps;
iii. Note the storage history of containers of raw material and whether there are containers partially full; and
iv. Determine distances between production areas or between processing equipment at critical points.
f. Obtain a listing of the facility's source for raw material for the implicated product;
g. Note any locations where an employee could have access to the contaminant being investigated;
i. Describe the security for the suspected contaminant including limitations of access, where it is stored, and responsibility for controlling access to the material;
ii. Describe what legitimate use, if any, the facility has for the suspected contaminant in each of the locations found; and
iii. Determine if there is a log for the material used and, if so, obtain a copy of the log.
h. Describe any laboratory control tests and in-process tests performed on the finished packaged product and in-process materials.
Determine whether reserve samples are retained of all lots;
i. Determine how rejects and re-worked materials are handled; and
i. Describe any unusual events that may have taken place during the period when the suspect material was in the facility.

Record Requests

Occasionally, the investigation may require a request for information, which is considered proprietary or otherwise not normally requested or made available.
1. Under general authority of FATA, federal investigators or DHSS/BERL personnel that are FDA commissioned officers may request certain data from manufacturers, distributors, or other parties involved in the investigation if, in the opinion of supervisory personnel it is necessary, or if the following criteria are met:
a. The apparent tampering incident may be serious and is assigned a high priority by FDA or 12FBI;
b. The data sought are normally of the type that FDA authorized personnel are trained to evaluate and have access to in other areas of routine activities, e.g. production records, formulae, distribution records, etc.;
c. The requested data are likely to be necessary to the successful resolution of the investigation;
d. Other alternatives to obtain the information are not as readily available.
2. If an FATA request for data is made, the DHSS/BERL FDA commissioned officer should direct a verbal request to the most responsible individual at the location;
a. Explain clearly and concisely your need for the data under the general authority of the FATA; and
b. Any refusal encountered during a tampering investigation should be documented and include that the above listed criteria were met and that the firm was aware of the non-routine nature of the request.
i. Consultation will be necessary with DHSS General Counsel and a search warrant, subpoena or court order may be appropriate in some circumstances.

Sampling in tampering incidents will have precautions above and in addition to those described in the Food Sampling subsection of the Communicable Disease Investigation Reference Manual Section 4 Disease Conditions
1. Whenever a sample is collected for suspect tampering:
a. Collect an authentic sample of the same product;
b. If possible, collect from the same lot and code; and
c. At least 6 intact units should be obtained.
2. Any containers that a tampered may have handled in placing the tampered product on the shelf should be collected:
a. If law enforcement or FDA personnel are present, let them collect the containers as they have training and equipment for collecting evidence;
b. If these personnel are not present, determine if the area where the containers are located can be secured until these personnel arrive; and
c. If these personnel are not expected to be on-scene and/or it is likely the container evidence will be compromised, then the on-scene environmental public health specialist should collect the containers with the following precautions;
i. Take care to avoid adding or smearing fingerprints;
a) Wear cotton gloves, use tongs, forceps, or pick up the container by opposing corners;
b) Carefully place an identifying mark, e.g. your initials and date, on product containers in as small an area as possible (this will be important if you are called to testify); and
c) Do not open outer containers to identify inner containers or inserts.
ii. When sampling or handling product;
a) Be alert for traces of evidence such as hair, dust, paint chips, glass
b) Secure such evidence in a separate container such as a glass vial, small manila envelope or plastic bag.
iii. Take caution in packaging samples to avoid smearing and/or removing fingerprints.
a) Paper bags work best;
b) Samples should be packed to avoid movement of the product container within the bag; and
c) Place samples in a secured area, such as your locked car, until they are transferred to another responsible official.

Reporting

Reports must be submitted on a timely basis to keep affected offices in DHSS and FDA informed of latest developments.

1. The on-scene investigator shall submit at least verbal reports to DHSS/BERL central office periodically during the investigation;
2. As needed during the investigation and at the conclusion of the investigation, a written report shall be submitted to DHSS/BERL central office; and
3. Central office staff will forward information to the DEH/CDP director's office and DHSS/OPI.

Current Good Manufacturing Practices and the Federal Food, Drug and Cosmetic ACT

The Food and Drug Administration (hereinafter, FDA) regulates food, drugs, and cosmetics in order to ensure that these products are safe and truthfully labeled. As part of its responsibilities under the Federal Food, Drug, and Cosmetic Act (hereinafter, Act) the FDA monitors the manufacturing practices of companies involved in the production of food, drugs, and medical devices. The FDA monitors the manufacturing practices of companies involved in the production of food, drugs, and medical devices. The manufacturing practices used by these companies must comply with certain standards, Indented in the Act as current good manufacturing practices. If a company's practices do not conform to CGMPs, the finished products are considered adulterated even if the products are technically perfect. The purpose of CGMPs is to assure the safety and efficacy of the finished products.

The Prevention of Food Adulteration Act, 1954

Introduction

Food is one of the basic necessities for sustenance of life. Pure, fresh and healthy diet is most essential for the health of the people. It is no wonder to say that community health is national wealth.

Adulteration of food-stuffs was so rampant, widespread and persistent that nothing short of a somewhat drastic remedy in the form of a comprehensive legislation became the need of the hour. To check this kind of anti-social evil a concerted and determined onslaught was launched by the Government by introduction of the Prevention of Food Adulteration Bill in the Parliament to herald an era of much needed hope and relief for the consumers at large.

Statement of Objects and Reasons

Laws existed in a number of States in India for the prevention of adulteration of food- stuffs, but they lacked uniformity having been passed at different times without mutual consultation between States. The need for Central legislation for the whole country in this matter has been felt since 1937 when a Committee appointed by the Central Advisory Board of Health recommended this step. 'Adulteration of food-stuffs and other goods' is now included in the Concurrent List (III) in the Constitution of India. It has, therefore, become possible for the Central Government to enact all India legislation on this subject. The Bill replaces all local food adulteration laws where they exist and also applies to those States where there are no local laws on the subject. Among others, it provides for (i) a Central Food Laboratory to which food samples can be referred to for final opinion in disputed cases (clause 4),
(ii) a Central Committee for Food Standards consisting of representatives of Central and State Governments to advise on matters arising from the administration of the Act (clause 3), and
(iii) The vesting in the Central Government of the rule-making power regarding standards of quality for the articles of food and certain other matters (clause 22).

ACT 37 OF 1954

The Prevention of Food Adulteration Bill was passed by both the house of Parliament and received the assent of the President on 29th September, 1954. It came into force on Ist June, 1955 as The Prevention of Food Adulteration ACT, 1954 (37 of 1954).

Adaptation Order and Amending Acts

1. The Adaptation of Laws (No.3) Order, 1956.
2. The Prevention of Food Adulteration (Amendment) Act, 1964 (49 of 1964).
3. The Prevention of Food Adulteration (Amendment) Act, 1971 (41 of 1971).
4. The Prevention of Food Adulteration (Amendment) Act, 1976 (34 of 1976).
5. The Prevention of Food Adulteration (Amendment) Act, 1986 (70 of 1986).

Food, Drug and Cosmetic Act, 1938

I. Short Title

II. Definitions

201(f) is the definition for a food, which explicitly includes chewing gum

a) 201(g) is the definition for a drug
b) 201(h) is the definition for a medical device
c) 201(s) is the definition of a food additive
d) 201(ff) is the definition of a dietary supplement

III. Prohibited Acts and Penalties

This section contains both civil law and criminal law clauses. Most violations under the act are civil, though repeated, intentional, and fraudulent violations are covered as criminal law. All violations of the FD&C Act require interstate commerce because of the commerce clause, but this is often interpreted broadly and few products other than raw produce are considered outside of the scope of the act. Notably, the FD&C Act uses strict liability due to the Dotterweich and Park Supreme Court cases. It is one of a very small number of criminal statutes that does.

IV. Food: There is a distinction in food adulteration between those that are added and those that are naturally present. Substances that are added are held to a stricter "may render (it) injurious to health" standard, whereas

substances that are naturally present need only be at a level that "does not ordinarily render it injurious to health"

V. Drugs and Devices

a) 505 is the description of the drug approval process
b) 510(k) is the section that allows for clearance of class II medical devices
c) 515 is the description of the (class III) device approval process

VI. Cosmetics

VII. General Authority

a) 704 allow inspections of regulated entities. Inspection results are reported on Form 483.

VIII. Imports and Exports

IX. Tobacco Products

X. Miscellaneous

6.0 The Prevention of Food Adulteration Rules, 1955;

PART I—PRELIMINARY

1. Short title, extent and commencement

(1) These Rules may be called the Prevention of Food Adulteration Rules, 1955.

(2) They extend to the whole of India.

(3) The rules other than those contained in Part III. Appendix 'B', Item A. 12- Margarine, Part VI and Part VII shall come into force on the date of their publication in the Official Gazette, the rules contained in Part III, Appendix 'B' Item A.12- Margarine shall come into force on the first day of June, 1956 and the rules contained in Part VI and Part VII shall come into force on the first day of December, 1956.

2. Definition -- In these rules, unless the context otherwise requires

(a) "Act" means the Prevention of Food Adulteration Act, 1954(37 of 1954);

(b) "Director" means the Director of the Laboratory;

(c) "Laboratory" means a Central Food Laboratory;

(d) "Form" means a Form set forth in Appendix A to these rules;

- "infant" means a child not more than twelve months of age;
- "infant food" means any food (by whatever name called) being marketed or otherwise represented as a complement of mother's milk to meet the growing nutritional needs of infant after the age of four months;
- "infant milk substitute" means any food being marketed or otherwise represented as partial or total replacement for mother's milk, whether or not it is suitable for such replacement';

(e) "Local Authority" means

(i) in the case of sea ports, the Health Officer as defined in the Indian Port Health Rules, 1955, in respect of that portion of local area falling within the jurisdiction of the ports;

(ii) in the case of airports, the Health Officer as defined in the Indian Aircraft (Public Health) Rules, 1954, in respect of that portion of the local area falling within the jurisdiction of the airport;

(iii) in the case of all railway stations or groups of railway stations (including any railway colony, office, yard, goods-shed, transshipment shed, workshop and other works owned and maintained by the Railway Administration for the purpose or in connection with Railways) the Medical Superintendent/ Divisional Medical Officer of the Railways in respect of that portion of the local area falling within the jurisdiction of the said railway station or group of railway stations.

(iv) In case of an ordnance factory or equipment factory, the General Manager of such factory or equipment factory or both.

PART II – THE CENTRAL FOOD LABORATORY

3. Functions- (1) In addition to the functions entrusted to the Laboratory by the Act, the Laboratory shall carry out the following functions, namely

(a) analysis of samples of food sent by any officer or authority authorized by the Central Government for the purpose and submission of the certificate of analysis to the authorities concerned;

(b) investigation for the purpose of fixation of standard of any article of food;

(c) investigation, in collaboration with the laboratories of Public Analysis in the various States and such other laboratories and institutes which the Central Government may approve in this behalf for the purpose of standardizing methods of analysis.

4. Analysis of Food Samples

(1) (a) Sample of food for analysis under sub section (2) of section 13 of the Act shall be sent either through a Messenger or by registered post in a sealed packet, enclosed together with a memorandum in Form I in an outer cover addressed to the Director.

(b) Samples of food for analysis under sub-section (2) of section of the Act or under clause (a) of Rule 3 shall be sent either through a Messenger or by registered post in a sealed packet enclosed together with a memorandum in Form I-A in an outer cover addressed to the Director.

(2) The container as well as the outer covering of the packet shall be marked with a distinguishing number.

(3) A copy of the memorandum and a specimen impression of the seal used to seal the container and the cover shall be sent separately by registered post to the Director.

(4) On receipt of a package containing a sample for analysis, the Director or on officer authorized by him, shall compare the seals on the container and the outer cover with specimen impression received separately and shall note the condition of the seals thereon.

(5) The fees payable in respect of such a certificate shall be Rs.1000 per sample of food analyzed.

(6) Certificates issued under these rules by the Laboratory shall be signed by the Director.

(7) The fee payable in respect of analysis of samples of imported food analyzed in any designed laboratory shall be Rs. 3000/- per sample payable by the importer.

PART III – Definitions And Standards of Quality

5. Standards of quality of the various articles of food specified in Appendix B to these rules are as defined in that unless he:

PART IV – Public Analysts and Food Inspectors

6. **Qualification of Public Analyst—**A person shall not be qualified for appointment as a public analyst unless he:

hold a Master's Degree in Chemistry or Bio-Chemistry Food Technology or Microbiology or Food and Drugs from a University established in India by Law or is an Associate of the Institution of Chemists (India) by examination in the section of Food Analyst conducted by the Institution of Chemists (India) or has an equivalent qualification recognised and notified by the Central Government for such purposes and has not less then three years' experience in the analysis of food;

(1) has been declared qualified for appointment as a public analyst by a Board appointed and notified by the Central Government for such purposed.

Provided that a person who is a public analyst on the date of commencement (24.8.1995) of these Prevention of Food Adulteration (Amendment) Rules, 1995 or who has worked as a public analyst for a period of three years before such commencement may hold office as such, subject to the terms and conditions of service applicable to him even though he does not fulfil the qualifications laid down in clauses (1) and (2).Provided further that a person who:-

(i) holds a degree in science with chemistry or Bio-chemistry or Food Technology or Food and Drugs from a University establishment in India by law or has an equivalent qualification recognised and notified by the Central Government for such purpose and has not less than five years of experience after graduation in the analysis of food, and

(ii) (a) has been declared qualified for appointment as a public analyst by a Board appointed and notified under clause (2) of this rule, prior to commencement of the Prevention of Food Adulteration (Amendment) Rules, 1955 or

(b) Shall be declared qualified for appointment as a public analyst by a Board appointed and notified under clause (2) of this rule upto the period of 31st March, 1999.

7. Duties of public analyst

(1) On receipt of a package containing a sample for analysis from a Food Inspector or any other person the Public Analyst or an officer authorised by him shall compare the seals on the container and the outer cover with specimen impression received separately and shall note the condition of the seals thereon.

Provided that in case sample container received by the public analyst is found to be is broken condition or unfit for analysis he shall within a period of seven days from the date of receipt of such sample inform the Local (Health) Authority about the same and send requisition to him for sending second part of the sample.

(2) The public analyst shall cause to be analyst such samples of article of food as may be sent to him by Food Inspector or by any other person under the Act.

(3) The public analyst shall, within a period of forty days from the date of receipt of any sample for analysis, send by registered post or by hand to the Local (Health) Authority a report of the result of such analysis in Form III.

Provided that where any such sample does not conform to the provisions of the Act or these rules, the public analyst shall send by registered post or by hand four copies of such report to the said Authority.

Note: In case of sample received under the proviso of Rule 7(1) or Rule 9A, the period of forty days shall be counted from the date of receipt of the second part of the sample.

8. Qualifications for Food Inspector

A person shall not be qualified for appointment as Food Inspector unless he—

(a) is a medical officer in charge of health administration of a local area; or

(b) is a graduate in medicine and has received at least one month's training in food inspection and sampling work approved for the purpose by the Central Government or a State Government or

(c) is a graduate in Science with Chemistry as one of the subjects or is a graduate in Agriculture or Public Health or Pharmacy or in Veterinary Science or a graduate in Food Technology or Dairy Technology or is a diploma holder in Food Technology or Dairy Technology from a University or Institution established in India by law or has equivalent qualifications recognised and notified by the Central Government for the purpose and has received three month's satisfactory training in food inspection and sampling work under a Food (Health) Authority or in an institution approved for the purpose by the Central Government.

Provided that the training in Food inspection and sampling work obtained prior to the commencement of Rule 3 of Prevention of Food Adulteration (Fourth Amendment) Rules, 1976 in any of the laboratories under the control of –

(i) a public analyst appointed under the Act, or

(ii) a fellow of the Royal Institution of Chemistry of Great Britain (Branch E); or

(iii) any Director , Central Food Laboratory; or the training obtained under a Food (Health) Authority, prior to the commencement (1.3.1980) of the Prevention of Food Adulteration (Amend-ment) Rules 1980, shall be considered to be equivalent for the purpose of the requisite training under these rules.

Provided further that a person who is a qualified Sanitary Inspector having experience as such for a minimum period of one year and has received at least three months training in whole or in parts in food inspection and sampling work, may be eligible for appointment as food inspector, upto the period ending on the 31st March, 1985 and may continue as such if so appointed even though he does not fulfil the qualifications laid down in clauses (a) to (c).

9. Duties of Food Inspector:- It shall be the duty of the food inspector--

(a) to inspect as frequently as may be prescribed by the Food (Health) Authority all establishments licensed for the manufacture, storage or sale of an article of food within the area assigned to him;
(b) to satisfy himself that the conditions of the licences are being observed;
(c) to procure and send for analysis; of necessary, samples of any articles of food which he has reason of suspect are being manufactured, stocked or sold or exhibited for sale in contravention of the provisions of the Act or rules thereunder;
(d) to investigate any complaint which may be made to him in writing in respect of any contravention of the provisions of the Act, or rules framed there under;
(e) to maintain a record of all inspections made and action taken by him in the performance of his duties, including the taking of sample and the seizure of stocks, and to submit copies of such record to the health officer or the Food (Health) Authority as directed in this behalf.
(f) To make such enquiries and inspections as may be necessary to detect the manufacture, storage or sale of articles of food in contra-vention of the Act or rules framed there under;
(g) To stop any vehicle suspected to contain any food intended for sale or delivery for human consumption;
(h) When so authorised by the health officer, having jurisdiction in the local area concerned or the Food (Health) Authority, to detain imported packages which he has reasons to suspect contain food, the import or sale of which is prohibited.
(i) To person such other duties as may be entrusted to him by the health officer having jurisdiction in the local area concerned or Local (Health) Authority or the Food (Health) Authority;

9-A. Sending of sample by Local Health Authority-- (a) Local (Health) Authority shall within a period of seven days of seven days of receipt of requisition for second part of the sample from Public Analyst under the proviso of Rule 7(1), send such sample of the Public Analyst.

(b) Local (Health) Authority, while sending second part of the sample under the provision of sub-section (2E) of section 13 of the Act, shall do so within a period of 20 days from the date of receipt of the report from the first public analyst.

9-B. Local (Health) Authority to send report to person concerned-- The Local (Health) Authority shall within a period of ten days after the institution of prosecution forward a copy of the report of the result of analysis is Form III delivered to him under sub-rule(3) of Rule-7, by registered post or by hand, as may be appropriate, to the person from whom the sample of the article was taken by the Food Inspector, and simultaneously also to the person, if any, whose name, address and other particulars have been disclosed under section 14A of the Act.

Provided that where the sample conforms to the provisions of the Act or the rules made there under, and no prosecution is intended under sub-section (2), or no action is intended under sub-section (2E) of section 13 of the Act, the Local (Health) Authority shall intimate the result to the vendor from whom the sample has been taken and also to the person, whose name, address and other particulars disclosed under section 14A of the Act, within 10 days from the receipt of the report from the public analyst.

10. Forms of order not to dispose of stock and of bond- Where the food inspector keeps any article of food in the safe custody of the vendor under sub-section (4) of section 10—

(a) he shall, after sealing such article of food, make an order to the Vendor in Form IV and the vendor shall comply with such an order, and
(b) He may require the vendor to execute a bond in Form IV A.

11. Form of receipt for food seized by a food inspector

For every articles of food seized and carried away by food inspector under sub-section (4) of section 10 of the Act, a receipt in Form V shall be given by the food inspector to the person from whom the article was seized.

12. Notice of intention to take sample for analysis

When a Food Inspector takes a sample of an article for the purpose of analysis, he shall give notice of his intention to do so in writing in Form VI, then and there, to the person from whom he takes the sample and simultaneously, by appropriate means, also to the persons, if any, whose name, address and other particulars have been disclosed under section 14A of the Act.

Provided that in case where a food inspector draws a sample from an open container, he shall also draw a sample from the container in original condition of the same article bearing the same declaration, if such container is available, and intimate this fact to the Public Analyst.

12 A. Warranty—Every manufacturer, distributor or dealer selling an article of food to a vendor shall give either separately or in the bill, cash memo or a label a warranty in Form VIA.

12 B. Form of nomination of Director or Manager and his content, under section 17-- (1) A company may inform the Local (Health) Authority of the concerned local area, by notice in duplicate, in Form VIII containing the name and address of the Director or Manager, who has been nominated by it under sub section (2) of section 17 of the Act to be in charge of, and responsible to the company for

the conduct of the business of the company or any establishment, branch or unit thereof.

Provided that no such nomination shall be valid unless the Director or Manager who has been so nominated, gives his consent in writing and has affixed his signature, in Form VIII in duplicate in token of such consent.

(2) The Local (Health) Authority shall sign and return one copy of the notice in Form VIII to the company to signify the receipt of the nomination and retain the second copy in his office for record.

12 C. Vendor to disclose name and address of Director/Manager in certain circumstances—Every vendor of an article of food shall disclose the name and address of the Director or Manager, as the case may be , nominated in Form VIII under Rule-12B to a purchase who informs such vendor of his intention of purchasing any such article him for analysis by a public analyst under section 12 of the Act.

13. Power of food inspector to deal with carriers of disease handling food—

Where the food inspector is of the opinion that any person engaged in selling or manufacturing any article of food is suffering from or harbouring the germs of any infectious disease, he may examine or cause to be examined such person. Provided that where such person is a female above the age of eight years she shall be examined by a woman duly authorised by the food inspector. If on such examination the food inspector finds that such person is suffering from any such disease, he may by order in writing direct such person not to take part in selling or manufacturing any article of food.

PART V - Sealing, Fastening and Dispatch of Samples

14. Manner of Sending of sample for analysis: Sample of food for the purpose of analysis shall be taken in clean and dry bottles or jars or in other suitable containers which shall be closed sufficiently tight to prevent leakage, evaporation or in the case of dry substance entrance of moisture and shall be carefully sealed.

15. Bottles or containers to be labelled and addressed- All bottles or jars or other containers containing samples for analysis shall be properly labelled and the parcels shall be properly addressed. The label on any sample of food sent for analysis shall bear:-

(a) code number and Serial number of the Local(Health) Authority
(b) Name of the sender with official designation, if any
(d)Date and Place of collection;
(e)Nature of article submitted for analysis;
(f)Nature and quantity of preservative if any, added to the sample;

Provided that in the case of a sample of food which has been taken from Agmark sealed container, the label shall bear the following additional information:-

(a) Grade;
(b) Agmark label no/Batch No;
(c) Name of packing station.

16. Manner of Packing and sealing the samples - All samples of food sent for analysis shall be packed , fastened and sealed in the following manner, namely :-

a) The stopper shall first be securely fastened so as to prevent leakage of the content in transit;

b) The bottle, jar or other container shall then be completely wrapped in fairly strong thick paper, The ends of the paper shall be neatly folded in and affixed by means of gum or other adhesive;

c) a paper slip of the size that goes round completely from the bottom to top of the container, bearing the signature and code and serial number of the Local (Health) Authority, shall be pasted on the wrapper ,the signature or the thumb impression of the person from whom the sample has been taken being affixed in such a manner that the paper slip and the wrapper both carry a part of the signature or thumb impression:

Provided that in case, the person from whom the sample has been taken refuses to affix his signature or thumb impression, the signature or thumb impression of the witness shall be taken in the same manner.

d) The paper cover shall be further secured by means of strong twine or thread both above and across the bottle, jar or other container, and the twine or thread shall then be fastened on the paper cover by means of sealing wax on which there shall be at least four distinct and clear impressions of the seal of the sender, of which one shall be at top of the packet, one at the bottom and the other two on the body of the packet. The knots of the twine or thread shall be covered by means of sealing wax bearing the impression of the seal of the sender.

17. Manner of despatching of containers of samples :- The containers of the sample shall be despatched in the following manner, namely:-

a) The sealed container of one part of the sample for analysis and a memorandum in Form VII shall be sent in a sealed packet to the public analyst immediately but not later than the succeeding working day by any suitable means:

b) The sealed containers of the remaining two parts of the sample and tow copies of the memorandum in Form VII shall be sent in a sealed packet to the Local (Health) Authority immediately but not later than the succeeding working day by any suitable means:

c) The sealed container of one of the remaining two parts of the sample and a copy of the memorandum in Form VII kept with the local (Health) Authority shall within a period of 7 days be sent to the Public Analyst on requisition made by him to it by any suitable means.

Provided that in the case of food which has been taken from container bearing Agmark seal, the memorandum in Form VII shall contain the following additional information, namely:-

a) Grade;
b) Agmark label No /Batch No:
c) Name of packing station

18. Memorandum and impression of seal to be sent separately:-

A copy of the memorandum and specimen impression of the seal used to seal the packet shall be sent, in a sealed packet separately to the Public Analyst by any suitable means immediately but not later than the succeeding working day.

19. Addition of preservatives to sample

Any person taking a sample of any food for the purpose of analysis under the Act may add a preservative as may be prescribed from time to time to the sample for the purpose of maintaining it in a condition suitable for analysis.

20. Preservative in respect of milk, cream, dahi , khoa or khoa based and paneer based sweets, such as Kalakand and Burfi, Chutney and prepared foods Gur, Coffee and Tea -- The preservative used in the case of samples of any milk including toned, separated and skimmed milk, standardised milk chhanna, skimmed milk chhanna , cream , ice candy, dahi khoa or khoa based and Paneer based sweets, such as Kalakand and Burfi, Chutney and prepared foods Gur, Coffee and Tea in liquid of semi-liquid form shall be the liquid commonly known as "formalin" that is to say, a liquid containing about 40 per cent of formaldehyde in aqueous solution in the proportion of 0.1ml. (two drops) for 25ml. Or 25 grams.

Provided that in case of samples of ice cream and mixed ice cream, the preservative used shall be the liquid commonly known as formalin, that is to say a liquid containing about 40 per cent of formaldehyde in aqueous solution in the proportion of 0.6ml.for 100ml. or 100 grams.

21. Nature and quantity of the preservative to be noted on the label—Whenever any preservative is added to a sample, the nature and quantity of the preservative is added shall be clearly noted on the label to be affixed to the container.

22. Quantity of sample to be sent to the public analyst—

The quantity of sample of food to be sent to the public analyst/Director for analysis shall be as specified.

22 A. Contents of one or more similar sealed containers having identical labels to constitute the quantity of a food sample—Where food is sold or stocked for sale or for distribution in sealed container having identical label declaration, the contents of one or more of such containers as may be required to satisfy the quantity prescribed in Rule 22 shall be treated to be a part of the sample.

22 B.Quantity of sample sent to be considered as sufficient – Notwithstanding anything contained in Rule 22 and Rule 22C, the quantity of sample sent for analysis shall be considered as sufficient unless the public analyst or the Director reports to the contrary.

22 C. Quantity of samples of food packaging material to be sent to the public analyst-- The quantity of sample of food packaging, material to be sent to the Public Analyst/Director for analysis.

PART VI – Colouring Matter

23. Unauthorised addition of colouring matter prohibited

The addition of a colouring matter to any article of food except as specifically permitted by these rules, is prohibited.

24. Extraneous addition of colouring matter to be mentioned on the label

Where an extraneous colouring matter has been added to an article of food, there shall be displayed one of the following statements in capital letters, just beneath the list of ingredients on the label attached to any package of food so coloured, namely:--

i. CONTAINS PERMITTED NATURAL COLOUR(S)

OR

ii. CONTAINS PERMITTED SYNTHETIC FOOD COLOUR(S)

OR

(iii) CONTAINS PERMITTED NATURAL AND SYNTHETIC FOOD COLOUR(S)

OR

(iv) CONTAINS PERMITTED NATURAL*/AND*SYNTHETIC COLOUR(S)

(For the period up to and inclusive of Ist September, 2001.)

(*strike out whichever is not applicable)

Note: Provided that where such a statement is displayed, the colour used in the product

Need not be mentioned in the list of ingredients.

25. Use of caramel permitted: Not with standing provisions of Rule 24 and Rule32 (b) caramel may be used without label declaration.

26. Natural colouring matter which may be used –

Except as otherwise provided in the rules the following natural colouring principles whether isolated from natural colours or produced synthetically may be used in or upon any article of food

b (i) Beta-carotene
(ii) Beta-apo-8 carotenal,
(iii) Methylester of Beta-apo-8 carotenoic acid,
(iv) Ethyl ester of Beta-apo-8 carotenoic acid;
(v) Canthaxanthin;
(c) Chlorophyll;
(d) riboflavin (Lactoflavin ;
(e) Caramel;
(f) Annatto;
(h) Saffron;
(i) Curcumin or turmeric

Explanation - In the preparation of the solution of annatto colour in oil, any edible vegetable oil listed in Appendix 'B' sto these rules may be used either singly or in combination and the name of the oil or oils used shall be mentioned on the label as provided in sub-rule (Z) of rule 42.

Table 1. Synthetic food colours which may be used

S. No.	Colour	Common Name (1956)	Colour index	Chemical Glass
(1)	(2)	(3)	(4)	(5)
1	Red	Ponceu 4R Carmoisine Erythrosine	16255 14720 45430	Azo Azo Xanthene
2	Yellow	Tartrazine Sunset yellow FCF	19140 15985	Pyrazolone Azo
3.	Blue	Indigo Carmine Brilliant Blue FCF	73015 42090	Indigoid Triarylmethane
4	Green	Fast green FCF	42053	Triarylmethane

27. Addition of inorganic matter and pigments prohibited-

Inorganic colouring matters and pigments shall not be added to any article of food;

Provided that chewing gum may contain Titanium dioxide – (food grade) up to a maximum limit of 1 per cent.

28A. Use of Lake colours as colourant in foods— Aluminum Lake of Sunset yellow FCF may be used in powdered dry beverages mix (powdered soft drink concentrate) upto a maximum limit of 0.04 percent weigh by weight. The maximum limit of color content in final beverage for consumption shall not exceed 8.3 ppm and that of aluminum content shall not exceed 4.4ppm of the final beverage for consumption.

Provided that the powdered dry beverages mix (powdered softdrink concentrate) label shall give clear instruction for reconstitution of product for making final beverage.

29. Use of permitted synthetic food colours prohibited - Use of permitted synthetic food colours in or upon any food other than those enumerated below is prohibited:--

(a) Ice- Cream, milk lollies, frozen deserts, flavoured milk, yoghurt, ice-cream mix powder;
(b) Biscuits including biscuits wafers, pastries, cake, confectionery, thread candies, sweets, savouries (dal moth, mongia, phululab, sago papad, dal biji only);
(c) Peas, strawberries and cherries in hermaticlly sealed container, preserved or processed oapaya, canned tomato juice, fruit syrup, fruit squash, fruit cordial, jellies, jam, marmalade, candied crystallised or glazed fruits;
(d) Non-alcoholic carbonated and non- carbonated ready-to- serve synthetic beverages including synthetic syrups, sherbets, fruit bar, fruit beverages, fruit drinks, synthetic soft drink concentrates;
(e) Custard powder;
(f) Jelly crystal and ice candy;
(g) Flavour emulsion and flavour pate for use in carbonated or non carbonated beverages only under label declaration as provided in clause (13) of sub-rule (ZZZ) of rule 42.

30. Maximum limit of permitted synthetic food colours—

The maximum limit of permitted synthetic food colours or mixture thereof which may be added to any food article enumerated in rule 29 shall not exceed 100 parts per million of the final food or beverage for consumption, except in vase of food articles mentioned in clause (c) of rule 29 where the maximum limit of permitted synthetic food colours shall not exceed 200 parts per million of the final food or beverage for consumption.

31. Colours to be pure—The colours specified in Rule 28 when used in the preparation of any article of food shall be pure and free from harmful impurities.

PART VII - Packaging and Labelling of Foods

32. Package of food to carry a label - Every package of food shall carry label and unless otherwise provided in these rules, there shall be specified every label:-

(a) the name trade name or description of food contained in the package, Provided that the name, trade name or the description of food given on the package of food shall not include the name of any food or ingredient prefixed or suffixed to it, if such food ingredient is not the main ingredient of the final food product.
(b) The names of ingredients used in the product in descending order their composition by weight or volume as the case may be.

Provided that in the case of artificial flavouring substances, the label may not declare the chemical names of the flavours, but in the case of natural flavouring substances or nature-identical falvouring substances, the common name of flavours shall be mentioned on the label. Provided also that whenever Gelatine is used as an ingredient, a declaration to this effect shall be made on the label by inserting the word " Gelatine-Animal Origin." Provided also that when any article of food contains whole or part of any animal including birds, fresh water or marine animals or eggs or product of any animal origin, but not including milk or milk products, as an ingredient, - A declaration to this effect shall be made by a symbol and colour code so stipulated for this purpose to indicate that the product is Non-Vegetarain Food. The symbol shall consist of a brown colour filled circle having a diameter not less than the minimum size specified in the Table given below, inside the square with brown outline having side double the diameter of the circle, as indicated in clause (16) of sub-rule of rule 42.

37. Labels not to contain false or misleading statements

A label shall not contain any statement, claim, design, device, fancy name or abbreviation which is false or

misleading in any particular concerning the food contained in the package, or concerning the quantity or the nutritive value or in relation to the place of origin of the said food.

Provided that this rule shall not apply in respect of established trade or fancy names of confectionery, biscuits and sweets such as Barley, sugar, Bulls, Cream Cracker, or in respect of aerated waters such as Ginger Beer or Gold Spot or any other name in existence in international trade practice.

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 every day. 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 posses.

REFERENCES

1. Food and Drug Administration, Center for Food Safety and Applied Nutrition. *Defect Action Level Handbook*. Washington, D.C.: Government Printing Office, 1995. Revised 1997, 1998. Available athttp://www.cfsan.fda.gov/dms/dalbook.html.
2. Food and Drug Administration, Office of Regulatory Affairs. *Compliance Policy Guides Manual*. Washington, D.C.: Government Printing Office, 2000; updated 2001. Available athttp://www.fda.gov/ora/compliance_ref/cpg/default.htm.
3. Food and Drug Administration. *Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed*. Washington, D.C.: Government Printing Office, 2000. Available athttp://www.cfsan.fda.gov/lrd/fdaact.html.
4. 1911 report of bureau of chemistry, U.S. Dept of Agriculture, Sept. 1, 1911.
5. Code of federal regulations, chapter 21, parts 210, 211. published by the office of the Federal register, National archives and Records Administration.