



Guidance on Over-the-Counter (OTC) Medications and Similar Products

Overview/Background

Over-the-counter (OTC) products are widely available for consumer use without a prescription. However, not all OTC products are created equal. They fall into distinct categories, such as **OTC drugs/medicines, vitamins and dietary supplements, and other health-related products**. Understanding the differences between these categories is essential for safe and effective use.

The key distinction lies in regulation, labeling, and intended use. OTC drugs are strictly regulated by the U.S. Food and Drug Administration (FDA) and must include a **Drug Facts panel**, while vitamins, and similar products are not held to the same standards and do not require a Drug Facts panel. **OTC Products with a Drug Facts panel** must be handled in accordance with the OTC Medication requirements as stated in **Appendix D, Section 7** of the **Partner Food Bank Agreement**.

OTC Drugs/Medicines

OTC drugs are medications that have been approved by the FDA for use without a prescription. They are intended to treat, cure, or prevent specific health conditions and are rigorously tested for safety and efficacy.

Key Characteristics:

- **Regulation:** Partner food banks will be under no obligation to accept OTC medications, however if they decide to do so, they must comply with any federal, state, or local restrictions or licensing requirements for the distribution. They **MUST** be within the product expiration date to be distributed.
- **Labeling:** Must include a **Drug Facts panel** that provides information on active ingredients, uses, warnings, directions, and other important details.

Examples:

- **Pain Relievers:** Ibuprofen (Advil, Motrin), Acetaminophen (Tylenol), Aspirin (Bayer).
- **Cold, Flu, and Allergy Medications:** Pseudoephedrine (Sudafed Sinus, Mucinex-D), Dextromethorphan (Robitussin), Phenylephrine (Sudafed-PE). Loratadine (Claritin), Cetirizine (Zyrtec), Diphenhydramine (Benadryl).
- **Antacids:** Calcium carbonate (Tums), Famotidine (Pepcid), Omeprazole (Prilosec OTC).
- **Topical Treatments:** Hydrocortisone cream, Antibiotic ointments (Neosporin), Antifungal creams (Lotrimin), Benzoyl Peroxide.
- **Toothpastes with Fluoride**



- **Skin_Care/Sun Protection:** Sunscreen, Aloe vera gel.
- **Personal Hygiene:** Hand Sanitizer, Antiperspirants that contain aluminum.

Vitamins and Dietary Supplements

Vitamins and dietary supplements are products intended to supplement the diet. They are not considered drugs and are not intended to treat, cure, or prevent diseases.

Key Characteristics:

- **Regulation:** Regulated as food, not drugs, under the **Dietary Supplement Health and Education Act (DSHEA)**. The FDA does not approve these products before they are marketed.
- **Labeling:** Must include a **Supplement Facts panel**, which lists ingredients, serving size, and daily value percentages.
- **Examples:**
 - **Vitamins:** Centrum, One A Day, Nature Made.
 - **Herbal Supplements:** Echinacea, Ginkgo biloba, St. John's Wort.
 - **Minerals:** Calcium, Magnesium, Zinc.
 - **Protein Supplements:** Whey protein, Plant-based protein powders.
 - **Other Supplements:** Fish oil, Probiotics, Melatonin.

Other Similar Over-the-Counter Products That Might Be Confused with OTC Drugs

Some products may be similar to OTC drugs but do not fall under the category of drugs or supplements. These products will not have a Drug Facts or Supplement Facts panel.

Examples:

- **Oral Care:** Toothpaste without fluoride, Breath mints, Dental floss.
- **First-Aid Supplies:** Bandages (Band-Aid), Antiseptic wipes, Gauze pads.
- **Personal Hygiene:** Deodorant, Lip balms, Soap, Shampoo.
- **Home Health Products:** Heating pads, Thermometers, Nasal strips.
- **Homeopathic Products:** Homeopathic cold remedies, sleep aids or allergy relief products.
- **Medical Devices:** Breathe Right nasal strips, Thermometers, or Blood pressure monitors.



3. **Cosmetics:** Lip balm, hand/body lotion (for moisturizing only, no SPF), makeup

Comparison Table

Category	Regulation	Labeling	Examples	Intended Use
OTC Drugs/Medicines	FDA-regulated as drugs	Drug Facts panel required	Ibuprofen, antacids, allergy medications, cough drops	Treat, cure, or prevent specific conditions
Vitamins/Supplements	Regulated as food	Supplement Facts panel	Multivitamins, herbal supplements	Support overall health and wellness
Other OTC Products	Varies by product type	Drug Facts panel not required	Toothpaste without fluoride, mouthwash without fluoride,	General health maintenance or hygiene

Why These Differences Matter

1. **Safety and Efficacy:** OTC drugs undergo rigorous testing to ensure they are safe and effective for their intended uses. Vitamins, supplements, and other OTC products are not held to the same standards.
2. **Labeling Clarity:** The Drug Facts panel provides clear, standardized information for consumers, while other products may have less detailed or consistent labeling.
3. **Intended Use:** Understanding the purpose of a product helps consumers make informed decisions about their health.

For additional information or questions about OTC products, consult your pharmacist, healthcare provider, or the FDA website.



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Drug Facts							
Active ingredient (in each tablet)	Purpose						
Chlorpheniramine maleate 2 mg.....	Antihistamine						
Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat							
Warnings Ask a doctor before use if you have ■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis ■ trouble urinating due to an enlarged prostate gland Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives							
When using this product ■ drowsiness may occur ■ avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ be careful when driving a motor vehicle or operating machinery ■ excitability may occur, especially in children 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 <table border="1"> <tr> <td>adults and children 12 years and over</td> <td>take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours</td> </tr> <tr> <td>children 6 years to under 12 years</td> <td>take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours</td> </tr> <tr> <td>children under 6 years</td> <td>ask a doctor</td> </tr> </table>		adults and children 12 years and over	take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours	children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours	children under 6 years	ask a doctor
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Drug Facts (continued)
Other information ■ store at 20-25° C (68-77° F) ■ protect from excessive moisture
Inactive ingredients D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch

Reference:

<https://www.fda.gov/drugs/understanding-over-counter-medicines/over-counter-drug-facts-label>