



AAHP Summit on Challenges and Solution in Quality and Safety of Homeopathic Drug Products

Topics in Labeling

Don'ts & Do's for Homeopathic Drug Products

A Compliance Thru Education Seminar

presented by the

American Association of Homeopathic Pharmacists

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- Secretary

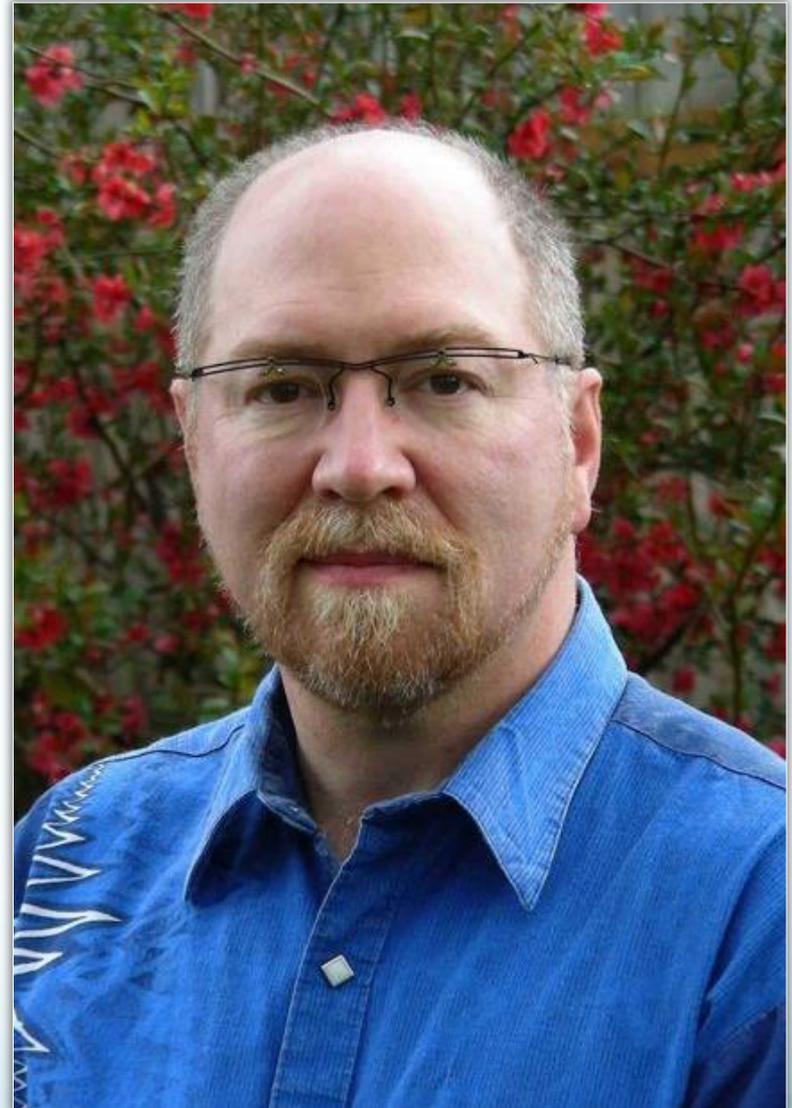
American Association of Homeopathic
Pharmacists

- Board Member

Homeopathic Pharmacopia Convention of
the United States

- Pharmacist

Over 40 years experience with production
and quality control of homeopathic drug
products



Homeopathic Labeling

- FDA's expressed concerns
- Reminders
- FDA's concerns about (some) "OTC" indications
- Crafting appropriate OTC labeling indications
- HPUS -- Labeling Guidelines
- "Traditional" Labeling
- "Drug Facts" Labeling
- Label formats and examples
- Prescription drug labeling

FDA Guidance- December 2017

Drug Products Labeled as Homeopathic

FDA will consider action against:

- Products with reported safety concerns.
- Products that contain or purport to contain ingredients associated with potentially significant safety concerns.
- Products for routes of administration other than oral and topical.
- Products intended to be used for the prevention or treatment of serious and/or life threatening diseases and conditions.
- Products for vulnerable populations.
- Products deemed adulterated under section 501 of the FD&C Act.

Reminder: 21 U.S.C. § 321 (Repeated in CPG 400.400)

(g)(1) “Drug”

(A) articles in the USP, HPUS, or NF, or any supplement;

(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;

(C) articles (other than food) intended to affect the structure or any function of the body of man or other animals;

(D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

Reminder: 21 U.S.C. § 321

(k) “Label” written, printed, or *graphic* matter upon the immediate container;

required information must also appear on the outside;
otherwise **not** complied with

(m) “Labeling” all labels and other written, printed, or *graphic* matter (1) upon any of its containers or wrappers, or (2) accompanying the article.

Labeling includes: brochures, booklets, catalogs, detail literature, films/videos, letters, mailing pieces, **webpages**, etc.

Reminder: 21 U.S.C. § 321

(n) Misbranded (“*labeling or advertising is misleading*”), determined not only by representations made, also suggested by statement, word, **design, device,**

but also the extent fails to reveal facts material with respect to consequences which may result from the use under the conditions in the labeling or advertising or under conditions as are customary or usual.

Reminder: 21 U.S.C. § 321

(p) “New Drug”

(1) composition is not generally recognized, among experts qualified by scientific training and experience, as safe and effective for use under the conditions recommended,

[unless] prior to June 25, 1938, was subject to the Food and Drugs Act of June 30, 1906, and labeling contains the same representations concerning the conditions of its use;

(2) composition, as a result of investigations has become recognized, but has not been used to a material extent or for a material time under such conditions.

Reminder: 21 U.S.C. § 353

Prescription Drug

(b)(1) A drug, with toxicity or other potential for harmful effect, or the method of its use, or the collateral measures necessary, which is not safe for use except under the supervision of a practitioner licensed by law to administer such drug;

dispense **only** upon a prescription.

NOT for OTC Sale

Contrary Dispensing ... misbranded while held for sale.

Reminder: 21 U.S.C. § 353

Prescription Product

(2) Label: name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription.

(4)(A) Misbranded: label fails to bear, at a minimum, the symbol “Rx only”.

Reminder: 21 U.S.C. § 353

Prescription Veterinary Drug

(b)(1) ... intended for use by animals other than man—

Same effective definition.

Same effective dispensing restriction

Same effective label requirements

Product: NOT for OTC Sale

Reminder: 21 CFR 201.5

Adequate directions for use: by which layperson can use a drug safely and for the purposes intended.

Inadequate because omission of:

(a) all conditions, purposes, or uses intended; **except** uses only under the supervision of a practitioner

(b) Quantity of dose, for each use intended, and usual quantities for persons of different ages and different physical conditions.

(c) Frequency (d) Duration. (e) Time of administration (in relation to meals, onset of symptoms, other time factors).

(f) Route of administration. (g) Preparation for use, i.e., shaking, etc.

Don'ts

Examples from warning letters

Prescription product: not safe for use except under the supervision of a licensed practitioner

- ... temporarily relieve symptoms of Tinnitus such as: ringing, buzzing, roaring . . . nerve and noise sensitivity . . .
- The product, “Cold Sores & Herpes” relieve . . .tingling and itching from herpes.
- Webpage states that *HOMEOPATHY CAN HELP* adjacent to picture of “Cold Sores & Herpes” product.
- “Rheumatoid Arthritis and Chronic Joint Pain!”
- “clinical treatment of diabetic kidney capsule.”
- “Patients with Thyroid Insufficiency . . . take our [*Product Name*] to help fix the underlying causes of a fried nervous system and burnt-out glandular system.”
- “Primary use in the treatment of cancer and arthritis. *Was used* to treat liver cancer, lung cancer, esophageal cancer, skin cancer, and leukemia.”

Examples from warning letters



Prescription product: not safe for use except under the supervision of a licensed practitioner

- “... is being studied for treating various forms of pain, cancers, autoimmune and neurological disorders.”
- “*Research the possibility* can be used to treat drug addiction.”
- Website titled “Research & Studies”: “*significant clinical evidence* . . . effectiveness of the treatment of various types of pain, including cancer pain, chronic pain, neuralgia, and pain associated with parkinsons [sic], arthritis, and herpes zoster.”
- Website Titled “FAQs”: “[*Product name*] primarily aimed at treating moderate to severe chronic pain.”
- Podcast entitled “Preventing Cancer” advises listeners to go to company website for detox remedies and podcast specifically recommend [*Product name*] (among other things) to prevent cancer.

New Drugs

- “violent illness with high fever”
- “blood poisoning”
- “Liver disorders”
- “Chicken pox; Measles; Mumps”
- The product name, “Food Allergy~Additive”
- “Vertigo”
- “Migraine Headaches with nausea and vomiting”
- “Depression”
- “Suicidal tendency”
- “Impotence”
- The product name, “Vaccination-Illness”

New Drugs

- “Cholera; Croup; Pneumonia; Small pox”
- “Measles; Influenza; Whooping cough; Diphtheria (sic)”
- “Mumps; Tuberculosis”
- “Injury to nerve; Neuralgia (nerve pain)”
- Grief, anxiety, despair and melancholy.
- Poor circulation, cold hands and feet and hardening of the arteries.
- Liver congestion and dysfunction due to toxic overload from alcohol and pharmaceutical drugs.
- Used with viral infections such as AIDS, Herpes, and some chronic cases of Hepatitis B & C, and even some Cancers.”
- immunological imbalances in Rheumatoid Arthritis, ... Bursitis, some Cancers and Lupus.”
- *healing of ulcerated intestinal surfaces*

New Drugs [warning letters for dietary supplements]

- ★ *popularly used in diarrhea, dysentery, and has digestive and carminative properties.*
- ★ *“may help lower systolic blood pressure levels.”*
- ★ *“help prevent articular joints cell degeneration, breakdown and inflammation of articular cartilages, and in-elasticity of inter vertebral discs.”*
- ★ *“boost physical functioning in people with arthritis, asthma and inflammatory bowel diseases”*
- ★ *“improving blood sugar control in people with prediabetes, type 1 and 2 diabetes.”*
- ★ *“a hepatoprotective in jaundice hepatitis and other liver problems and also in alcoholism induced hepatotoxicity.”*
- ★ *“[has] been shown to dilate peripheral and coronary blood vessels. This helps alleviate hypertension and high blood pressure and reduces the severity and frequency of angina attacks.”*
- ★ *“Helpful In: High blood pressure, High cholesterol”*



Website: false / misleading -- makes effectiveness claims, but lacks adequate descriptions of the risks, warnings, and contraindications of your product.

- "**...prevent the Flu**"
- "**...avoid vaccinations** with conventional needles and potential harmful side effects"
- "**Proven highly effective** in helping you resist the season's Flu strains. Influenzinum 9C (2014-2015) is an **excellent Flu shot alternative**"

Acting Secretary of HHS, has determined a public health emergency exists nationwide involving the opioid crisis. The marketing and sale of unapproved opioid addiction treatment products is a potentially significant threat to the public health.

Section 319 of the Public Health Service Act, 42 U.S.C. 274d

- Temporary relief of cravings, irritability, and inability to concentrate related to use and over-use of: . . . Alcohol, Narcotics”
- “helps provide recovery, restoration or relief from the symptoms of overconsumption of alchols [sic] and other drugs”
- “Diminish cravings and desires”
- “Prevent or alleviate addictions,”
- “Provide support while you work to overcome your addictions”



New animal drugs: not generally recognized as safe and effective

- Inflammation of kidneys.
- Dropsy (edema) with suppression of urine in pets
- Acute, sudden and violent illness with high fever in pets.
- Oppressed breathing in pets.
- Liver disorders; in pets.
- Destroys worms, especially ascarides (roundworms) in pets.
Vermifuge for tapeworms in pets.

Examples from warning letters



Evidence of intended use: personal testimonials recommending or describing use for the cure, mitigation, treatment or prevention of disease, and/or to affect the structure or function of the body.

Examples from warning letters

Evidence of intended use: personal testimonials recommending or describing use for the cure, mitigation, treatment or prevention of disease, and/or to affect the structure or function of the body.

- “My wife has tried numerous drugs with no relief for her fibromyalgia. She is using [*Product name*] now and getting great relief!”
- “My husband has a bad back and I just used the [*Product name*] on his back the other night and he was amazed at how well it worked...”
- “I suffer with Peripheral Neuropathy and I’m not a Diabetic. I have been using [*Product name*] religiously for 3 months with great success. Nothing has controlled my symptoms better...”
- “Patient began taking [*Product name*] for chronic lower back pain. The back pain abated with treatment, but patient reported that within 3 days of beginning the regimen the bowel condition was markedly and unexpectedly improved...”

[Claims on website](#) establish product is intended for treatment of one or more diseases that are not amenable to self-diagnosis.

- ★ “Users report improved vaginal health and reduction in . . . Vaginal irritation, discomfort, and itch...”
- ★ “An unbalanced vaginal pH can leave you more susceptible to serious issues like fertility problems, infections, STDs and PID (Pelvic Inflammatory Disease). *Product name* is a natural defense against unbalanced vaginal pH and can help get things back to normal quickly.”
- ★ “This stuff is a lifesaver...for chronic BV and yeast.”
- ★ “This is just so helpful if you suffer from yeast infections and BV.”

Examples from warning letters



“FDA discourages the use of the term “rheumatism” as we believe it is less readily understood by most consumers, does not increase consumers' understanding of the use of product.”

★ “It helps in the treatment of minor joint pains. It has a powerful antirheumatic action.”



From FDA:

“The labeled inactive ingredients, such as “Arnica Plant Extract, Carbopol, Cat’s Claw Plant Extract, Devil’s Claw Plant Extract, Chuchuhuasi Plant Extract, Glucosamine, and Trietanolamina,” are not included in FDA’s inactive ingredient database for approved drug products.

“Nor are we aware of these ingredients being used as inactive ingredients in any OTC drug product.

“We remind you that it is your responsibility to ensure your product contains only suitable inactive ingredients that are safe in the amounts administered and do not interfere with the effectiveness of the preparation or with suitable tests or assays to determine if the product meets its professed standards of identity, strength, quality, and purity.”



From FDA:

“A footer on website displays the phrase “FDA Registered” next to logo for [*Product Name*]. “FDA” appears in a unique graphical form used as the agency’s official logo for many years. This presentation is false or misleading.

“First, it is drug **establishments** that are subject to registration with FDA, and FDA has no record of a drug establishment registration associated with the only entity identified on the website.

“Second, the placement of “FDA Registered” with your products’ logo suggests that the phrase refers to the drug product. To state that any drug product is “FDA Registered” is inaccurate; drugs are subject to listing with FDA, not registration.”



Cont.

“Moreover, registration of an establishment or listing of a drug does not denote approval of the establishment, the drug, or any other drugs of the establishment, nor does it mean that a product may be legally marketed.

“However, the general public is not likely to be familiar with the details of FDA regulation.

“The assertion of “FDA Registered” status in conjunction with the [*Product Name*] logo in the website’s footers misleadingly suggests that the [*Product Name*] drug products are them-selves approved or endorsed by FDA in some way when this is not true, an impression reinforced by the use of an FDA logo.

Thus, the products you offer for sale are misbranded because their labeling is false or misleading in any particular. “

What about what one can say?

What about what one can say?



OTC Monographs

- Identifies specific ingredient(s)
- Identifies specific dosage(s)

Not directly relevant to homeopathic drug products, but

- Wording utilized in them
- For Indications
- For Warnings and other statements
- Use as guideposts for crafting indications.

FDA OTC Monographs (reviewed ~ 90)

Acne	Benign Prostatic Hypertrophy	Food Overindulgence	Pancreatic Insufficiency
Alcohol	Boil Treatment	Hair Growth & Loss	Pediculicide
Allergy	Bronchodilator	Hormone	Poison Oak/Ivy Poison Treatment
Analgesic, External	Camphorated Oil	Hypophosphatemia/ Hyperphosphatemia	Prostatic Hypertrophy
Analgesic, Internal	Cholecystokinetic	Ingrown Toenail	Psoriasis
Anorectal	Cold & Cough	Insect Bite & Sting	Seborrheic Dermatitis
Antacid	Colloidal Silver	Insect Repellent, Oral	Sedative, Daytime
Anthelmintic	Callus Remover	Internal Analgesic	Skin Bleaching
Antibiotic, First Aid	Corn Remover	Internal Deodorant	Skin Protectant
Anticaries	Dandruff	Laxative	Sleep Aid, Nighttime
Anticholinergic	Daytime Sedative	Leg Muscle Cramps	Smoking Deterrent
Antidiarrheal	Decongestant, Nasal	Male Genital Desensitizers	Stimulant
Antiemetic	Dental Care	Menstrual	Stomach Acidifier
Antiflatulent	Deodorant, Internal	Nailbiting	Sunscreen
Antifungal	Diaper Rash	Nasal Decongestant	Sweet Spirits Of Nitre
Antihistamine	Digestive Aid	Nighttime Sleep Aid	Thumbsucking
Antimalarial	Drink Overindulgence	Ophthalmic	Topical Analgesic
Antimicrobial	Exocrine Pancreatic Insufficiency	Oral Health Care	Vaginal Contraceptive
Antiperspirant	Expectorant	Oral Wound Healing	Vaginal Drug Products
Antipyretic	External Analgesic	Otic	Vitamins & Minerals
Antirheumatic	Fever Blister	Overindulgence, Food & Drink	Wart Remover
Antitussive	First Aid Antibiotic		Weight Control
Aphrodisiac			
Astringent			

FDA OTC Monographs

Acne

Allergy

Analgesic, External

Analgesic, Internal

Anorectal

Antacid

Anthelmintic

Antibiotic, First Aid

Anticaries

Antidiarrheal

Antiemetic

Antiflatulent

Antifungal

Antihistamine

Antimicrobial

Antiperspirant

Antipyretic

Antirheumatic

Antitussive

Bronchodilator

Cholecystokinetic

Cold & Cough

Callus Remover

Corn Remover

Dandruff

Decongestant, Nasal

Dental Care

Deodorant, Internal

Expectorant

External Analgesic

First Aid Antibiotic

Ingrown Toenail

Insect Bite & Sting

Internal Analgesic

Internal Deodorant

Male Genital Desensitizers

Nasal Decongestant

Nighttime Sleep Aid

Ophthalmic

Oral Health Care

Otic

Pediculicide

Poison Oak/Ivy Poison

Treatment

Psoriasis

Seborrheic Dermatitis

Skin Protectant

Sleep Aid, Nighttime

Stimulant

Sunscreen

Topical Analgesic

Wart Remover

FDA OTC Monographs (finalized ~35)

Acne

Allergy

Analgesic, External

Analgesic, Internal

Anorectal

Antacid

Anthelmintic

Antibiotic, First Aid

Anticaries

Antidiarrheal

Antiemetic

Antiflatulent

Antifungal

Antihistamine

Antimicrobial

Antiperspirant

Antipyretic

Antirheumatic

Antitussive

Bronchodilator

Cholecystokinetic

Cold & Cough

Callus Remover

Corn Remover

Dandruff

Decongestant, Nasal

Dental Care

Deodorant, Internal

Ear Wax Removal

Expectorant

External Analgesic

First Aid Antibiotic

Ingrown Toenail

Insect Bite & Sting

Internal Analgesic

Internal Deodorant

Lip Protectant

Male Genital Desensitizers

Nasal Decongestant

Nighttime Sleep Aid

Ophthalmic

Oral Health Care

Otic

Pediculicide

Poison Oak/Ivy Poison
Treatment

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Seborrheic Dermatitis

Skin Irritation

Skin Protectant

Sleep Aid, Nighttime

Stimulant

Sunscreen

Topical Analgesic

Wart Remover

What about what one can say?



Example – 21 CFR 338 NIGHTTIME SLEEP-AID DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Labeling contains established name of the drug, if any, and identifies the product as a “nighttime sleep-aid.”

Indications: labeling states **one or more** of the phrases in this paragraph. *Other truthful and nonmisleading statements,* describing only the indications for use that have been established and listed in this paragraph may also be used.

Cont.

What about what one can say?



Example – 21 CFR 338 NIGHTTIME SLEEP-AID DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Indications: labeling states **one or more** of the following

- (1) (“Helps you” or “Reduces time to”) “fall asleep if you have difficulty falling asleep.”
- (2) “For relief of occasional sleeplessness.”
- (3) “Helps to reduce difficulty falling asleep.”

Note: Does NOT use the word “insomnia”.

Example – 21 CFR 338 NIGHTTIME SLEEP-AID DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

(c) *Warnings*: labeling contains the following:

- (1) “Do not give to children under 12 years of age.”
- (2) “If sleeplessness persists continuously for more than 2 weeks, consult your doctor. Insomnia may be a symptom of serious underlying medical illness.”
- (3) “Do not take this product, unless directed by a doctor, if you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma or difficulty in urination due to enlargement of the prostate gland.”

What about what one can say?



Example – 21 CFR 338 NIGHTTIME SLEEP-AID DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

(c) *Warnings*: labeling contains the following:

(4) “Avoid alcoholic beverages while taking this product. Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor.” ? *Not relevant for homeopathic product?*

(5) “Do not use with any other product containing diphenhydramine, even one used on skin.” ? *Not relevant for homeopathic product?*

The word “physician” may be substituted for the word “doctor” in any of the labeling statements in this section.

LABELING REQUIREMENTS

www.hpus.com

There are labeling requirements within the Guidelines for Manufacturing Homeopathic Medicines section, some of which apply to specific situations.

The labeling of medicated granules should be marked with the degree of strength and the concentration used in their preparation.

Each container shall bear a label stating the preservatives used. Multiple-dose containers shall not exceed 30 days and must include a warning that the preparation should be used within 30 days after the seal has been broken.

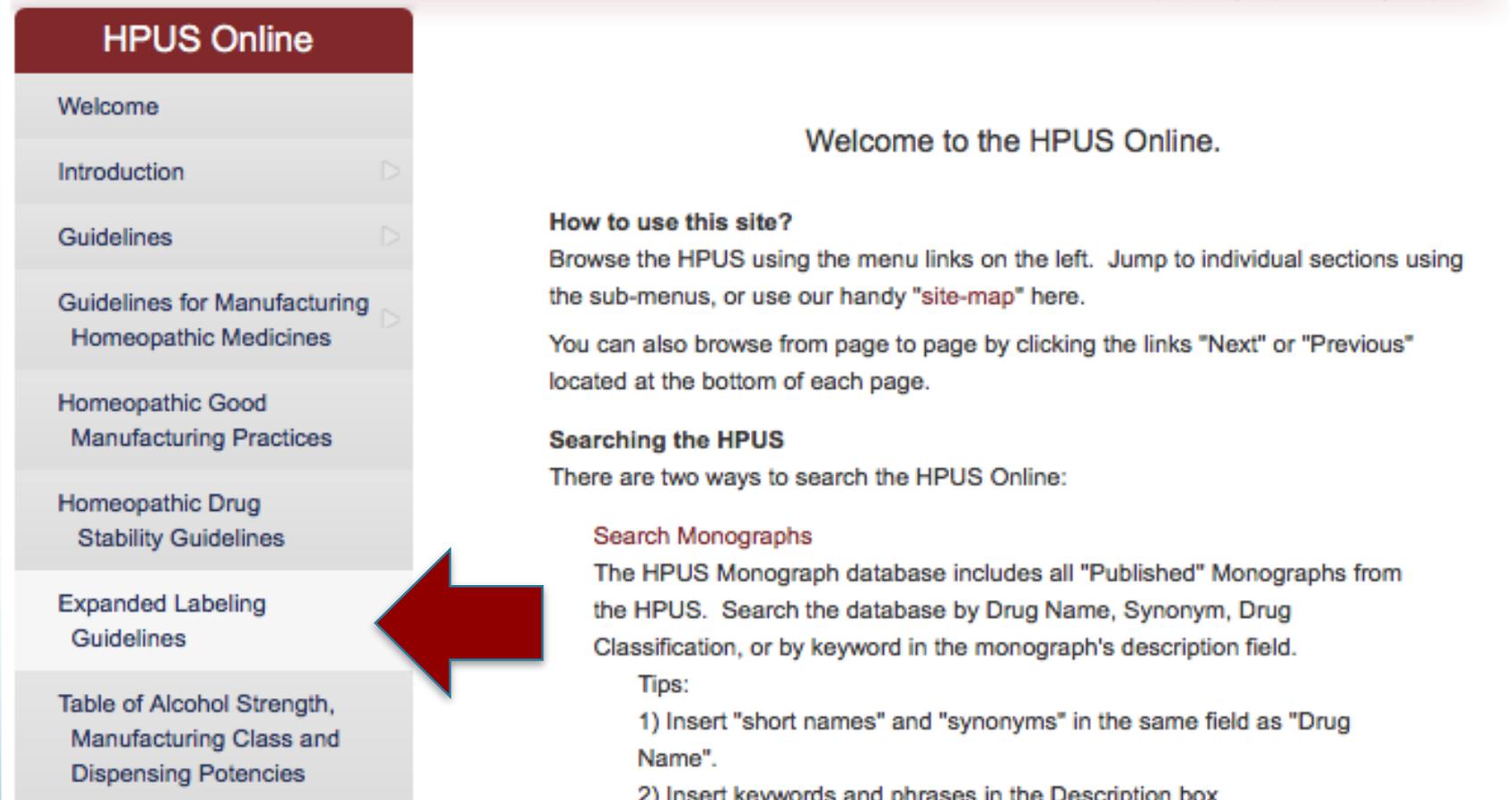
Each container shall bear a label stating all preservative, isotonicity, viscosity and stabilization agents.

Class M tinctures are identified by the symbols "Tr"∅"; or "MT" followed by "Class M" or "(M)" indicating the tincture strength [e.g., *Thlaspi bursa pastoris* ∅ (M)]. All attenuations prepared from these tinctures must bear the term "Class M" or "(M)" on all labeling.

There are also Labeling Guidelines in the HPUS; these both

- Reinforce 21 CFR and CPG 400.400 labeling requirements and
- Address labeling circumstances that might be unusual in the broader pharma world, but are not uncommon in the homeopathic sub-universe.

The HPUS Labeling Guidelines are in addition to CFR requirements.



HPUS Online

Welcome

Introduction ▶

Guidelines ▶

Guidelines for Manufacturing Homeopathic Medicines ▶

Homeopathic Good Manufacturing Practices

Homeopathic Drug Stability Guidelines

Expanded Labeling Guidelines

Table of Alcohol Strength, Manufacturing Class and Dispensing Potencies

Welcome to the HPUS Online.

How to use this site?
Browse the HPUS using the menu links on the left. Jump to individual sections using the sub-menus, or use our handy "site-map" here.

You can also browse from page to page by clicking the links "Next" or "Previous" located at the bottom of each page.

Searching the HPUS
There are two ways to search the HPUS Online:

Search Monographs
The HPUS Monograph database includes all "Published" Monographs from the HPUS. Search the database by Drug Name, Synonym, Drug Classification, or by keyword in the monograph's description field.

Tips:

- 1) Insert "short names" and "synonyms" in the same field as "Drug Name".
- 2) Insert keywords and phrases in the Description box

H.P.U.S. Labeling Guidelines

- Must contain adequate directions for use [21 CFR 205 & CPG 400.400].
- Declaration of net quantity of contents [21 CFR 201.51].
- Liquids for oral or sublingual administration must declare the percentage of alcohol, if present, in the final dosage form. [21 CFR 328]
- Name and place of business of manufacturer, packer, or distributor [21 CFR 201.1].
- Homeopathic products intended solely for self-limiting disease conditions amenable to self-diagnosis (of symptoms) and treatment may be marketed OTC. Homeopathic products offered for conditions not amenable to OTC use shall be marketed as prescription products. *[Sound familiar???]*

H.P.U.S. Labeling Guidelines

Small Containers

If container is too small, label must contain at least:

- Statement of identity of the HDP (Also in CPG 400.400)
- Attenuation of the HDP (Also in CPG 400.400)
- Lot or control number
- Name of manufacturer, packer or distributor (Also in CPG 400.400)
- **All other required information must appear on outer carton, or a leaflet inside package.** (Also in CPG 400.400)

H.P.U.S. Labeling Guidelines

- Label must have a Statement of Identity of each homeopathic drug product (HDP) in the package; this is the official, or the established short name(*), in the current HPUS.
- (* See table of Established Short Names)



H.P.U.S. Labeling Guidelines

Expanded Labeling Guidelines

Table of Alcohol Strength, Manufacturing Class and Dispensing Potencies

Bibliography

Standards & Controls

Published Monographs

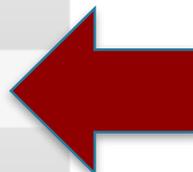
Drug Data Tables

Official Short Names

List of Synonyms

Search HPUS Monographs

Archives



The HPUS monograph database includes all published monographs from the HPUS. Search the database by Drug Name, Synonym, Drug Classification, or by keyword in the monograph's description field.

Tips:

- 1) Insert "short names" and "synonyms" in the same field as "Drug Name".
- 2) Insert keywords and phrases in the Description box
- 3) Try variations of keywords if your initial search doesn't find results...(i.e. "coneflower" or "cone" instead of "cone flower".

Search General Pharmacy

Use this search application to search the General Pharmacy and any other section of the HPUS not included in the Monograph Search.

Tips:

- 1) Single word searches will yield more results.
- 2) Encapsulate multiple word phrases in quotations marks (i.e. "Class C")
- 3) Sort results by relevance or by "date". Sorting by date will yield pages most recently updated or published online.

Published Monographs

View a complete list of [Published Monographs](#) and link back and forth between views.

Established Short Names

- Aethiops mercurialis-mineralis
- Berberis vulgaris
- Caulophyllum thalictroides
- Kali bichromicum
- Magnesia carbonica
- Myristica sebifera
- Narcissus pseudo-narcissus
- Nepeta cataria
- Stannum metallicum
- Aethiops merc
- Berb vulg
- Caulophyllum
- Kali bic
- Mag carb
- Myristica
- Narcissus
- Nepeta
- Stannum

H.P.U.S. Labeling Guidelines

- Must have the Attenuation Level and Quantity of each HDP in the package.

(Also stated in CPG 400.400: “...must bear a statement of the quantity and amount of ingredient(s) in the product...”)

Why?

Imagine 3 different formulas

Product #1 contains

33.3 parts Alphaium 12X
33.3 parts Betaium 6X
33.3 parts Gammaium 3X
And no other ingredients.

Product #2 contains

20 parts Alphaium 12X
20 parts Betaium 6X
20 parts Gammaium 3X
40 parts Vehicle

Product #3 contains

0.1 parts Alphaium 12X
0.1 parts Betaium 6X
0.1 parts Gammaium 3X
99.7 parts Vehicle

How to declare the
ingredients on the label?

Contains:
equal parts of
Alphaium 12X,
Betaium 6X,
Gammaium 3X

H.P.U.S. Labeling Guidelines

- Must have the Attenuation Level and Quantity of each HDP in the package.

(Also stated in CPG 400.400: “...must bear a statement of the quantity and amount of ingredient(s) in the product...”)

- Examples are given in HPUS Labeling Guidelines for how to declare each HDP in combination products (sequence and quantity declaration). And by extension, the quantity declarations would apply to single ingredient homeopathic products.

H.P.U.S. Labeling Guidelines

- Must state, in **prominent** type, “Homeopathic” or Homœopathic”.
- The letters “HPUS” are ***restricted*** to use only for HDPs approved for publication in current HPUS. ***AND...***
- ... Must also state “The letters ‘HPUS’ indicate the component(s) in the product is (are) officially monographed in the Homeopathic Pharmacopia of the United States” *May only include this statement if all HDPs in product are official.*

21 CFR §369.7

Warnings required by official compendia

- “Any drug included in the official compendia defined by the act shall bear such warning or caution statement as may be required by such compendia, and no statement in subpart B or subpart C of this part is intended to alter, modify, or permit the omission of any such statement required by such compendia.”

21 CFR §369.7

Warnings required by official compendia

HPUS has begun to add monograph specific warnings:

Aloe, Mentholum, Plumbum met., Plumbum Salts

For example Mentholum:

All Consumer Labeling for Products containing Mentholum 3X and Below should contain the following Warning Statement:

THIS PRODUCT SHOULD NOT BE USED TOPICALLY ON CHILDREN YOUNGER THAN 2 YEARS OF AGE, NOR SHOULD IT BE APPLIED ON ANY MUCOUS MEMBRANES OF ANY AGE CHILD OR ADULT. SEEK THE ADVICE OF YOUR HEALTH CARE PROFESSIONAL BEFORE USING THIS PRODUCT TOPICALLY ON CHILDREN 2 TO 12 YEARS OF AGE.

A Labeling Example

For a critical examination.



Phoxman's Pharmaceuticals

COUGHAWAY

FOR THE RELIEF OF TEMPORARY COUGHS DUE TO COLD OR FLU



Contains: 50 ml
NDC 1234-5678-90

Drug Facts	
Active Ingredients	Purpose*
Menthol 2X HPUS	Cough
Antimonium tartaricum 6X	Moist Cough
Bryonia 6X HPUS	Dry cough
Use* To relieve the discomfort of cough, whether dry (unproductive) or moist (with phlegm production).	
Warnings • Do not use if cough is accompanied by bloody phlegm, if you have shortness of breath or you are allergic to any of the ingredients.	
• Ask a doctor before use if you have asthma, bronchitis, or emphysema, or if the cough accompanies smoking.	
• Ask a doctor or pharmacist before use if you are taking other homeopathic medicines at the same time.	
• Stop use and ask a doctor if cough persists for more than 7 days, recurs, or is accompanied by fever, rash or a persistent headache, or if you have a sore throat that resists lasts for more than 2 days.	
• Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.	

This space available for promotional text, either regarding the product, the company or the general therapeutic category.

The balance here is all filler text that is unimportant for purposes of this working session. For these purposes the usual filler text is used

Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat. Duis aute irure dolor in reprehenderit in voluptate velit esse cillum dolore eu fugiat nulla pariatur. Excepteur sint occaecat cupidatat non proident, sunt in culpa qui officia deserunt mollit anim id est laborum.

The well know filler wording is based on some (sixteenth century scrambled) text from Cicero, which translates in part as:

Nor is there anyone who loves or pursues or desires to obtain pain of itself, because it is pain, but occasionally circumstances occur in which toil and pain can procure him some great pleasure.

Do Not Use if Tamper Evident ring around base of cap is missing or broken.

Drug Facts (continued)
Directions Adults: Take 15 drops in a little water every 4 hours. • Children Ages 3-12: Take 10 drops in a little water every 6 hours. • Children under 3: Use only if directed by a health care practitioner
Other Information
• Store at room temperature away from sunlight.
• The letters 'HPUS' indicate that the components in this product are officially monographed in the Homeopathic Pharmacopoeia of the United States.
Inactive Ingredients Purified water, 20% Alcohol, Menthol.
Questions Call 1-800-Phoxman (1-800-746-9626)

Made for Phoxman Pharmaceuticals in Great Britain.

*Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.



BATCH NUMBER 1234567
BEST BEFORE 02-2021



COUGHAWAY

FOR THE RELIEF OF
TEMPORARY COUGHS
DUE TO COLD OR FLU

NDC 1234-5678-90

Phoxman's Pharmaceuticals

HOMEOPATHIC

COUGHAWAY

FOR THE RELIEF OF
TEMPORARY COUGHS
DUE TO COLD OR FLU

Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.



Contains 20% Alcohol
Net Contents: 50 ml

This space available for promotional text, either regarding the product, the company or the general therapeutic category.

The balance here is all filler text that is unimportant for purposes of this working session. For these purposes the usual filler text is used

Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat. Duis aute irure dolor in reprehenderit in voluptate velit esse cillum dolore eu fugiat nulla pariatur. Excepteur sint occaecat cupidatat non proident, sunt in culpa qui officia deserunt mollit anim id est laborum.

The well know filler wording is based on some (sixteenth century scrambled) text from Cicero, which translates in part as:

Nor is there anyone who loves or pursues or desires to obtain pain of itself, because it is pain, but occasionally circumstances occur in which toil and pain can procure him some great pleasure.

Drug Facts

Active Ingredients	Purpose*
Mentholum 4X HPUS 30%	Cough
Bryonia 6X HPUS 30%	Dry cough
Antimon tart 6X HPUS 30%	Moist Cough

Use* To relieve the discomfort of cough, whether dry (unproductive) or moist (with phlegm production).

Warnings

- Do not use if cough is accompanied by bloody phlegm, if you have shortness of breath or you are allergic to any of the ingredients.
- Ask a doctor before use if you have asthma, bronchitis, or emphysema, or if the cough accompanies smoking.
- Ask a doctor or pharmacist before use if you are taking other homeopathic medicines at the same time.
- Stop use and ask a doctor if cough persists for more than 7 days, recurs, or is accompanied by fever, rash or a persistent headache, or if you have a sore throat that resists lasts for more than 2 days.
- If pregnant or breastfeeding, 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.

Drug Facts (continued)

Directions

Adults	Take 15 drops in a little water every 4 hours
Child Age 3-12	Take 10 drops in a little water every 6 hours
Child Under 3	Use only if directed by a health care practitioner

Other Information

- Contains 20% alcohol.
- Store at room temperature away from sunlight.
- The letters 'HPUS' indicate that the components in this product are officially monographed in the Homeopathic Pharmacopœia of the United States.

Inactive Ingredients Purified water, Alcohol, Menthol.

Questions Call 1-800-Phoxman (1-800-746-9626)

Made in the United Kingdom for Phoxman Pharmaceuticals

* Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

Do Not Use if Tamper Evident ring around base of cap is missing or broken.



BATCH NUMBER 1234567

BEST BEFORE 02-2021

What's required on the PDP?

- Statement of Identity (Also in CPG 400.400) (**HPUS Latin names are O.K.**) and general pharmacological category or main intended action. (Also in CPG 400.400) Must be “generally parallel to the base.” [21CFR 201.61]
- The word “Homeopathic” – not specified in CFR or CPG 400.400, but absence would be “a failure to reveal a material fact”. [See HPUS Labeling Guidelines, too.]
- NDC Number – *Optional* [if placed on PDP, must be in top 1/3 of PDP] [21CFR 201.2]
- Alcohol Content (if any) [21CFR 328]

Continued...

What's required on the PDP?

- Net Quantity of Contents. Weight, liquid measure or numerical count. (Also in CPG 400.400) May add metric units, also. [Must be in bottom 30% of PDP and be separated from all other printed information a) vertically by the height of the type size used, and b) horizontally by a space = 2x width of the letter “N”.] [21CFR 201.62]
- Type Size for Net Quantity of Contents:
 - If PDP is not > 5 sq in, type size not less than 1/16th inch.
 - If PDP is > 5 sq in & not > 25 sq. in. , type size not less than 1/8th inch.
 - If PDP is > 25 sq in & not > 100 sq. in. , type size not less than 3/16th inch.
 - If PDP is > 100 sq in & not > 400 sq. in. , type size not less than 1/4th inch.
 - If PDP is > 400 sq in, type size not less than 1/2 inch.

Traditional Labeling: What's required on the Info Panel?

- Active and Inactive ingredients [21CFR 201.10]
- Indication(s) (Also in CPG 400.400)
- Adequate Directions for Use (Also in CPG 400.400) [21 CFR 201.05]
- Product Specific Warnings (Also in CPG 400.400)
- General Warnings (e.g. pregnancy warning: “As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product.”) [21CFR 201.63]
- Accidental ingestion / Overdose Warning (“Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center immediately.”) [21CFR 369.9]
- Tamper Evident Statement [21CFR 211.132]

Continued...

Traditional Labeling: What's required on the Info Panel?

- Sodium/Calcium/Magnesium/Potassium Warning statements [21 CFR 201.64, 201.70, 201.71, & 201.72]
- If > 5% Alcohol and labeled for use by adults and children 12 years and older: “Consult a physician for use in children under 12 years of age.”
OR If > 0.5% Alcohol and labeled for use by children ages 6 to under 12 years old: “Consult a physician for use in children under 6 years of age.”
[21CFR 328]
- Country of Origin for Imported Products (“Product of” or “Made in”) must also be on the label; placement is not specified. [19 CFR 134.0 – 134.55; esp. 134.11]
- A mechanism for Adverse Event Reporting: e.g. “To report **SUSPECTED ADVERSE REACTIONS**, contact (manufacturer phone and web address) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.”



And something else on the PDP and Info Panel?

The FTC Act:

Objective product claims be truthful and substantiated.

Must decide what is appropriate substantiation.

However, to prevent claims from being misleading , can include additional explanatory information – a disclaimer.



And something else on the PDP and Info Panel?

Can use any disclaimer.

But it should be consumer tested to ensure it communicates the additional information effectively and is not deceptive.

On advertising, labels, and labeling:

“Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.”



And something else on the PDP and Info Panel?

For compliance with FTC:

- 1 Wording
- 2 placement
- 3) prominence

FTC: “Any disclosure should stand out and be in close proximity to the efficacy message.”

Drug Facts Labeling

FDA: “An express exemption would not be appropriate [for homeopathic drugs]. However the agency’s stated policy is that such products **ordinarily** will not be recommended for regulatory action if the product is a homeopathic drug as described in Compliance Policy Guide [400.400]... and the product follows the labeling and all other recommendations of that document.”

HDPs may be labeled either with the Traditional Labeling format, or using a Drug Facts format.

Drug Facts Labeling

Standardized Format

Sequence of information
 – Specified

Layout of information –
 Specified

Graphical elements –
 Specified

Regulations since 1999
 21 CFR 201.66

Drug Facts	
Active ingredient (In each tablet) Chlorpheniramine maleate 2 mg	Purpose 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 ■ you may get drowsy ■ 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	
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

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	

Drug Facts Labeling

- Drug Facts Panel [DFP] and its Contents required on retail package.
- Rules do not require (but FDA encourages) same on Immediate Container.
- Different categories (headings) of information.
- Specific rules for format are quite detailed.

Drug Facts Labeling Categories

Format details

- **Drug Facts**
- If DFP is continued on next side, **“Drug Facts (continued)”** must be at top of (each) subsequent DFP
- Must be first at top of DFP; left justified; First Letters Upper Case; must be largest type in DFP; no smaller than 8 point; Bold; Italic
- Left justified; First Letters Upper Case; must be either 8 point or 2 point sizes larger than general text, whichever is bigger; no smaller than 6 point; Bold; Italic. **Same applies to all subsequent Headings**
- [Exception: “(continued)” is **NOT** Bold or Italic.]

Drug Facts Labeling Categories

- **Active Ingredients** must use Established Name and **quantity** – per dosage unit. If not in dosage units (cream, eye drops, etc.): **must state proportion**.
- **Purpose** is “the general pharmacological category or principle intended action.” Must include for each Active Ingredient.
- Must be left justified. Must be listed in alphabetical order
- **Right** justified, each on same line as corresponding Active Ingredient (to create 2 column format). If more than one Active Ingredient has same purpose, need not repeat purpose **IF** label clearly indicates which active ingredients have same purpose.

Drug Facts Labeling Categories

- **Use** is the indication(s) for drug product.
- Text may appear on same line as Heading. **Same applies to all subsequent Headings, with one exception.**
- **Warnings** includes both general and product specific warnings. Rules include specific wordings which may be required/suitable for product:
- EXCEPTION: **Warnings** heading must appear on its own line. *Other text is prohibited from being on same line as **Warnings** heading.*

Continued....

Drug Facts Labeling Categories

Warnings (continued)

- Do not use if *[absolute contraindication]*
- Ask a doctor before use if you have *[preexisting condition]*
- Ask a doctor or pharmacists before use if you are *[drug/drug or drug/food interactions]*
- When using this product *[side effects or activities to avoid]*
- Stop use and ask a doctor if *[adverse reaction or toxicity]*
- Pregnancy / nursing warning statement.
- Keep out of reach of children/ accidental overdose statement.

Drug Facts Labeling Categories

- **Directions**
- **Other information**
Anything else required or optional by OTC rules, such as sodium content, storage conditions, etc.
- **Inactive Ingredients**
must use established name of each.
- **Questions** Optional
- If 3 or more directions [due to age, population specific, etc] then must be in a table format.
- In alphabetical order; however, if product is also a cosmetic, then use cosmetic label rules.
- May include phone number if consumers have questions.

Drug Facts Labeling Formatting

Other format information:

- No specific font. Font must “be legible and clearly presented; there must be 0.5 point leading between lines; font must have not more than 39 characters per inch.
- Hyphens are prohibited (except in a compound word)
- DFP must be printed in one color on a white or neutral background.
- The DFP may appear on more than one side of package. But must keep to same prescribed sequence of info.
- A graphic “arrow” must direct reader to which adjacent side the DFP is continued upon.

Continued...

Drug Facts Labeling Formatting

- No unapproved graphics within DFP
- The DFP must be separated from everything else on package by a graphic box or similar enclosure.
- **Barlines** are to separate the label categories; run edge to edge (i.e. touch outer graphic box).
- Hairlines are to separate title and following category; may also be used between different statements within a category. To be centered and to extend to within 2 spaces of, but not to touch, outer graphic box.

Continued...

Drug Facts Labeling Formatting

- Bullets – to be used for more than one statement within a heading.
- Bullets must be 5 point size; uniform in color and shape throughout.
- Bullets must be vertically aligned.
- More than one bullet on a line must be “uniformly spaced”[*] and their text can not continue to next line.

[* “Uniformly spaced” means there is a space equal to two letter “M”s between heading and 1st bullet and between each bullet and text.]

Drug Facts Labeling Details

Title:
14 pt. Helvetica Bold
Italic, left justified

Body text:
6 pt. Helvetica Regular with
6.5 pts. leading, left justified

Subheadings:
6 pt. Helvetica Bold,
left justified

Bullet: 5 pt.
Solid square

Headings:
8 pt. Helvetica Bold
Italic, left justified

Title for
continued panel:
8 pt. Helvetica Bold Italic

Drug Facts

<i>Active ingredient (in each tablet)</i>	<i>Purpose</i>
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
 ■ you may get drowsy ■ 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.

<i>Directions</i>	
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

Right justified

2.5 point barline

2.5 point box barline

0.5 point hairline

Table format for 3 or more dosages

Graphic leading to next panel

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

8 pt. Helvetica Regular

I. Section 201.66 Standard Labeling Format

A. Overall

1. The "Drug Facts" labeling is set off in a box or similar enclosure by the use of a barline with all black type printed on a white, color contrasting background.

B. Typeface and size

1. "Drug Facts" is set in 14 point Helvetica Bold Italic, left justified.
2. "Drug Facts (continued)" is set in 8 point Helvetica Bold Italic for the words "Drug Facts" and 8 point Helvetica Regular for the word "(continued)" and is left justified.
3. The headings (e.g., "Directions") are set in 8 point Helvetica Bold Italic, left justified.
4. The subheadings (e.g., "Ask a doctor or pharmacist before use if you are") are set in 6 point Helvetica Bold, left justified.
5. The information is set in 6 point Helvetica Regular with 6.5 point leading, left justified.
6. The heading "Purpose" is right justified.
7. The bullet is a 5-point solid square.
8. Two em spacing separates bullets when more than one bullet is on the same line.
9. A table format is used for 3 or more dosage directions.
10. A graphic appears at the bottom of the first panel leading the reader to the next panel.

C. Barlines and hairlines

1. A 2.5-point horizontal barline extends to each end of the "Drug Facts" box (or similar enclosure), providing separation between each of the headings.
2. A 0.5-point horizontal hairline extends within 2 spaces on either side of the "Drug Facts" box (or similar enclosure), immediately following the title and immediately preceding the subheadings.
3. A 0.5-point horizontal hairline follows the title, immediately preceding the heading, when a heading appears on a subsequent panel immediately after the "Drug Facts (continued)" title.

D. Box or Enclosure

1. All information is enclosed by a 2.5-point barline.

Drug Facts Labeling

Small Package – Modified Format

Small Packages:

- If the required DFP format would fill more than “60% of the surface area available to bear labeling”, then may use the Modified Format. [Must calculate the 60% area based on the minimum number of uses in **Use** category]

Modifications include:

- **Drug Facts** no smaller than 7 point
- Other headings must be either 7 point or 1 point size larger than general text, whichever is bigger

Continued...

Drug Facts Labeling

Small Package – Modified Format

- Leading can be reduced to less than 0.5 point “provided ascenders and descenders do not touch”:

Not allowed  equip
a flake

- Bullets need not be vertically aligned.
- Bullet text may continue onto next line.
- Need not enclose DFP in a graphic box if it is “set off from the rest of the labeling by use of a color contrast”.

Drug Facts Labeling

Small Package – Modified Format

Title:
9 pt. Helvetica Bold
Italic, left justified

Body text:
6 pt. Helvetica Regular with
6.5 pts. leading, left justified

Bullet: 5 pt.
Solid square

Subheadings:
6 pt. Helvetica Bold,
left justified

Headings:
8 pt. Helvetica Bold
Italic, left justified

Drug Facts

Active ingredients (in each tablet)	Purpose
Aluminum hydroxide gel 200 mg.....	Antacid
Magnesium hydroxide 200 mg.....	Antacid
Simethicone 25 mg.....	Antigas

Uses

- relieves symptoms referred to as gas
- relieves: ■ heartburn ■ acid indigestion ■ sour stomach
■ upset stomach due to these symptoms

Warnings

Ask a doctor before use if you have kidney disease

Ask a doctor or pharmacist before use if you are taking a prescription drug. Antacids may interact with certain prescription drugs.

Stop use and ask a doctor if symptoms last for more than 2 weeks

Keep out of reach of children.

Directions ■ chew 1 to 4 tablets 4 times daily
■ do not take more than 16 tablets in 24 hours or use the maximum dosage for more than 2 weeks

Inactive ingredients D&C red no. 30, D&C yellow no. 10, dextrose, FD&C blue no. 1, glycerin, magnesium stearate, mannitol, saccharin sodium, sorbitol, starch, sugar, talc

Right justified

2.5 point barline

0.5 point hairline

Bulleted information may start on same line as headings (except Warnings) and subheadings and need not be vertically aligned

Dark type on light background

Box barline omitted; color contrast used to highlight Drug Facts information

II. Section 201.66 Modified Labeling Format

A. Overall

1. The "Drug Facts" labeling is presented in all black type printed on a white color contrasting background.

B. Typeface and size

1. "Drug Facts" is set in 9 point Helvetica Bold Italic, left justified.

2. The headings (e.g., "Directions") are set in 8 point Helvetica Bold Italic, left justified.

3. The subheadings (e.g., "Ask a doctor or pharmacist before use if you are") are set in 6 point Helvetica Bold, left justified.

4. The information is set in 6 point Helvetica Regular with 6.5 point leading, left justified.

5. The heading "Purpose" is right justified.

6. The bullet is a 5-point solid square.

7. Bulleted information may start on same line as headings (except for the "Warnings" heading) and subheadings, with 2 em spacing separating bullets, and need not be vertically aligned.

C. Barlines and hairlines

1. A 2.5-point horizontal barline extends to each end of the "Drug Facts" box (or similar enclosure), providing separation between each of the headings.

2. A 0.5-point horizontal hairline extends within 2 spaces on either side of the "Drug Facts" box (or similar enclosure), immediately following the title and immediately preceding the subheadings.

D. Box or Enclosure

1. All information is set off by color contrast. No barline is used.

Prescription Drug Labeling

- All Prescription Drug labeling applies to HDPs; there are **no** exemptions, or exceptions for HDPs.
- Label is straight forward:
 - Statement of Identity
 - Declaration of Net Quantity of Contents
 - Statement of (usual or recommended) Dosage
 - NDC Number
 - Name + Address of Manufacturer or Distributor
 - Country of Origin (for imported products only)

However...

Prescription Drug Labeling

- Product must be accompanied by a Health Professionals Package Insert (HPPI) which is a part of the Labeling.
- New Rules for Content and Format of HPPI in 2006 (various dates of implementation based on original approval date).
- HPPI Requires 3 Sections: Highlights, Contents, Full Prescribing Information.
- Covers (up to) 17 categories of Information, as spelled out in the rules.
- Specific wording, sequence, format and graphics are detailed in the Rules.

Prescription Drug Labeling

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use **TEKAMLO** safely and effectively. See full prescribing information for **TEKAMLO**.

Tekamlo (aliskiren and amlodipine) tablets

Initial U.S. Approval: 2010

WARNING: AVOID USE IN PREGNANCY

See full prescribing information for complete boxed warning.

When pregnancy is detected, discontinue Tekamlo as soon as possible. Drugs that act directly on the renin-angiotensin-aldosterone system can cause injury and even death to the developing fetus. (5.1, 8.1)

INDICATIONS AND USAGE

Tekamlo is a combination of aliskiren, a renin inhibitor, and amlodipine, a dihydropyridine calcium channel blocker, indicated for the treatment of hypertension:

- As initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals. (1)
- In patients not adequately controlled with monotherapy. (1)
- As a substitute for its titrated components. (1)

DOSAGE AND ADMINISTRATION

- Add-on therapy or initial therapy: Initiate with 150 mg/5 mg. Titrate as needed up to a maximum of 300 mg/10 mg. (2.1, 2.3, 2.5)
- The blood pressure lowering effect is largely attained within 1-2 weeks. (2.2)
- Replacement therapy: may substitute for titrated components. (2.4)
- Administer one tablet daily with a routine pattern with regard to meals. (2.7)
- May administer with other antihypertensive agents. (2.7)
- Additive effects with ACE inhibitors at maximal doses have not been studied.

DOSAGE FORMS AND STRENGTHS

Tablets (aliskiren/amlodipine): 150 mg/5 mg, 150 mg/10 mg, 300 mg/5 mg, 300 mg/10 mg. (3)

WARNINGS AND PRECAUTIONS

- Avoid fetal and neonatal exposure. (5.1)
- Head and neck angioedema: Discontinue Tekamlo and monitor until signs and symptoms resolve. (5.2)
- Hypotension in volume- and/or salt-depleted patients: Correct imbalances before initiating therapy with Tekamlo. (5.3)
- Increased angina or myocardial infarction with calcium channel blockers may occur upon dosage initiation or increase. (5.4)
- Patients with renal impairment: Decrease in renal function may be anticipated with susceptible individuals. (5.5)
- Patients with hepatic impairment: Titrate slowly. (5.6)
- Patients with heart failure: Titrate slowly. (5.7)
- Hyperkalemia: Monitor serum potassium when co-administering with ACEI, potassium-sparing diuretics, potassium supplements, or other potassium-containing salt substitutes.

ADVERSE REACTIONS

The most common adverse event (incidence ≥ 2 % and more common than with placebo) is peripheral edema. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Novartis Pharmaceuticals Corporation at 1-888-669-6682 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

Aliskiren:

- Cyclosporine: Concomitant use is not recommended. (7)

USE IN SPECIFIC POPULATIONS

Nursing Mothers: Discontinue drug or nursing. (8.3)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling

Revised: 08/2010

Prescription Drug Labeling

FULL PRESCRIBING INFORMATION: CONTENTS*

WARNING: AVOID USE IN PREGNANCY

1 INDICATIONS AND USAGE

2 DOSAGE AND ADMINISTRATION

- 2.1 General Considerations
- 2.2 Dose Selection
- 2.3 Dose Titration
- 2.4 Initial Therapy
- 2.5 Add-on Therapy
- 2.6 Replacement Therapy
- 2.7 Use with Other Antihypertensive Drugs
- 2.8 Relationship to Meals
- 2.9 Dosing in Specific Populations

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS

- 5.1 Fetal/Neonatal Morbidity and Mortality
- 5.2 Head and Neck Angioedema
- 5.3 Hypotension
- 5.4 Risk of Myocardial Infarction or Increased Angina
- 5.5 Impaired Renal Function
- 5.6 Patients with Hepatic Impairment
- 5.7 Patients with Congestive Heart Failure
- 5.8 Renal Artery Stenosis
- 5.9 Cyclosporine

6 ADVERSE REACTIONS

- 6.1 Clinical Studies Experience
- 6.2 Clinical Laboratory Test Abnormalities
- 6.3 Post-marketing Experience

7 DRUG INTERACTIONS

8 USE IN SPECIFIC POPULATIONS

- 8.1 Pregnancy
- 8.3 Nursing Mothers
- 8.4 Pediatric Use
- 8.5 Geriatric Use

10 OVERDOSAGE

11 DESCRIPTION

12 CLINICAL PHARMACOLOGY

- 12.1 Mechanism of Action
- 12.2 Pharmacodynamics
- 12.3 Pharmacokinetics

13 NONCLINICAL TOXICOLOGY

- 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
- 13.2 Animal Toxicology and/or Pharmacology

14 CLINICAL STUDIES

16 HOW SUPPLIED/STORAGE AND HANDLING

17 PATIENT COUNSELING INFORMATION

* Sections or subsections omitted from the full prescribing information are not listed

Additional Resources

CPG 400.400 – Conditions Under Which Homeopathic Drugs May Be Marketed:

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-400400-conditions-under-which-homeopathic-drugs-may-be-marketed>

FDA Draft Guidance - Drug Products Labeled as Homeopathic Guidance for FDA Staff and Industry:

<https://www.fda.gov/media/109780/download>

Background information regarding the OTC Drug Monograph Process:

<https://www.fda.gov/drugs/current-good-manufacturing-practices-cgmp-drugs-reports-guidances-and-additional-information/over-counter-otc-drug-monograph-process>

Additional Resources

List of All OTC Monograph Reviews with Current Status:

<https://www.fda.gov/drugs/over-counter-otc-drugs/status-otc-rulemakings>

FDA Guidance -- Label Comprehension Studies for Nonprescription Drug Products:

<https://www.fda.gov/media/75626/download>

FDA Guidance – *Dosage Delivery Devices for Orally Ingested Liquid Drug Products:*

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/dosage-delivery-devices-orally-ingested-otc-liquid-drug-products>

FDA Guidance – *Labeling OTC Human Drug Products — Questions and Answers [Drug Facts Format Q&A]*

<https://www.fda.gov/media/72441/download>

Additional Resources

21 CFR 201 Drug Labeling

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=201>

- General information, and definitions; See Part A, § 201.1 – 201.22
- Prescription Product Labeling information; See Part B, § 201.50 – 201.58
- OTC Product Labeling information; See Part C, § 201.60 – 201.80
- Drug Facts Panel Format & Requirements; See Part C, § 201.66
- Labeling information for specific product, or product categories; See Part G, § 201.300 – 201.328, and § 201.357

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Consulting

- cGMPs
- Homeopathic
Methods
- Compliance



THANK YOU

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