ICS 11.120

CCS C 10

CNPPA

Social Organization Standard

T/CNPPA 3024-2023

口服药品标签设计指南

Guideline for labeling design of oral medications

Issued on 11-30-2023 Effective on 11-30-2023

Issued by China National Pharmaceutical Packaging Association

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Preface

This guideline is drafted in accordance with GB/T 1.1-2020 "Guidelines for Standardization Work Part 1: Structure and Drafting Rules of Standardization Documents".

This guideline is under the jurisdiction of China Pharmaceutical Packaging Association.

Please note that some contents of this document may involve patents. The issuing authority of this document does not bear the responsibility of patent identification.

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Introduction

In general, oral drugs can be divided into oral administration and intraoral administration. With oral administration, the drug reaches the gastrointestinal tract after taking. Relative dosage forms include tablets, capsules, granules, powder, oral liquid, etc. Intraoral administration refers to the mode of administration in which the drug acts directly on the oral mucosa or is absorbed through the oral mucosa, including tablets for intraoral use, oral sprays, gargarisma, etc.

This guideline aims to instruct drug marketing authorization holders, drug labeling designer and producers on how to use key elements such as marks, fonts, patterns, colors, layouts and other elements properly in drug labeling design to increase the identifiability of label contents, reduce medication use errors and ensure drug safety.

This document is formulated according to “Drug Administration Law of the People's Republic of China”, “the provisions on the administration of drug package inserts and labels” (Order No.24 of the State Food and drug administration, published in 2006), “Measures for the Administration of Drug Registration” (Order No.27 of the State Administration of Market Supervision and Administration), draw lessons from “Guidelines for drug packaging and pharmacy dispensing design” formulated by National Patient Safety Agency (NPSA), and with reference to “Guidelines for drug labeling design of injectable medications” (T/CNPPA3004-2019) and “Guidelines for drug labeling design of medications for pediatric use” (T/CNPPA3021-2022).

Drug marketing authorization holders, drug labeling designer and producers can refer to this guideline under the premise of relevant national regulations.

All the pictures used in the guide are schematic diagrams. The drug names are for illustration purposes only. They are irrelevant to the actual drug properties.

Guideline of drug labeling design for oral medications

1、Scope

This guideline specifies terms, definitions, and design principles for drug labels on oral medications.

This guideline is applicable for guiding the graphic design and producing of inner and outer labels of oral medications, including labels that is directly made (or printed) on the surface of medications, and that is pasted on the surface of packaging after made (or printed).

2、Normative references

There are no normative references in this guideline.

3、Terms and definitions

The following terms and definitions apply to this guideline.

3.1 Label

Label refers to the identification printed or affixed on the drug package, which can be divided into inner label and outer labeling.

3.1.1 Inner Label

Inner label refers to the label that directly contacts the drug packaging container, including direct printed packaging of drug containers.

3.1.2 Outer Labeling

Outer Labeling refers to the label of packages except the inner label, which is usually divided into the minimum packaging label for marketing, packaging label for transportation or storage. The outer label in this document refers to the minimum packaging label for marketing (sale).

3.2 Specified label

By using patterns and colors in label, specified label can improve the distinguishability of special information. It plays a prompt, warning and distinguishing function for users, and is conducive to management.

Note: Specified label can be divided into administrative mandatory label and recommended label.

3.2.1 Administration label

Administration labels are issued by national drug regulatory departments. For example, the general rule 0100 in Part IV of "the Chinese Pharmacopoeia (2020 Edition)" stipulates that the labels and instructions of narcotic drugs, psychotropic drugs, toxic drugs for medical use, radioactive drugs, external drugs, and non-prescription drugs must be printed with administration labels.

Note: The administration labels (see Figure 1) shall be placed on a fixed position at the upper right corner of the label.

Psychotropic drugs

Narcotic drugs

Radioactive drugs

Toxic drugs

Class A OTC drugs

Class B OTC drugs

Figure 1: Specified labels

3.2.2 Recommendation label

This refers to the label recommended by the national drug regulatory authority, such as the label that can inform patients the generic drug has passed the consistency evaluation (see Figure 2), and special labels issued by academies/associations related to drug quality and safe medication use, such as label for drugs of pediatric use (see Figure 3).

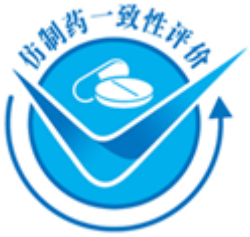


Figure 2: Label for generic drugs passed consistency evaluation

Figure 3: Specified label for pediatric medications

3.3 Multi-unit packaging

Multi-unit packaging refers to the packaging form in which part of the drugs can be taken out in several times without changing the safety and quality of the remaining drugs.

Note: Multi-unit packaging can contain independent unit packaging, and multi-unit packaging is generally the minimum packaging for marketing, such as bottled tablets or capsules, bottled oral liquid, and aluminum-plastic packaging tablets or capsules, etc.

3.4 Single-unit packaging

Single-unit packaging refers to the form of drug packaging that contains specific quantity of medicine and must be used once after opening.

Note: Single-unit packaging use inner labels in general, such as oral liquid in tubular bottles, granules in bags, tablets and capsules in aluminum-plastic packaging plates, etc.

3.5 Variable information

Variable information refers to relevant information that needs to be labeled according to the regulations and cannot be predetermined as the production time and production batch of the drug changes.

Note: such as production batch (batch specific code), date of manufacture, expiration date, etc., the variable information area and size shall be fixed during the package and labeling design.

3.6 Direct printing packaging

Direct printing packaging refers to the direct printing of drug label information on packaging containers, which is usually used as inner label.

3.7 Traceability code

Traceability code refers to a unique code assigned by the drug manufacturer on the drug package.

Note: It can be a one-dimensional or two-dimensional code, or marked with radio frequency identification (RFID) technology. By reading the drug traceability code, one can obtain information such as the drug name, specifications, approval number, batch number, expiration date, manufacturer, etc. It's mainly used for drug information (including package insert) query, drug circulation, traceability and anti-counterfeiting.

4、Principles of label designing

4.1 Overview

The drug marketing authorization holder and label designer shall improve the identifiability of important contents on oral drug labels through reasonable and optimized design, so as to reduce errors during the process of drug filling, dispensing and administration. In the process of developing and designing the label and package of oral drugs, the end users (such as the elderly, the blind, etc.) and their use environment shall be taken into consideration.

The design scheme should pay special attention to drug safety, as well as reflecting the economic and environmental requirements. Patient compliance should also be taken into consideration. In light of the use scenarios of terminal patients, humanistic care can be embodied by using bold font, increasing contrast, adding braille and additional drug commodity code functions (such as reading package inserts after scanning).

The drug marketing authorization holder shall establish a label design scheme review and approval system in accordance with relevant national regulations. During the design, review and approval of drug labeling and packaging, the main information and variable information shall be arranged in sufficient areas separately for accurate identification, and the following principles should be followed.

a) Consistency of information. The designer, reviewer and producer of the label are all responsible for ensuring that the label content is consistent with the drug package inserts.

b) Information integrity. The inner and outer label shall contain intact main information required by the laws and regulations. Special information can be marked appropriately if necessary.

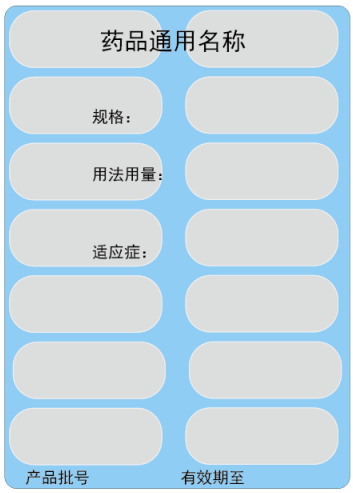
4.2 Main information

4.2.1 The following main information shall be indicated on the inner label: generic drug name, special identification, specification, indication/functional indications, administration and dosage, production date, product batch number, date of manufacture or expiration date, manufacturer, etc. If the inner label or independent unit packaging label is too small to cover the above contents, information including the generic drug name, specification, product batch number, expiration date, etc. shall be marked at the minimum.

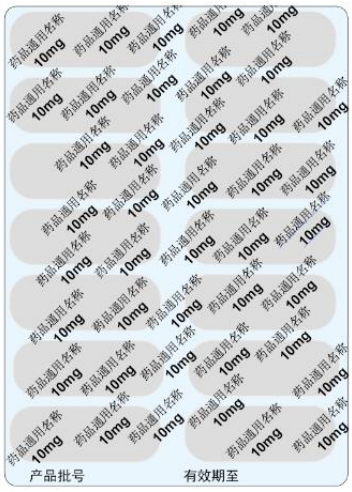
4.2.2 The following main information shall be indicated on the outer label: generic drug name, special identification, specification, main ingredients, properties, indications/functional indications, administration and dosage, adverse reactions, contraindications (including precautions), storage, date of manufacture, product batch number, expiration date, drug approval number, manufacturer, etc.

4.2.3 To ensure patients have a sufficient understanding of information on the label, such as the indications/functional indications, administration and dosage, adverse reactions, contraindications and precautions, etc., when it cannot be fully expressed, it should not be simplified and marked on the outer label, it can be marked with the phrase “see the package insert for details” .

4.2.4 The main information on the aluminum plastic blister packaging shall be arranged repeatedly to ensure that at least one complete main information, such as the generic name, specification, batch number, or expiration date of the drug, will be displayed when the packaging is processed such as cutting (see Figure 4).



a) Inappropriate legend (Incomplete or missing information on single-unit drugs after cutting)



b) Recommended legend (Individual drug information remains visible after cutting)

Figure 4: Printed information on blister packaging covering materials

4.3 Special information

Special information includes product name, company logo, braille, ethnic minority script, etc. Special information design and labeling should not affect the identification of primary information.

4.4 Design of the outer labeling

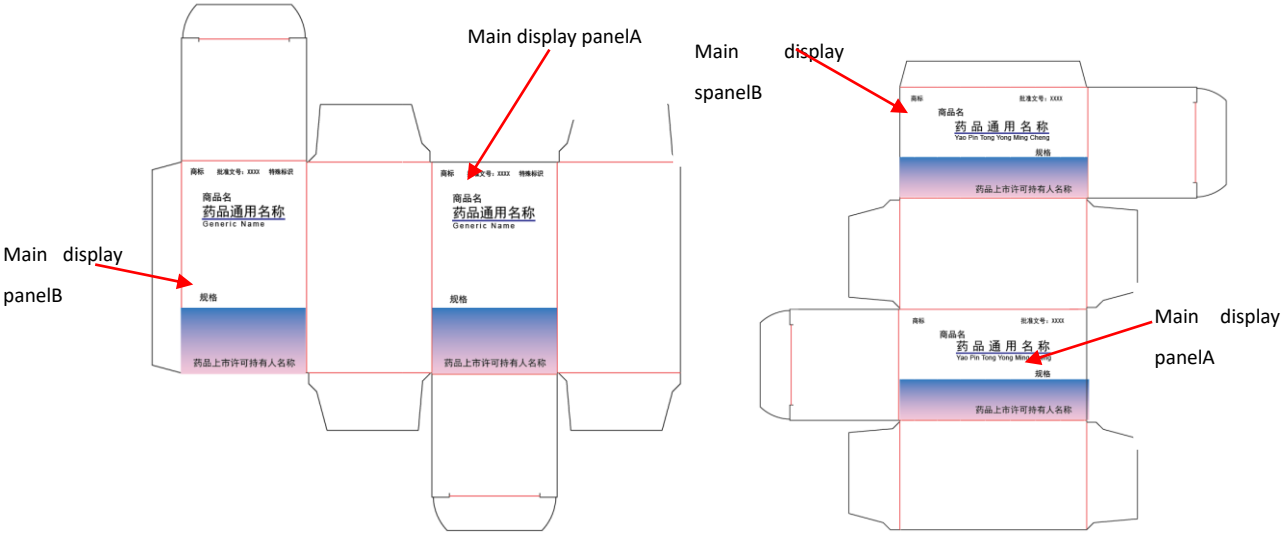
4.4.1 The premise of safety should be taken in the outer label design to ensure that users can read and check it without confusion or misreading.

The display surface of the outer label shall be reasonably arranged. The label designer shall fully consider the location, size, color, contrast and other elements of the main and special information, to plan the layout accordingly, and ensure that the main information can be accurately identified.

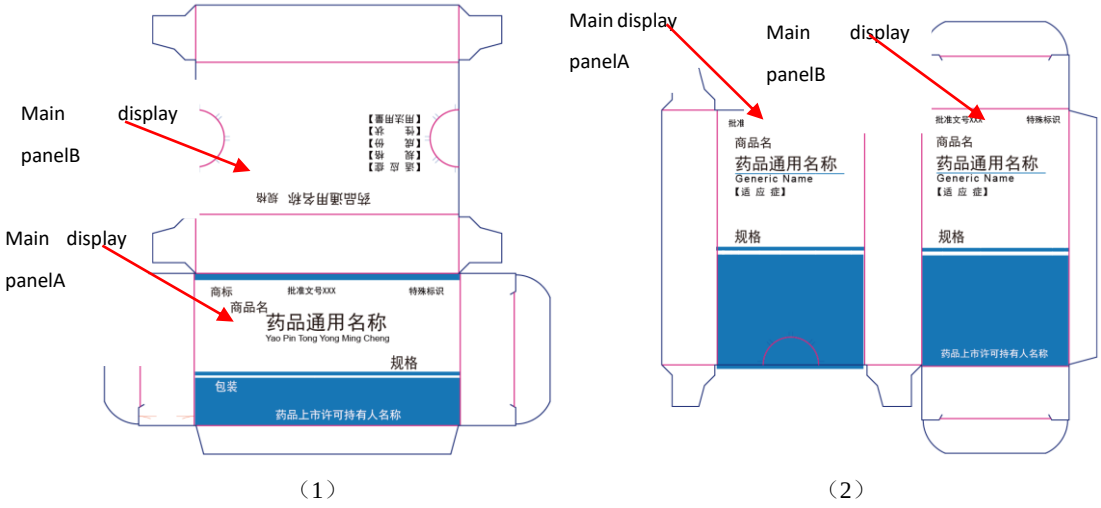
Use concise and lucid legend and character design on the outer label. Specifically, the main display should avoid using unnecessary patterns, shadows, etc. which may affect and interfere with the identification of main information. It is not recommended to used colors or patterns similar to

the same generic drug available on the market, to avoid confusion among users, dispending or drug using errors.

4.4.2 The main display panel A can be used to mark generic drug name, trade name, the ingredient content and package specifications, special identifications, company logo, main ingredients, etc. The main information can be repeated and supplemented on the main display panel B (see Figure 5).



a) Design of the main display panel of columnar packaging

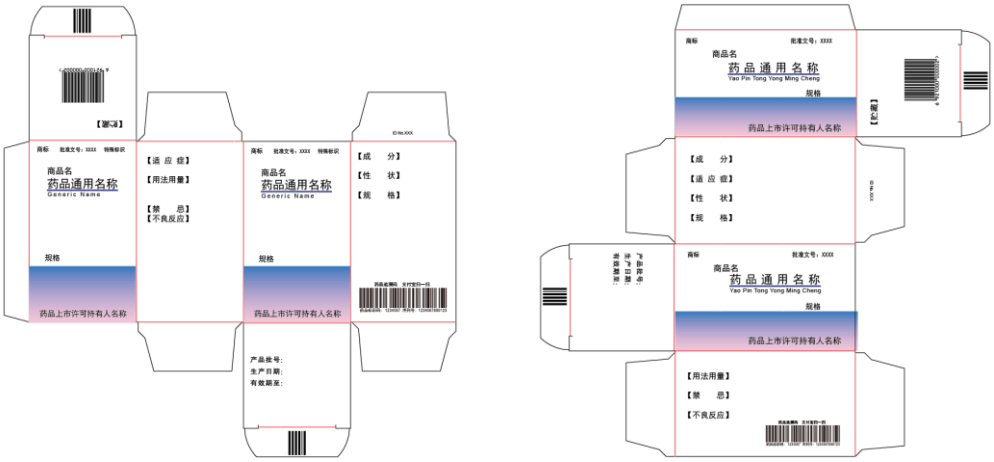


b) Design of the main display panel of flat packaging

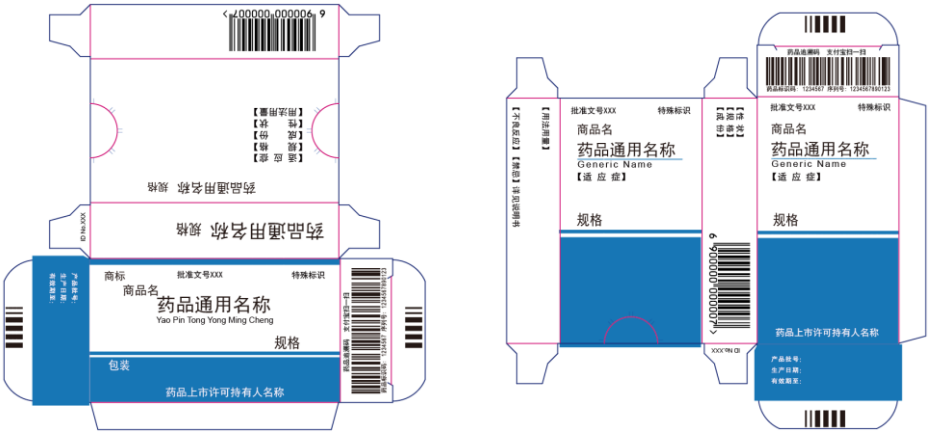
Figure 5: Example of the design legend on main display panel A and B of the outer labeling

4.4.3 The following information can be properly arranged on both sides, top and the bottom of the outer label: indications/functional indications, specification, administration and dosage, adverse

reactions, contraindications, storage, product batch number and expiration date, traceability code, manufacturer address and the contact information, etc. (see Figure 6).



a) Design legend on both sides, top and the bottom of the outer label on columnar packaging



b) Design legend on both sides, top and the bottom of the outer labeling on flat packaging

Figure 6: Example of the design legend on both sides, top and the bottom of the outer labeling

4.5 Characters

4.5.1 The drug generic name shall be obvious and prominent, and its font, size and color must be consistent. The distinguishability of the trade name, such as the color contrast and size, should not be stronger than the general name.

4.5.2 The generic name of a drug shall be printed using the standardized Chinese characters published by the National Language and Character Working Committee. When using other characters for comparison, the expression of Chinese characters shall be the standard. Avoid using fonts that are not easy to recognize such as cursive script, seal script. Avoid using italic, hollow, shadow or other forms to embellish the font (see Figure 7).

a) Inappropriate legend (Use non-standard characters) b) Recommended legend (Use standard characters)

c) Inappropriate legend (The distinguishability of the trade name is stronger than the generic name)

d) Recommended legend (The distinguishability of the generic name is stronger than the trade name)

Figure 7: Legend of using standardized font, size and color, etc. on drug name

4.5.3 Chemicals can be labeled with the English INN name at appropriate position on the label, and the traditional Chinese medicines can be marked with Chinese phonetic alphabet in accordance with “the Naming Principles of Generic Names of Chinese Medicines”. Marking English or Chinese phonetic alphabet shall not affect the reading of other main information.

4.5.4 On the left side of the label, range the following information from top to bottom: trademark, trade name, generic drug name, the INN name or Chinese phonetic alphabet, specification, indications, administration and dosage, etc.

4.5.5 Specified labels and warnings set by regulations shall be arranged on top of the right side of the label (see Figure 8).

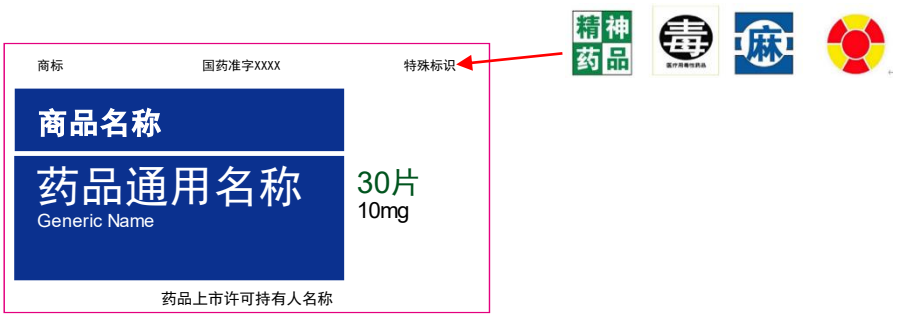


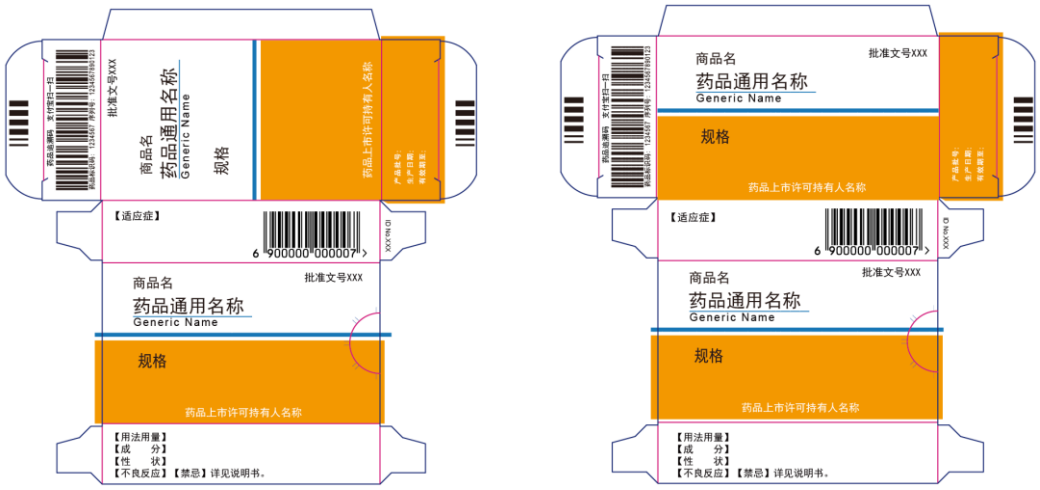
Figure 8 Standard display of specified labels and warnings

4.5.6 Drug marketing authorization holders, or the special requirements such as how to open the medication, additional device information, etc. can be listed on the bottom of the label.

4.5.7 It is recommended to leave a blank in the appropriate position of main display panel A or B for pharmacists to paste or write directions (medical order information) (see Figure 9).

Figure 9: Leave blank in the appropriate position of main display panel A or B

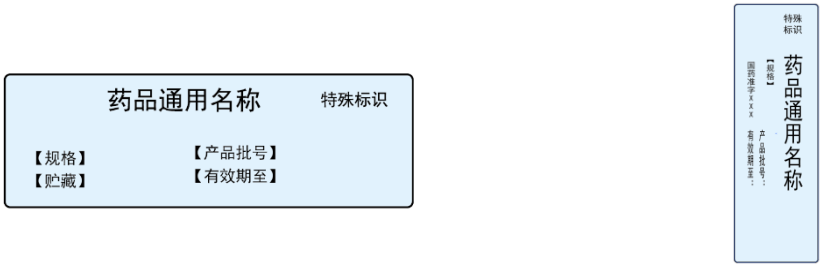
4.5.8 The text on each display panel shall be arranged in the same direction for the convenience of reading (see Figure 10).



a) Inappropriate legend b) Recommended legend

Figure 10: Legend of text arranging on each display panel

4.5.9 The character arrangement of the main information, such as the drug name on the inner label of independent unit packages, should be easy to read to avoid incomplete understanding. If unable to write information in the same line due to size limitation, try to change the line without disturbing the reading. If the label size is too small to cover all the important information, the generic name, specified labels, product batch number, expiration date shall be marked at the minimum (see Figure 11).



a) Horizontal label of independent unit packages b) Vertical label of independent unit packages

Figure 11: Legend of character design on the label of independent unit packages

4.5.10 The expression of directions, such as the route of administration, shall use positive words to guide patients to take it correctly. Avoid using negative or incomprehensible expressions that may lead to incorrect use. For example, "Do not bite, chew, break or crush" is often misled or mistaken for "bite, chew, break or crush" (see Figure 12).

a) Inappropriate legend b) Recommended legend

Figure 12: Use positive words to express correct usage

4.6 Colors and graphics

4.6.1 Color's quantity: In the label design scheme, using 3 to 4 colors is preferred, do not use more than 5 colors. Avoid using unnecessary crafts that may affect reading, such as bronzing, embossing, film covering, and liquid lamination.

4.6.2 Text color: The generic drug name should be striking. Use black or white color, which can form a strong contrast with the corresponding light or dark background.

4.6.3 Use font, color or patterns to increase the discrimination of similar drugs.

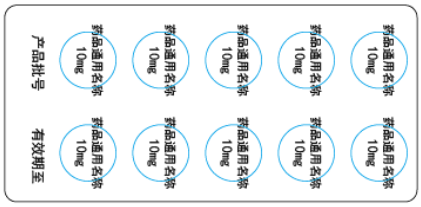
a) Drug name: Pay special attention to different generic name or trade name medications that have the similar exterior (look alike) or pronunciation (sound alike). Specifically, when the look alike or sound alike medications share the same manufacture, differentiation should be made using design elements such as character size, thickness, color, and patterns (see Figure 13).

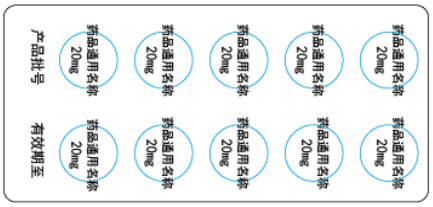
a) Inappropriate legend (two products of the same manufacturer can mixed up easily)

b) Recommended legend（distinguish or highlight fonts with colors and patterns）

Figure 13: Legend of using design elements to differentiate similar medications

b) If the content and specification of a medication made by the same manufacturer are different, their package and label shall be clearly distinguishable using colors and patterns (see Figure 14).



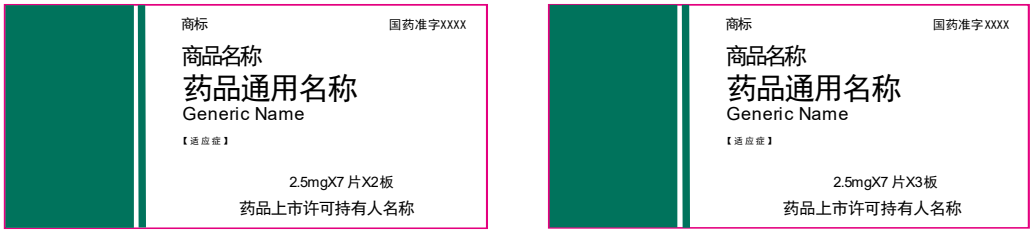


a) Inappropriate legend（Inner and outer label of drugs with different content but hard to differentiate）

b) Recommended legend（Using colors and patterns to increase discrimination of the inner and outer label of drugs with different content）

Figure 14： Legend to increase the differentiation of two drugs with different content and specifications using colors or patterns

c) For the same drug from the same manufacturer, if the package specifications are different, the packaging and labels should be clearly distinguished by color or pattern, or volume (see Figure 15).



a) Inappropriate legend（the outer label of drugs with different package specifications that are hard to distinguish）

b) Recommended legend（Use colors or patterns to increase the differentiation between two different package identifications）

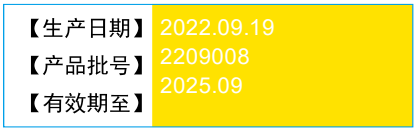
Figure 15： Legend to use colors and patterns to increase the differentiation between two different package identifications

4.7 Variable information

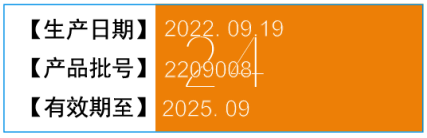
4.7.1 Variable information is important information specified in regulations, including product batch number, term of validity or expiration date, drug traceability code, etc. Product batch number, term of validity or expiration date: It consists of characters and numbers. The text information part is generally pre-printed. Variable information shall be arranged in an identifiable area of the inner or outer label. During label design, reserve sufficient space for the digital part of variable information and keep an appropriate distance from other information, to avoid disturbing the recognition of information.

4.7.2 Although the digital part of the variable information does not require check and approval according to regulations, accurate identification is of great importance as it is used to indicate manufacture information and term of validation. The digital part of variable information can be marked by printing, laser burning, steel sealing, etc.

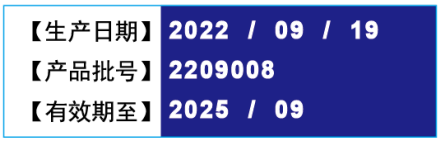
For printed labels, the numbers should be clear and legible, forming a clear background contrast. Additional attention should be paid to the adhesion and firmness of the ink, and the layout design should be reasonable to avoid misreading (see Figure 16).



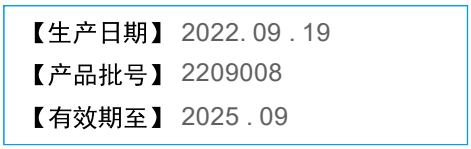
a) Inappropriate legend（lack of contrast）



b) Inappropriate legend（blurring writing with jamming information）



c) Recommended legend（Increased contrast and clear writing）



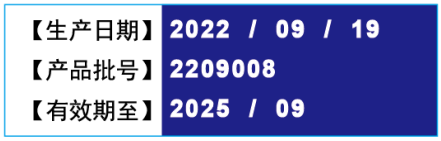
d) Recommended legend （using inkjet）

e) Recommended legend（using steel seal）

Figure 16: Legend of numbers in variable information

4.7.3 The characters and numbers of the variable information must be in a straight line, without dislocation, so as to avoid the information recognition error (see Figure 17).

a) Inappropriate legend（The text and number parts are not in the same line.）

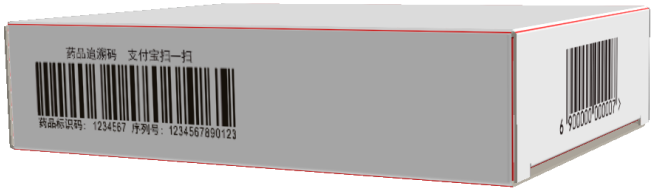


b) Recommended legend （The text and number parts are in the same line.）

Figure 17: Legend for the characters and numbers of the variable information.

4.7.4 Drug traceability code and commodity code: In general, the drug traceability code and commodity code should be arranged on the two sides of the display panel or the upper and lower display panels respectively. Considering the need for online scanning and reading of automatic drug dispensing equipment, if the location and space are limited, the tracking code can be identified by two-dimensional code to save space (see Figure 18).

a) Inappropriate legend (Drug traceability code and commodity code are on the same display panel.)



b) Recommended legend (Drug traceability code and commodity code were arranged on the different display panels.)

Figure 18: Legend of drug traceability code and commodity code

4.8 Others

4.8.1 Statement of main ingredients

The content of main ingredients on the label must be accurate and clear, in consistent with the package insert. For drugs with single ingredient, the content in each unit of preparation can be marked directly, such as 20mg (or 0.02g) per tablet, without marking the weight of the actual tablet.

Traditional Chinese medicine preparations with clear effective ingredients can be expressed in the same way; Chinese medicine preparations made by traditional crafts can be expressed using the weight of each unit of preparation, such as 0.38 grams per tablet, 4.2 grams per pellet.

4.8.2 Warnings

Warnings in the package insert must be specially printed on the label to avoid mistaken use. Label notes for special patient population, for example, “athletes should use with cautions”, or “avoid use during pregnancy” (see Figure 19).

a) “Athletes shall use with caution” tag b) “Avoid use during pregnancy” tag

Figure 19：Legend of warnings which are specially printed on the label

4.8.3 The opening method

When adopting the concept of safe packaging structure, the packaging that can only be opened in special ways, such as child-resistant packaging and elderly friendly packaging, should be indicated in the label. Try to use graphics as listed below (see Figure 20).

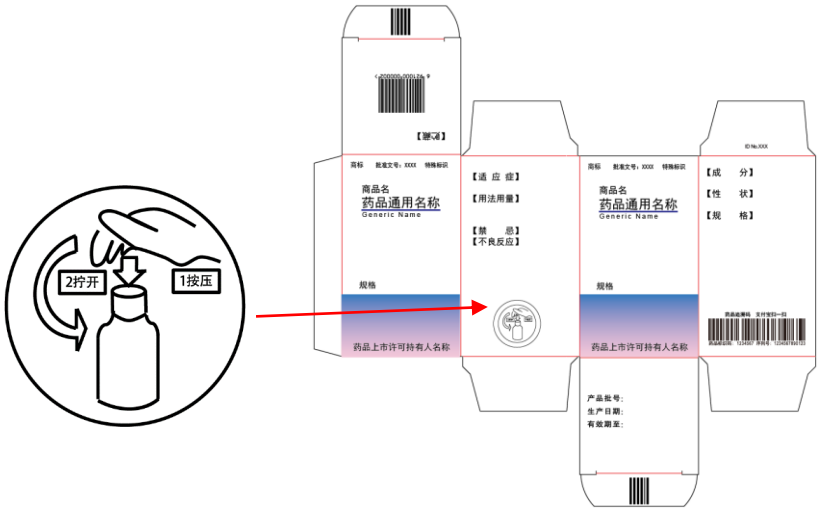
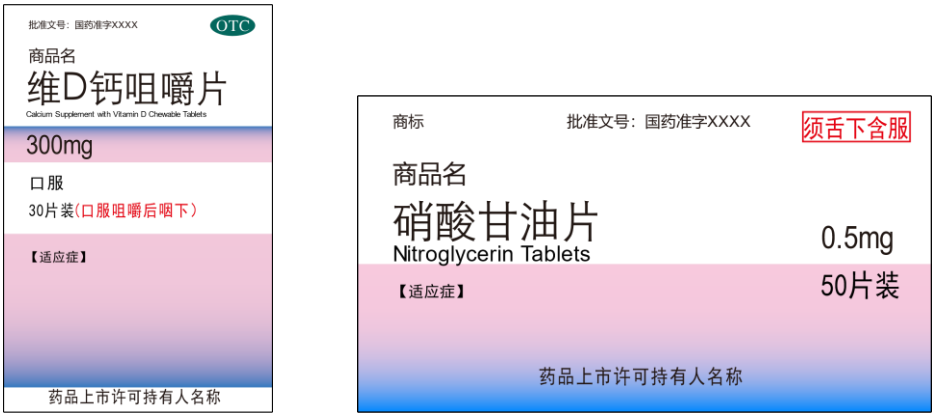


Figure 20: Legend of using graphics to mark packages that can only be opened by special methods

4.8.4 Administration of special dosage forms

Some oral medications have special administration methods that must be indicated on the label. For example, sustained-release and controlled-release dosage forms need to be swallowed completely and indivisible (see Figure 12b and Figure 13b for recommended legends); for chewable tablets, they should be swallowed after chewing, especially for infants; special tips should also be marked for the buccal dosage forms (see Figure 21).



a) Mark how to take chewable tablets b) Mark how to take sublingual tablets

Figure 21： Special administration methods shall be marked on the label

4.8.5 Indication of life span after opening

For the drugs with a definite term of validation after opening, the information should be clearly indicated on the label. An appropriate blank space should be reserved for marking the opening date to prevent usage after expiration (see Figure 22).

a) Inappropriate legend　　b) Recommended legend

Figure 22： Marking the opening date for the drugs with a definite term of validation after opening

4.8.6 Special storage requirements

For drugs with special storage requirements, such as multi-unit packaging drugs that are susceptible to moisture after opening, the package insert stated "Do not discard the desiccant in the package", and the label should also clearly indicate this information (see Figure 23).

Figure 23 Mark special storage requirements for medications clearly on the label

References

1. Drug Administration Law of the People's Republic of China (2nd version)
2. The provisions on the administration of drug package inserts and labels (Order No.24 of the State Food and drug administration, published in 2006)
3. Measures for the Administration of Drug Registration (Order No.27 of the State Administration of Market Supervision and Administration)
4. Chinese Pharmacopoeia 2020 Edition
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