 Sorption indicate **binding of molecules to polymer** includes both **adsorption and absorption**.

 Sorption occurs through chemical or physical means.

 Sorption may occur with **active pharmacologic agents** or with **excipients.**

 Sorption may be initiated by the **adsorption of a solute to the inner surface of a plastic container.**

 After saturation of the surface, the solute may diffuse into the container and bound within plastic container.

 Plastic materials with polar groups are prone to sorption. Because **sorption depends on penetration or diffusion of a solute into plastic.**

 un-ionized species of solute has greater tendency to bound than ionized species. The degree of ionization of a solute affected by pH of solution, the pH may influence sorption of particular solute.

 The sorption of excipients :colorants, preservatives, or stabilizers would likewise alter the quality of product.

 Methylparaben may be sorbed to some types of plastics, resulting in a decrease in the available concentration of preservative.

Deformations, **softening**, **hardening**, and other physical changes in plastic containers can be caused by the action of container's contents or external factors, including changes in temperature and physical stress placed upon the container in handling and shipping.

Pharmaceuticals labeling

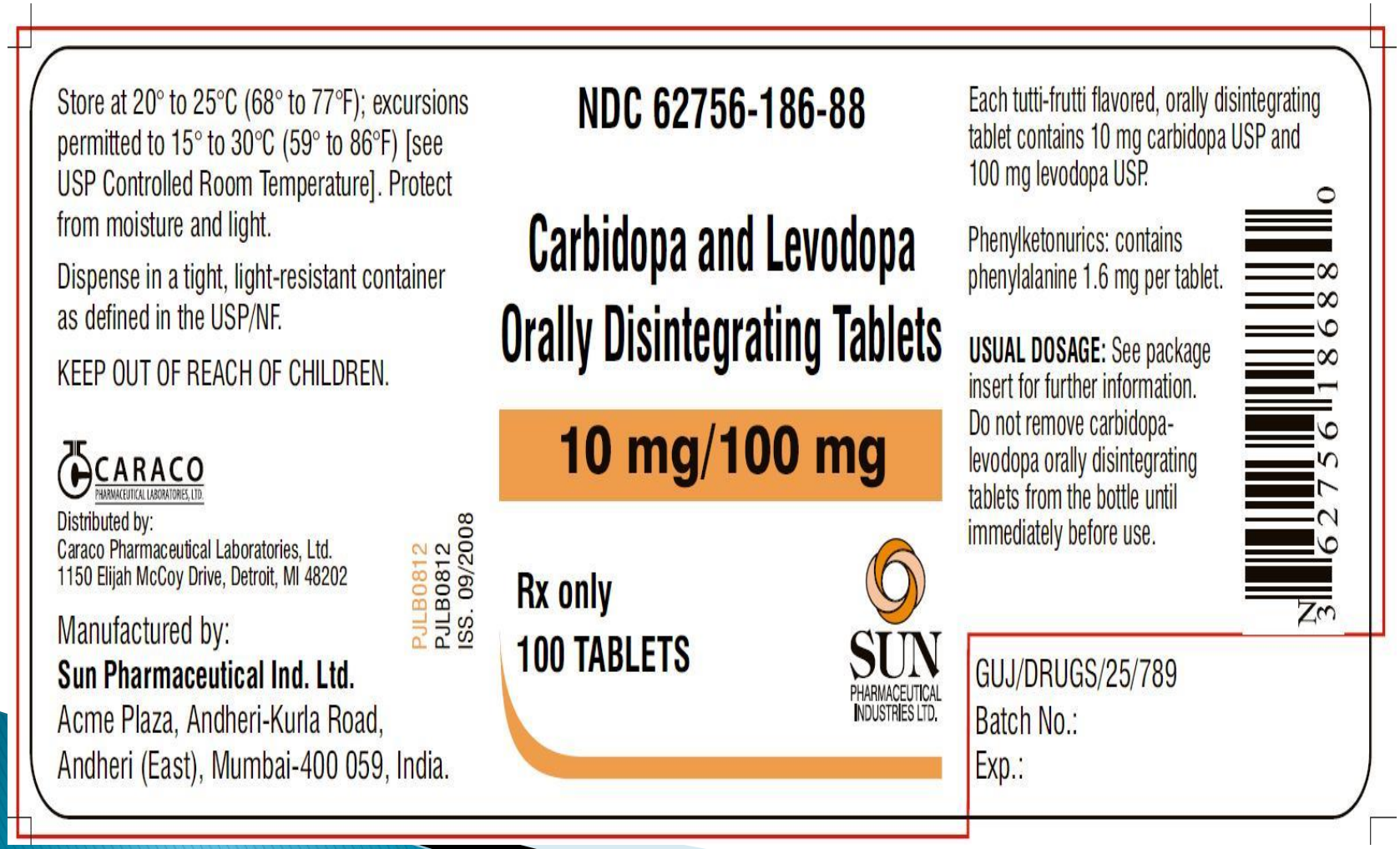
All drug products distributed must **meet labeling requirements**: Investigational drugs, Manufacturer's prescription drugs, Controlled substances, Dispensed prescription medication, OTC products, Products for animals, Medical devices.

In addition of labeling on the immediate container and packaging, **manufacturers' drug product insert**:

- Company literature
- Advertising and promotional material (brochures, booklets, bulletins, sound recordings, price lists, catalogs, sound recordings, motion picture films, exhibits, and computer-accessed information etc.)
- Important information for a prescription-only drug is provided to health professionals

Manufacturer's Product Label

The information usually appearing on label affixed to the container is the following

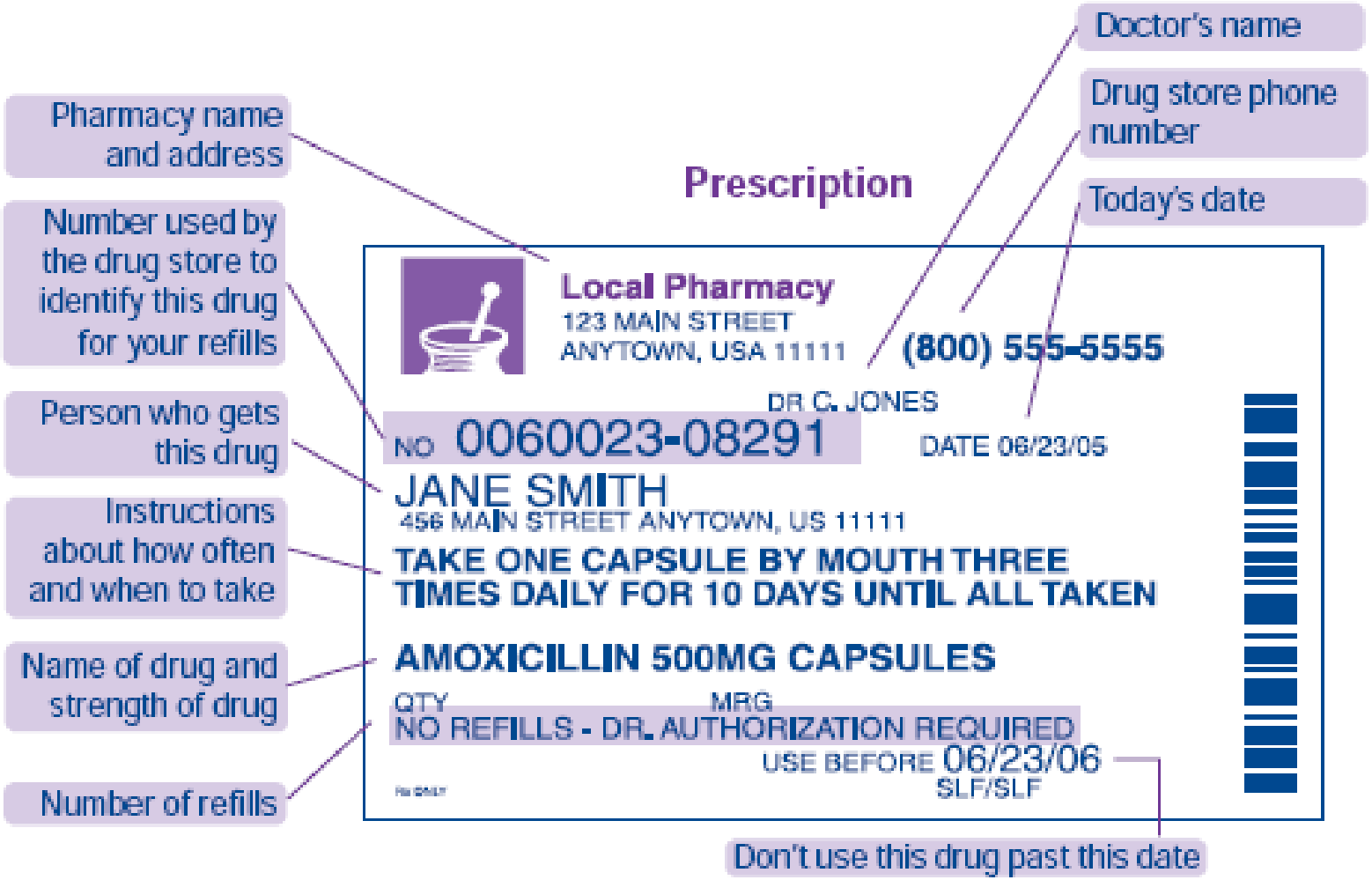


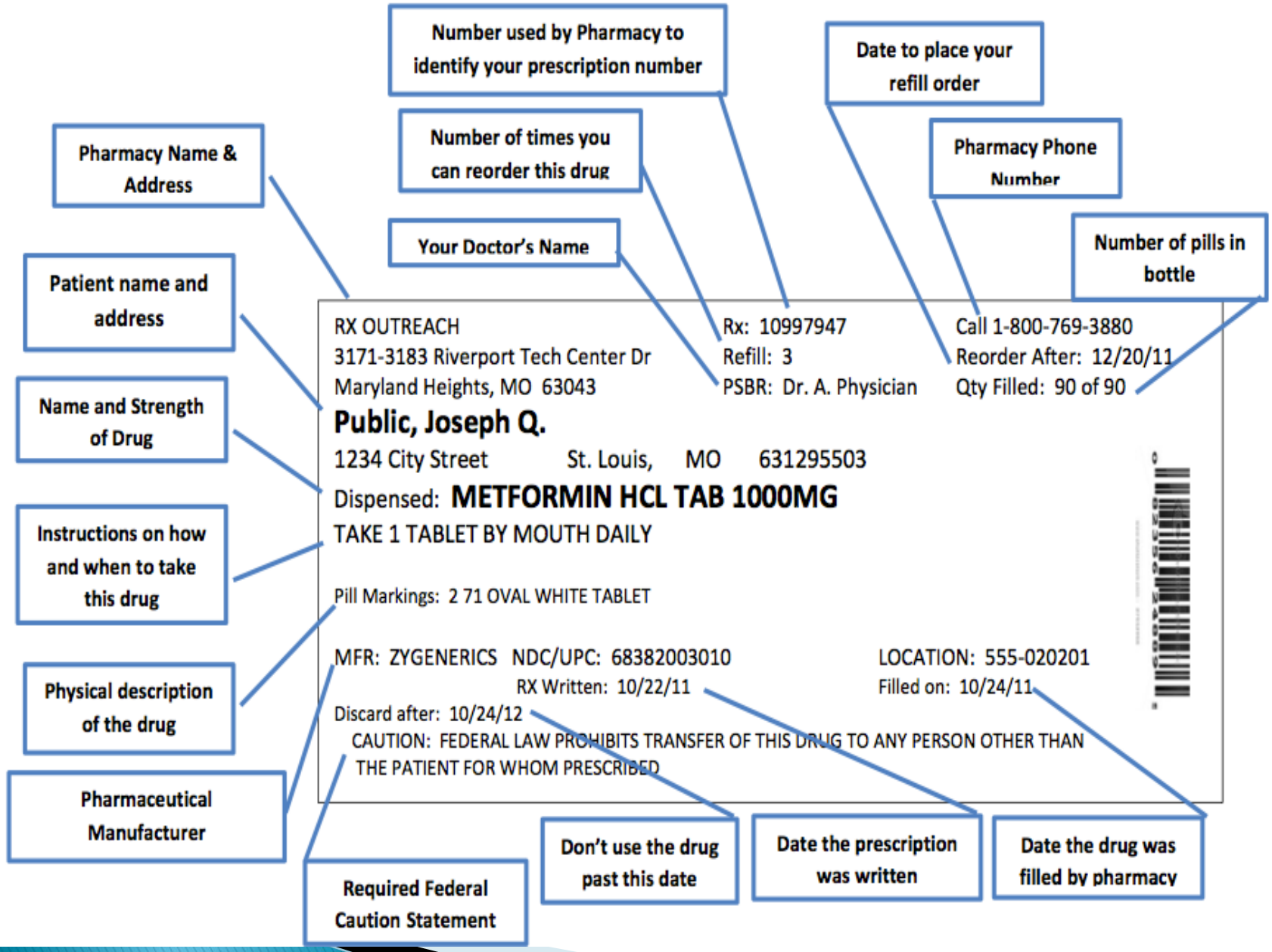
- The **nonproprietary name** of drug
- The **name of the manufacturer**, or distributor of the product
- A quantitative statement of **the amount of each drug per unit of weight**, volume, or dosage unit, whichever is most appropriate
- The pharmaceutical **type of dosage form** constituting the product
- The **net amount of drug product** contained in the **package**, in units of weight, volume, or number of dosage units, as appropriate
- The **logo "Rx only"** or the federal legend "Caution—Federal law prohibits dispensing without prescription" or a similar statement

- A **label reference** to refer to the accompanying **package insert** or other product literature for dosage and other information
- Special **storage instructions** when applicable
- The **National Drug Code identification** number for the product and a bar code
- An identifying lot or control number
- An **expiration date**
- “Warning—May be habit forming” may also appear.

Prescription Label

When dispensing a prescription include the following information on the label of the dispensed medication:




Number used by Pharmacy to identify your prescription number
Date to place your refill order
Pharmacy Name & Address
Number of times you can reorder this drug
Pharmacy Phone Number
Your Doctor's Name
Number of pills in bottle
Patient name and address
RX OUTREACH
3171-3183 Riverport Tech Center Dr
Maryland Heights, MO 63043
Rx: 10997947
Refill: 3
PSBR: Dr. A. Physician
Call 1-800-769-3880
Reorder After: 12/20/11
Qty Filled: 90 of 90
Public, Joseph Q.
1234 City Street St. Louis, MO 631295503
Name and Strength of Drug
Dispensed: METFORMIN HCL TAB 1000MG
Instructions on how and when to take this drug
TAKE 1 TABLET BY MOUTH DAILY
Pill Markings: 2 71 OVAL WHITE TABLET
Physical description of the drug
MFR: ZYGENERICS NDC/UPC: 68382003010
LOCATION: 555-020201
RX Written: 10/22/11
Filled on: 10/24/11
Discard after: 10/24/12
CAUTION: FEDERAL LAW PROHIBITS TRANSFER OF THIS DRUG TO ANY PERSON OTHER THAN THE PATIENT FOR WHOM PRESCRIBED
Pharmaceutical Manufacturer
Required Federal Caution Statement
Don't use the drug past this date
Date the prescription was written
Date the drug was filled by pharmacy

- The name and address of the pharmacy
- The serial number of the prescription
- The date of the prescription or the date of its filling or refilling (state law often determines which date is to be used)
- The name of the prescriber
- The name of the patient
- Directions for use, including any precautions, as indicated on the prescription

In addition, state laws may require additional information:

• The address of the patient

- The initials or name of the dispensing pharmacist
- The telephone number of the pharmacy
- The drug name, strength, and **manufacturer's lot or control number**
- The expiration date of the drug
- The **name of the manufacturer or distributor**
- In an effort to decrease medication errors, there is thought to include the **"indication"** on the prescription label to help the pharmacist assure the prescribed drug is appropriate

Over- The-Counter Labeling

the name of the product, the name and address of the manufacturer or distributor, the quantity of net contents, the bar code and other product-identifying items, the expiration date, and the other drug-specific required information

Drug Facts

Active ingredient (in each capsule) — **Purpose**

Diphenhydramine HCl 25 mg ..... Antihistamine

Uses ■ temporarily relieves these symptoms of the common cold: ■ runny nose ■ sneezing ■ temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ runny nose ■ sneezing ■ itching of the nose or throat ■ itchy, watery eyes

Warnings

Do not use with any other product containing diphenhydramine, even one used on skin.

Ask a doctor before use if you have ■ a breathing problem such as emphysema or chronic bronchitis ■ glaucoma ■ trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.

When using this product ■ excitability may occur, especially in children ■ marked drowsiness may occur ■ avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ be careful when operating machinery or driving a motor vehicle

Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

■ take every 4 to 6 hours, not more than 6 doses in 24 hours

adults and children 12 years of age and over	take 1 or 2 capsules
children 6 to under 12 years of age	take 1 capsule
children under 6 years of age	consult a doctor
children under 4 years of age	**do not use**

Other information

■ store at room temperature 15°-30°C (59°-86°F) in a dry place ■ protect from light ■ do not use if imprinted safety seal under cap is broken or missing ■ do not use if red band around capsule is broken or missing ■ *This product is not manufactured or distributed by McNeil Consumer Healthcare, Division of McNeil-PPC, Inc., owner of the registered trademark Benadryl® Allergy Kapgels®.

Inactive ingredients

D&C Red #28, FD&C Blue #1, FD&C Red #40, gelatin, lactose and starch.

Over- the-counter labeling

Additional information, “drug facts” must appear in label

 Names and quantities of all active ingredients /dosage unit. Inactive ingredients also listed.

 Statement of pharmacologic category (e.g., antacid, antihistaminic, analgesic, etc….)

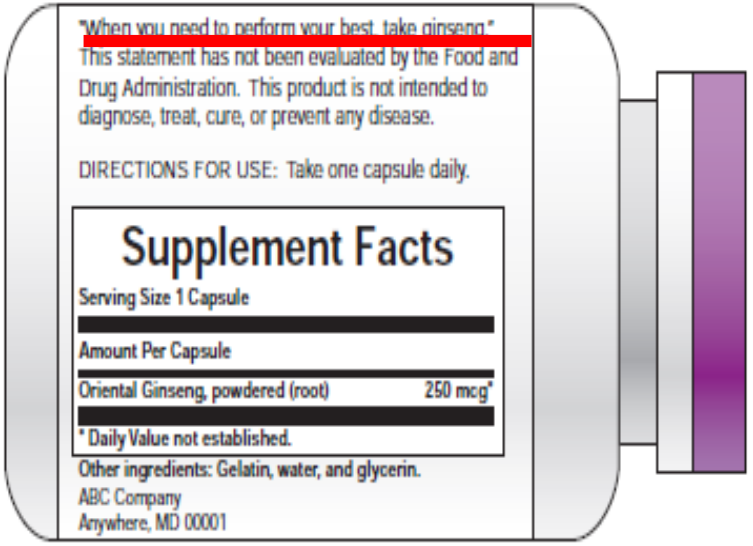
 adequate directions for safe and effective use. Ex. dose, frequency of dose, dose and age considerations, route of administration, and preparation for use, such as shaking before use or dilution.

 Name of any substances in the preparation. Ex. sodium content for certain orally ingested product that contains 5 mg of sodium or more/single dose or 140 mg or more in maximum daily dose. Storage conditions

Dietary Supplement Labeling

- A vitamin
- A mineral
- An herb or other botanical
- An amino acid
- A dietary substance for use
- A concentrate, metabolite, constituent, extract, or a combination of any above ingredient

- Disallows "**disease claims**" that infer or imply that the product can be used to prevent, treat, cure, mitigate or diagnose a disease



Dietary Supplement Labeling

Storage

 The product must be stored in proper conditions to ensure product stability during its shelf life.

 The labeling of product includes **the desired storage conditions,** and such terms employed (USP):

 Cold: Any temperature **not exceeding 8°C.**

-A **refrigerator** is a cold place in which the temperature is maintained thermostatically **between 2° and 8°C**.

-A freezer is a cold place in which the temperature is maintained thermostatically **between -25° and -10°C.**

 Cool: Any temperature **between 8° and 15°C**.

 Room temperature: The temperature prevalent in a working area which is ranged **20°C to 25°C**. (but also allows for temperature variations between 15°C and 30°C.

- **Warm:** Any temperature **between 30° and 40°C**.
- **Excessive heat: Above 40**°C.

- Protection from freezing: freezing subjects products to the **risk of container breakage**, **loss of strength** or **potency,** or to **destructive alteration of dosage form**
- Transportation to and within geographic areas of extreme temperatures and humidity requires special consideration