Introduction

1. All homeopathic drugs are drugs within the meaning of the Federal Food, Drug, and Cosmetic Act and therefore are subject to the applicable statutory and regulatory requirements.


3. The label of a single ingredient product shall contain a statement of identity of the drug, this being the official or established short name for the ingredient given in the current Homœopathic Pharmacopœia of the United States and any supplements thereto.

4. The label of a mixture or combination of Homeopathic Pharmaceutical Ingredients shall bear a descriptive or proprietary name and indicate the official or established short name of each of the Homeopathic Active Pharmaceutical Ingredients in the mixture or combination.

5. The Federal Food, Drug, and Cosmetic Act requires that all OTC drug labels bear a complete statement of the inactive ingredients in the product.

6. The labeling of all dosage forms shall state the quantity and attenuation level of all of the Homeopathic Active Pharmaceutical Ingredients.

7. Specific dosage forms have additional labeling requirements:
   a. The labeling of liquids for oral or sublingual administration must declare the percentage of alcohol, if present, in the final dosage form.
   b. The labeling of multiple-dose containers of ophthalmic solutions shall include a warning that the preparation should not be used more than thirty (30) days after the seal has been broken unless stability data indicates a different time period.
   c. The labeling of all topical dosage forms, including suppositories, shall state the quantity and attenuation level of the Homeopathic Active Pharmaceutical Ingredients used in their preparation. This declaration may be made in one of two ways:
      i. Finished Attenuation Nomenclature Format: When the vehicle used for the dosage form is also the entire diluent for the finished attenuation, (i.e. the previous attenuation step is incorporated in the vehicle in a 1:10 ratio, [or 1:100 ratio] and the whole is succussed), the Homeopathic Active Pharmaceutical Ingredient may be declared as the finished attenuation strength. For example, one (1) part of Arnica 2X is added to nine (9) parts [or one (1) part Arnica 5C is added to ninety-nine (99) parts] of ointment base, and the whole is succussed, the final product may be labeled as Arnica 3X [or Arnica 6C].
      ii. Ingredient Attenuation Nomenclature Format: When the vehicle used for the dosage form is not used as a diluent for a succussion step, the quantity of the Homeopathic Active Pharmaceutical Ingredient is declared. For example, one (1) part of Arnica 2X is added to nine (9) parts of ointment base, and no succussion is performed, the final product is labeled “Contains Arnica 2X 10%”, or “Contains 10% Arnica 2X”.

Combinations

8. The label of a mixture or combination of several Homeopathic Active Pharmaceutical Ingredients shall indicate the attenuation of each Homeopathic Active Pharmaceutical Ingredient in the mixture or combination. The quantity or proportion of each Homeopathic
Active Pharmaceutical Ingredient shall be stated in descending order of the quantity, by percentage, weight or volume, delivered in the final dosage form. When two or more Homeopathic Active Pharmaceutical Ingredients are delivered in the same quantity, they may be stated in alphabetical order, or in sequence of increasing attenuation. For example:

- "Each tablet contains Gelsemium Semp. 3X 50%, Aconitum Nap. 12X 35% and Belladonna 6X 15%"
- "This ointment contains Aconitum Nap. 3X 2.5%, Gelsemium semp. 3X 2.5% and Belladonna 3X 1.5%"
- "Each 200 mg tablet contains 33.3% of Aconitum Nap. 6X, Belladonna 3X, and Gelsemium semp. 12X"
- "Each Tablet contains Gelsemium Semp. 3X 50 mg, Aconitum Nap. 6X 50 mg, and Belladonna 12X 50 mg"
- "A 5 ml dose contains Aconitum Nap. 3X 0.5 ml, Belladonna 3X 0.5 ml, and Gelsemium Semp. 3X 0.5 ml"
- "100 ml contains Belladonna 6X 10 ml, Aconitum Nap. 12X 10 ml, and Gelsemium Semp. 30X 10 ml"

a. Where the Homeopathic Active Pharmaceutical Ingredients are combined, with no additional diluent or excipient, and mixed until homogeneous, the labeling must state the quantity or proportion as well as the attenuation level of the homeopathic attenuations or triturations used to make the mixture.

b. Where the Homeopathic Active Pharmaceutical Ingredients are combined and one (1) part of the combination is attenuated with nine (9) or ninety-nine (99) parts of appropriate diluent or excipient and subsequent attenuation and succussion steps may be performed, the labeling must state the quantity or proportion as well as the attenuation level of the homeopathic attenuations or triturations that result in the combination. If desired, the number of attenuation steps carried out on the combination itself may be declared.

c. Where one (1) part each of X number of Homeopathic Active Pharmaceutical Ingredients are combined and ten (10) minus X or one hundred (100) minus X parts of appropriate diluent or excipient are used to attenuate the combination, the labeling must state the quantity or proportion as well as the attenuation level of the homeopathic attenuations or triturations that results in the combination. If desired, the number of attenuation steps carried out on the combination itself may be declared.

**Net Contents**

9. The label shall bear a declaration of net quantity of contents as provided in 21 CFR 201.51. The net contents for pellets, triturates or tablets shall be stated in terms of numerical count, e.g., 100 pills, or 250 tablets. The statement of quantity of pellets, globules, liquids and ointments shall be stated by weight or volume, e.g. 5 ml (milliliters) of granules, 15 grams (g) of ointment, or 15 ml of dilution or tincture.

**Directions**

10. 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.
11. Each drug product offered for retail sale shall bear adequate directions for use in conformance with Section 502(f) of the Act and 21 CFR 201.5. An exemption from adequate directions for use under Section 503 is applicable only to prescription drugs.

12. A suitable time frame should be included in the statement to consult a physician if symptoms persist. (e.g. “If symptoms worsen or persist for more than 7 days, consult a physician.”)

13. All homeopathic preparations for parenteral administration shall bear the statement “Rx only” on their labeling.

14. All prescription homeopathic drug products shall bear the prescription legend, "Rx only,” in conformance with Section 503(b)(1) of the Act, and a package insert bearing complete labeling information for the homeopathic practitioner shall accompany the product. The National Drug Code (NDC) number must appear on the label.

15. For OTC homeopathic products, a statement of the recommended or usual dosage as described under 21 CFR 201.5 shall be included, meaning:
   a. The quantity of the dose for adults and children,
   b. The frequency of administration (except with respect to attenuations of 30X and higher), and one of the following:
      i. For single remedies and combination products sold through retail distribution channels, a statement of the conditions, purposes or symptoms and/or indications for which the single remedy or combination product is intended stated in terms likely to be understood by lay persons.
      ii. For single remedies sold directly from a manufacturer or pharmacist to a health professional, one of the following must be included:
         1. a statement of the conditions, purposes, symptoms and/or indications for which the drug or combination is intended;
         2. the words, "Caution: for manufacturing, processing or repacking ONLY."
      iii. For Homeopathic Pharmaceutical Necessities (see potency tables in HPUS):
         1. Each container must bear the legend, "Caution, for manufacturing or reprocessing only, not to be dispensed or taken."

**Warnings**

16. OTC homeopathic drugs intended for systemic absorption, unless specifically exempted, must bear a warning statement in conformance with 21 CFR 201.63(a). Other warnings, such as those for indications conforming to those in OTC drug final regulations, are required as appropriate.

**Other**

17. The label shall contain, in prominent type, the word HOMEOPATHIC or HOMŒOPATHIC.

18. The designation "HPUS" is restricted (or may be appended only) to Homeopathic Active Pharmaceutical Ingredients for which monographs have been reviewed by the Convention and which have been approved for publication in the current Pharmacopœia by the Board of Directors. In addition, the following statement must appear at the end of the formula section of each label when all Homeopathic Active Pharmaceutical Ingredients (s) contained therein are official: "The letters 'HPUS' indicate that the component(s) in this product is (are) officially monographed in the Homœopathic Pharmacopœia of the United
States." This statement may not appear unless all Homeopathic Active Pharmaceutical Ingredients are official.

19. The label shall contain an identifying lot or control number.

20. Each product shall bear the name and place of business of the manufacturer, packer, or distributor in conformance with Section 502(b) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 201.1.

21. The National Drug Code (NDC) Number is requested but not required to appear on all OTC drug labels. See also #13 above. If the number is not included, the FDA Establishment Number of the manufacturer or of the distributor may be shown.

22. The label shall also contain any other appropriate phrases, information and / or warnings required by current FDA labeling regulations, in a manner consistent with the requirements of the HPUS.

**Special Cases**

23. If the container is too small or otherwise unable to accommodate a label with sufficient space to bear the information required, provided the remaining information specified above appears on the carton or other outer container or if such information is placed on an outsert or a leaflet inserted inside the package, the label may contain:

   a. the statement of identity of the drug;
   b. the identifying lot or control number;
   c. the name of the manufacturer, packer, or distributor of the drug;
   d. the attenuation of the drug and, for a combination drug: the attenuation and proportion of each component drug (if the combined drugs are other than equal parts);
   e. the net contents;
   f. the expiry date of the drug if applicable.

24. In the case of extemporaneous preparations only, the label may indicate the date of sale for a reference number.

25. Home Remedy Kits: Homeopathic home remedy kits may contain several products used for a wide range of conditions amenable to OTC use. When limited space does not allow for a list of those conditions on the labels of the products, the required labeling must appear in a pamphlet or similar informational piece which is enclosed in the kits. However, as a minimum, each product must also bear a label containing a statement of identity and attenuation.