Guidance for Drug Electronic Supervision

(Draft for Comment)

*Guidance for Drug Electronic Supervision* is concluded in accordance with the relevant provisions of drug Electronic Supervision, in order to further strengthen the drug Electronic Supervision and ensure the completion of the target to promote the construction of the national drug Electronic Supervision system and improve the traceable drug Electronic Supervision system covering the whole species and the whole process specified in the *12th Five-Year Plan of National Drug Safety*, based on the *Guidance for Drug Electronic Supervision Technology* developed by State Bureau.

I. Drug monitoring management departments (omitted)

II. Drug production enterprises

   (I) Establish and improve organizations.

15. Organizations. Drug production enterprises shall establish organizations in conformity with the drug Electronic Supervision, and shall be equipped with appropriate management and operation staff. In addition, staff related to drug Electronic Supervision shall be made clear and understood their duties and be familiar with the requirements relevant to their duties, and receive necessary trainings.

16. Job duties

   (1) Drug production enterprises shall register the drug included in the Electronic Supervision in accordance with the relevant provisions of State Bureau.

   (2) Drug production enterprises shall apply for monitoring code on the basis of the variety, standards and actual production capacity of the drug products produced.

   (3) Drug production enterprises shall implement the relevant technical requirements of the *Standards for the Encoding and Application of Drug Electronic Supervision codes (Annex 2)* in respect of the printing and sticking of the monitoring codes.

   (4) Drug production enterprises shall designate a person responsible for the maintenance and updating, and registration and cancellation after verification of the Electronic Supervision information about the production of drugs in this enterprise, registration and cancellation after verification, and ensure that the reported
information is reported promptly, completely and accurately.

(5) Drug production enterprises shall not forge, falsely use or re-use the monitoring codes, if the monitoring codes have any surplus, they shall be kept or recorded safely after being destroyed; if any is lost or leaked, promptly report to the local drug monitoring department in writing and at the same time send a copy to State Bureau.

(Ⅱ) Routine operating management (detailed operation is shown in Annex 1)

17. Network access management. Drug production manufacturers included in the Electronic Supervision drug products, access procedures to the drug Electronic Supervision network should be handled in accordance with the relevant provisions.

18. Information management. If business information, drug information, units information, etc. of drug production enterprises have any changes, alterations must be promptly made to the China drug Electronic Supervision system. The information in need of the examination by the drug monitoring department should be equipped with corresponding complete information.

19. Prewarning management. The drug production enterprises should promptly deal with the prewarning arising from the drug Electronic Supervision network.

(Ⅲ) Requirements for equipment and facility

20. Enterprise facilities. Drug production enterprises shall be equipped with the workplaces and hard (soft) equipment for the implementation of the drug Electronic Supervision.

(1) Establish a computer system which can meet the whole process of the registration and cancellation after verification, and the configuration of the computer system shall be consistent with the technical requirements of drug Electronic Supervision;

(2) There is a stable and safe network environment as well as fixed methods getting access to the Internet;

(3) Option and use of handheld equipment shall in compliance with the technical requirements of the drug Electronic Supervision;

(4) Enterprise client software for China drug Electronic Supervision network shall be installed in the computer system.
(IV) Coding requirements for drug production enterprises

21. General coding requirements for drug. In accordance with the requirements of the documentation of State Bureau, drug Electronic Supervision code with a uniform identification shall be printed (pasted) at all levels of the sales package of drug included into the Electronic Supervision in accordance with the Standards for the Encoding and Application of Drug Electronic Supervision Codes (Annex 2).

22. Coding requirements for drug with special package. In special circumstances that the minimum sales packaging volume of the product is too small or belongs to the profiled bottles, and the drug Electronic Supervision code with a uniform identification cannot be printed (pasted) on the smallest product packaging, the Electronic Supervision code with a uniform identification can be printed (pasted) on the package at next higher level of the minimum package. Specific varieties of the drug shall be applied to the provincial bureau at the seat of the enterprise by the enterprise for review and confirmation in the drug Electronic Supervision system.

23. Safety management requirements for monitoring codes. Drug production enterprises can commission the suppliers to directly make the monitoring codes on the packaging materials, and the monitoring code data which have been downloaded and decompressed can be provided to the suppliers of packaging materials. In the production of the identification of the monitoring codes, enterprises shall observe the following points:

(1) Drug production enterprises shall check the technical and managerial ability of the packaging materials suppliers undertaking the production of the identification of the monitoring codes, and sign a agreement to commission the supplier who has met the requirements of production technology and management of the monitoring codes to manufacture the monitoring codes, wherein the printing quality of the identification of the monitoring codes shall be made clear. The packing materials suppliers shall ensure that all the identification of the monitoring codes printed can meet the requirements of the Standards for the Encoding and Application of Drug Electronic Supervision Codes (Annex 2).

(2) The packing materials suppliers undertaking the production of the identification of
the monitoring codes shall be equipped with relevant business qualification, sound verification, registration, management, delivery, defective products destruction and other management systems. The packing materials suppliers shall ensure that the data security of the monitoring code data of the drug enterprises having access to the network in the printing process so as to avoid the outflow of the data.

(3) The drug production enterprises shall establish printed matters and the management system of the monitoring code accordingly, and develop the warehouse entry-delivery registration and processing administrative provisions for printed matters with the identification of the monitoring codes.

24. Inspection and management requirements for the identification of the monitoring codes. The identification of the monitoring codes of drug production enterprises shall satisfy the Standards for Encoding and Application of Drug Electronic Supervision codes (shown in Annex 2) to ensure that the monitoring codes on the drug packing materials are in normal use in every link of the production and circulation.

(V)Associated requirements for the production line coding

25. Technical requirements. The associated system of the production line coding must be able to accurately establish the associated relationship of the monitoring codes in all levels of package. In accordance with the associated files generated by the Interface Standards of China Drug Electronic Supervision Network, and upload the associated files the China drug Electronic Supervision network on the day.

26. Implementation requirements. Drug production enterprises shall complete the transformation of the associated system of the production line coding in accordance with the actual situation of the enterprises based on the Interface Standards of China Drug Electronic Supervision Network.

(VI) Requirements for registration and cancellation after verification of drug

27. Collecting requirements for monitoring codes. Drug production enterprises shall collect monitoring codes on the outside package of coding drug in accordance with the Interface Standards of China Drug Electronic Supervision Network.

28. Requirements for registration and cancellation after verification. Drug
production enterprises shall carry out the registration and cancellation after verification work as stipulated.

(1) The monitoring codes on the package of the drug manufactured by enterprises shall be scanned when the drug is entering or delivering the warehouse, and upload flow date of monitoring codes;

(2) The registration and cancellation after verification work shall be fulfilled on the day when the drug is into or out of the inventory.

29. **Inventory management.** Drug production enterprises shall ensure the online inventory is consistent with the actual inventory.

**III. Drug operation enterprises (omitted)**

**IV. Upgrading and service of drug Electronic Supervision network (omitted)**

Annex 1. Operating Standards for Drug Electronic Supervision

Annex 1: Operating Standards for Drug Electronic Supervision

The standard is concluded for the purpose of further regulating the business process of drug Electronic Supervision work and operation, and improving the operation level of drug Electronic Supervision.

1. Network access operating standard

(I) Network access process of monitoring department (omitted)

(II) Enterprise network access process

1. Enterprise should fill in the network registration form, mail the related materials to the provincial bureau, and pay digital certificate service charge to China drug Electronic Supervision network if it wants to log on China drug Electronic Supervision network;

2. The drug supervisory and administrative departments at all levels in the government of China drug Electronic Supervision network should be responsible for examining and verifying the enterprises’ members of China drug Electronic Supervision network within their jurisdiction;

3. Customer service center of Chinese drug Electronic Supervision network should be responsible for making digital certificate for the enterprises which have been approved and have paid their digital certificate service charge;

4. After the digital certificates were completed, customer service center of China drug Electronic Supervision network should mail them to the enterprises applying for access to network.
企业入网流程  Network access process for enterprises
申请入网企业  Enterprises applying for access to network
企业直属药监局  Enterprises directly under the Bureau of Drug Monitoring
中国药品电子监管网客户服务中心  Clients service center of China drug Electronic Supervision network
登录中国药品电子监管网  Log on China drug Electronic Supervision network
在线填报（入网登记表）提交并打印  Fill out （network registration form）online,
submit and print
审核不通过 Fail to pass the examination
邮寄盖有企业公章的《入网登记表》及相关材料 Mail the Network Registration Form with a enterprise official seal
收到材料 Receipt of material
审核企业信息 Examine the enterprise information
公对公汇款 Business to business remittance
审核通过 Pass the examination
公对公汇款 Business to business remittance
收到款项 Receipt of the payment
制造数字证书 Make a digital certificate
派发数字证书和发票 Dispatch the digital certificate and invoice
收到数字证书和发票 Receipt of the digital certificate and invoice

II. Operation standard of data upload
(I) Upload process of production enterprise drug associated relationship
1. Drug Production enterprises should establish packaging associated relationship at all levels for endowed drug at the production line;
2. The government of China drug Electronic Supervision network should complete the report work of associated relationship after the drug off the assembly line through the client of Chinese drug Electronic Supervision network. The new productive drug can enter warehouse after the manufacturer completed the information report work of associated relationship.

(II) Upload process of drug registration and cancellation after verification
1. When the drug arrived and were entered warehouse, enterprises should immediately collect the Electronic Supervision code on the arrival drug packaging; after the information of warehouse entry was completed, the enterprise should complete the report work of warehouse entry information immediately through the client of China drug Electronic Supervision network;
2. When the drug were removed from warehouse, enterprises should immediately collect the Electronic Supervision code on the removal drug packaging; after the
information collection of removal warehouse was completed, the enterprise should complete the report work of removal warehouse information immediately through the client of China drug Electronic Supervision network;

Ⅲ Information maintain, change operation standard

(I) Drug information maintenance procedures

1. Manufacturer should check the drug information of the enterprise in “Data Query” when logs on state food and drug administration (hereinafter referred to as State Bureau) website, and the manufacturer can apply China drug Electronic Supervision network for drug information maintenance if the information is consistent with the reality;

2. If the relevant information can not be found out at State Bureau or the information of "The drug registration approval of state food and drug administration" held by the manufacturer are different, enterprise should do record update to State Bureau at first, Tel: 010-63923253, Fax: 010-63923254;

3. If the relevant information can not be found out at State Bureau, enterprise should apply to add or change the drug information to State Bureau. Process is as follows:

4. Production enterprise should stamp an official seal in the completed registration form, then fax it to the customer service center of China drug Electronic Supervision network, Fax: 010-51342277, and send electronic version to cdea@sFDA.gov.cn;

5. Customer service center of China drug Electronic Supervision network should be responsible for adding or changing drug information at the government of China drug Electronic Supervision network after Enterprise Product Registration Form was received provided by manufacturer.
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药品信息维护流程

生产企业 Production enterprise

国家局 State Bureau

通过国家局网站核对药品信息 Check the drug information through the Internet of State Bureau

相符 Consistent with

否 No

申请备案更新 Updating of the application for record

维护国家局网站数据库 Maintenance of the database on the Internet of State Bureau

是 Yes

下载“生产企业产品登记表” Download Registration Form for Products of Production Enterprises
Fill in *Registration Form for Products of Production Enterprises*, seal affixed, send fax and e-mail

核对药品信息 Check the drug information

相符 in compliance

否 No

是 Yes

新增或变更中国药品电子监管网药品信息

Add or change the drug information of China drug Electronic Supervision network

(Ⅱ) Enterprise information change process

1. Enterprise should submit enterprise information application regarding changes through the client of China drug Electronic Supervision network;

2. Provinces and bureaus are responsible for examining and verifying the enterprise information change within their jurisdiction in the government of China drug Electronic Supervision network.

(Ⅲ) Enterprise certificate information maintenance process

1. Enterprises submit the maintain application of production, business certificate or GMP, GSP certificate through the client of China drug Electronic Supervision network;

2. Provinces and bureaus are responsible for examining and verifying the enterprise information maintenance within their jurisdiction in the government of China drug Electronic Supervision network.

Ⅳ. Prewarning processing operation standard

(I) Prewarning management

1. Drug approval number is the expired forewarning

Processing methods: monitoring department verifies whether the enterprise has illegal production (approval number is expired)

Case 1: If the enterprise gets out of line to process in accordance with the relevant provisions, the results should be filled in the system by the end of the processing, and the prewarning should be shut down manually by monitoring departments;
Case 2: Provinces and bureaus are responsible for modifying the validity of approval number through the government function of China drug Electronic Supervision network, then the system shall close prewarning automatically if it was caused by not updated drug approval number validity information.

Provincial bureau should change the relevant information through the government of China drug Electronic Supervision network by the end of drug approval number validity change.

2. The expired prewarning of enterprise certificate
Processing methods: monitoring department verifies whether the enterprise has illegal production or operation (Enterprise certificate is expired)

Case 1: If the enterprise gets out of line to process in accordance with the relevant provisions, the results should be filled in the system by the end of the processing, and the prewarning should be shut down manually;

Case 2: If enterprise has replaced the new certificate, provincial bureau modifies the drug approval number or certificate validity through the government function of China drug Electronic Supervision network, then the system shall close prewarning automatically if it was caused by not updated certificate information.

3. Ultra - plan production prewarning
Processing methods: monitoring department verifies whether the enterprise has produced special drug illegitimately (The approved annual national output is expired)

Case 1: If the enterprise has produced special drug illegitimately, the processing should be processed in accordance with the relevant provisions, the results should be filled in the system by the end of the processing, and the prewarning should be shut down manually;

Case 2: If the special annual drug production and acquisition plan maintenance had error or plan did not be maintained and added in time, Special Drug Monitoring Department of National Bureau of Drug Safety & Inspection should be connected in time, the government of China drug Electronic Supervision network should be noticed to update plan in time, after the plan was updated, regulatory authorities should shut down the prewarning manually through the government of China drug Electronic
Supervision network.

4. Ultra-plan purchase prewarning
Processing methods: monitoring department verifies whether the enterprise has purchased special drug illegitimately (The approved annual national volume of purchase is expired)
Case 1: If the enterprise has purchased special drug illegitimately, the processing should be processed in accordance with the relevant provisions, the results should be filled in the system by the end of the processing, and the prewarning should be shut down manually;
Case 2: If the special annual drug production and acquisition plan maintenance had error or plan did not be maintained and added in time, Special Drug Monitoring Department of National Bureau of Drug Safety & Inspection should be connected in time, the government of China drug Electronic Supervision network should be noticed to update plan, after the plan was updated, regulatory authorities should shut down the prewarning manually through the government of China drug Electronic Supervision network.

5. Growth prewarning of abnormal purchase
Processing methods: monitoring department verifies whether the enterprise has purchased the drug under special monitoring illegitimately.
Case 1: If the enterprise has purchased the drug under special monitoring illegitimately, the processing should be processed in accordance with the relevant provisions, the results should be filled in the system by the end of the processing, and the prewarning should be shut down manually;
Case 2: If the enterprise has operated the drug legitimately, the results should be filled in the system and the prewarning should be shut down manually by monitoring departments through the government of China drug Electronic Supervision network;

6. Prewarning of inventory loss and overflow
Processing methods: monitoring department verifies whether the enterprise has operated the drug illegitimately.
Case 1: If the enterprise has operated the drug illegitimately, the processing should be
processed in accordance with the relevant provisions, the results should be filled in the system by the end of the processing, and the prewarning should be shut down manually by monitoring departments;

Case 2: If the enterprise has operated the drug legitimately, the results should be filled and the prewarning should be shut down manually through the government of China drug Electronic Supervision network;

7. Not blending prewarning
Processing methods: the enterprise verifies the prewarning information.
Case 1: The receipts of warehouse entry (delivery) should be repayed if the enterprise did not report them, if the receipts are correct, the prewarning should be closed by system automatically.
Case 2: If the receipts of warehouse entry (delivery) could not be repayed, the results should be filled and the prewarning should be shut down manually through the government of China drug Electronic Supervision network by the end of event processing.

8. Unmatched blend prewarning
Processing methods: the enterprise verifies the prewarning information.
Case 1: Misstatement data of enterprise should be revised through uploading new documents, the prewarning shall be shut down manually by the system according to the uploaded new documents by the end of successful analysis;
Case 2: If the receipts of warehouse entry (delivery) could not be revised, the results should be filled and the prewarning should be shut down manually through the government of China drug Electronic Supervision network by the end of event processing by the provincial bureau.

9. The expired drug prewarning
Processing methods: the enterprise verifies the prewarning information.
Case 1: Misstatement valid data or requirement of enterprise should be revised, the results should be filled in the system by the end of the processing and the prewarning shall be shut down manually by monitoring department;
Case 2: If the enterprise operates the drug illegitimately, the processing should be
done in accordance with the relevant provisions, the results should be filled in the system by the end of the processing, and the prewarning should be shut down manually by monitoring department;

**V. Customer service of China drug Electronic Supervision network**

**(I) Mailing information**

Recipient's Name: Customer service center of China drug Electronic Supervision network

Postal Address: 19th Floor, Building A, Fairmont Tower, 33# Guangshun North Avenue, Chaoyang District, Beijing

Zip Code: 100102

**(II) Remittance information**

Username: Citic 21st Century (China) Technology Co., LTD

Name of Bank: Beijing East Third Ring Road Branch of Shanghai Pudong Development Bank

Account Number: 91150155360000080

**(III) Contact way**

Telephone Number: 95001111 or 010-51342299

E-mail: cdea@sfda.gov.cn

Fax Number: 010-51342277

Business QQ: 95001111
Coding and Application Standard for Drug Electronic Supervision Code

July 2012
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In order to implement the 2011-2015 Work Plan for Electronic Supervision of Drugs, to further standardize the application of drug electronic supervision code in every cycle of drug, and to enhance the automatic and in-depth application of drug electronic supervision code in every cycle, this Standard is hereby formulated. This Standard specifies relevant requirements for coding, attaching, printing quality and data collection of drug electronic supervision code. This Standard applies for programs and work associated with the implementation of drug electronic supervision by enterprises related to drug production, distribution and retails.

I. Definition of Terms

Drug electronic supervision code: Drug electronic supervision code (hereinafter referred to as “drug code”) is an electronic identification used in providing information services for drugs, such as authentication, information storage and collection, and logistic flow statistics. A drug code is a code encrypted with a 20-digit number, presented in the form of Code 128C one-dimensional barcode and numeric characters, and supports automatic identification devices and human eye identification. Drug codes are divided into class I drug codes (smallest sales packages for drugs), class II drug codes (medium packages for drugs), class III drug codes (outer packages for drugs, and so on), used to label drugs in smallest sales packages, drugs in individual intermediate packages, and drugs in individual outer packages, respectively. One product one code: refers to the action of sticking (printing) one distinct drug code on each smallest sales package, similar to assigning a unique electronic identification number to each drug product. Verification for warehouse entry: a mandatory action during the entry of drugs into warehouse by relevant enterprises, of scanning the drug codes of the drug products entering warehouse, and uploading the data collected to the “China drug electronic supervision network” for record.
Verification for warehouse exit: a mandatory action during the warehouse exit of drugs from warehouse by relevant enterprises, of scanning the drug codes of the drug products entering warehouse, and uploading the data collected to the “China drug electronic supervision network” for record.

Activation: the action of formally sticking (printing) drug codes on each class of outer packages of drug products, and uploading the drug codes stuck to the “China drug electronic supervision network” for registration by the enterprises downloading the drug codes. After such registration, a drug code has been given all the production data of the drug, and can undergo verification for warehouse entry, verification for sales and query.

I. Application Scope of Drug Codes

Drug codes are applied in the modernized information administration of drugs, which enables real-time monitoring of drug production, logistics and storage using coding and network technologies and by means of “one product one code” and “whole course”.

III. Coding Standard for Drug Codes

(I) Coding System of Drug Codes

The 20-digit number of a drug code is encrypted using the Code 128C coding standard, and it can be calculated that the barcode is composed of 145 modules, i.e. 145X.

(II) Representation of Drug Codes

| 起始字符 | start characters |
| 数据字符 | data characters |
| 符号校验字符 | symbol check characters |
| 终止字符 | end characters |
| 左侧空白区 | blank space in left |
In order to meet the needs of various package shapes, production enterprises can choose any one among these as the case may be.

中国药品电子监管码: China Drug Electronic Supervision Code

样式 A: Style A

样式 B: Style B

样式 C

中国药品电子监管码: China Drug Electronic Supervision Code
(III) Coding Rules of Drug Codes

A drug code applies 20-digit coding, among which, the first 7 digits (product resources code) include information such as enterprise information, drug name, dosage form, approval number, packaging specifications, which facilitates data storage and can be applied in logistic and retail settlement cycles.

The 8th to 16th digits of a drug code comprise the serial number of the single product, while the last 4 digits are the check digits generated by a special encryption algorithm.

The coding principles are shown in the following picture:

(IV) Coding Capacity of Drug Codes
Due to the specificity of the coding approach of drug codes, they can sufficiently support a great number of drug categories and a large coding capacity, shown in the following table:

<table>
<thead>
<tr>
<th>Code digits</th>
<th>Code categories</th>
<th>Number of code digits</th>
<th>Supported number</th>
<th>Total capacity of drug codes</th>
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<tbody>
<tr>
<td>1st-7th digits</td>
<td>Product resources code</td>
<td>7 digits</td>
<td>10 million</td>
<td>1 quadrillion</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(categories)</td>
<td>(products)</td>
</tr>
<tr>
<td>8th-16th digits</td>
<td>Product serial code</td>
<td>9 digits</td>
<td>1 billion</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(products)</td>
<td></td>
</tr>
</tbody>
</table>

IV. Application Standard for Drug Codes

(I) Data Collection via Drug Codes

1. Data Collection in Production Cycle

During the production cycle of a drug product, the following data should be collected via the drug code:

Mandatory: drug generic name, dosage form, formulation specifications, packaging specifications, packaging unit, photo of outer package, name of production enterprise, approval number, drug storage life, production batch number, production date, expiry date, production quantity, quality inspection report sheet, name of drug purchaser, warehouse exit order number, warehouse exit type, warehouse exit date, etc.
Optional: name of upstream drug shipper (mandatory for return of goods), warehouse entry order number (mandatory for return of goods), warehouse entry type (mandatory for return of goods), warehouse entry date (mandatory for return of goods), warehouse exit and storage requirements, reason for return of goods (mandatory for warehouse entry and exit of returned goods), reason for destruction (mandatory for warehouse exit for destruction), sales price, carrier (mandatory for special drugs), carriage certificate number (mandatory for special drugs), expected carriage time (mandatory for special drugs), product barcode, standard drug code, etc.

2. Data Collection in Wholesale Cycle

During the wholesale cycle of a drug product, verification for warehouse entry and exit of drug code should be carried out, and the following data should be collected:

Mandatory: name of upstream drug shipper, warehouse entry order number, warehouse entry type, warehouse entry date, name of downstream drug shipper, warehouse exit order number, warehouse exit type, warehouse exit date, etc.

Optional: storage temperature, reason for return of goods (mandatory for warehouse entry and exit of returned goods), reason
for destruction (mandatory for warehouse exit for destruction), purchase price, sales price, carrier (mandatory for special drugs), carriage certificate number (mandatory for special drugs), expected carriage time (mandatory for special drugs), etc.

3. Data Collection in Retail Cycle

During the retail cycle of a drug product, verification for warehouse entry and exit of drug code should be carried out, and the following data should be collected:

Mandatory: name of upstream drug shipper, warehouse entry order number, warehouse entry type, warehouse entry date, warehouse exit type, warehouse exit date, etc.

Optional: storage temperature, warehouse exit order number (mandatory for warehouse exit of returned goods), reason for return of goods (mandatory for warehouse exit of returned goods), reason for destruction (mandatory for warehouse exit for destruction), purchase price, sales price, ID card number and medical insurance card number of drug buyer, etc.

(II) Recovery and Reuse of Drug Codes

In order to fully utilize effective coding resources, if any of the following conditions is met, the drug code assigned to the enterprise will be recovered, and can be redistributed and reused.
1. Beyond five years after warehouse exit and destruction of the drug;
2. Beyond five years after storage life for general drug products, and beyond ten years after storage life for special drug products (poisonous, narcotic, psychotropic and radioactive drugs).
3. The drug code has not been activated by the downloading enterprise over one year from the date of downloading;
4. The drug code has not been downloaded by the applying enterprise over six months from the date of generation;

(III) Naming Rules for Drug Code documents

Enterprises download drug code documents from the platform of China drug electronic supervision network, and the naming rules for drug code documents are as follows:

"Drug generic name_Application form number_Code beginning serial number (the first 16 digits of the 20-digit drug code)_Document serial number (a 3-digit number)_Packaging specifications_Packaging class"

For example:

Composite Radix Sophora Flavescentis Injection _20090813-1_8200008400050520-000_5 bottles per carton _1

Drug Name: Composite Radix Sophora Flavescentis Injection;
Application form number: 20090813-1;
Code beginning serial number: 8200008400050520;
Document serial number: 000
Packaging specifications: 5 bottles per carton
Packaging class: 1 (in packaging classes, 1 is the smallest package)

V. Printing Standard for Drug Codes

(I) Printing Parameters of Drug Codes

<table>
<thead>
<tr>
<th>Name of parameter</th>
<th>Value of parameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barcode types</td>
<td>Code 128C</td>
</tr>
<tr>
<td>Barcode density</td>
<td>≥7mils</td>
</tr>
<tr>
<td></td>
<td>(Recommended≥10mils)</td>
</tr>
<tr>
<td>Data type</td>
<td>numerals</td>
</tr>
<tr>
<td>Data length</td>
<td>20 digits</td>
</tr>
<tr>
<td>Barcode height</td>
<td>≥8mm</td>
</tr>
<tr>
<td>Barcode quality classes</td>
<td>Above Class C (1.5)</td>
</tr>
</tbody>
</table>

(II) Available Pairing of Colors for Barcodes

<table>
<thead>
<tr>
<th>Serial No.</th>
<th>Gap color</th>
<th>Bar color</th>
<th>Availability</th>
<th>Serial No.</th>
<th>Gap color</th>
<th>Bar color</th>
<th>Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>White</td>
<td>Black</td>
<td>✓</td>
<td>8</td>
<td>Yellow</td>
<td>Green</td>
<td>✓</td>
</tr>
<tr>
<td>2</td>
<td>White</td>
<td>Blue</td>
<td>✓</td>
<td>9</td>
<td>Yellow</td>
<td>Black</td>
<td>✓</td>
</tr>
<tr>
<td>3</td>
<td>White</td>
<td>Green</td>
<td>✓</td>
<td>10</td>
<td>Yellow</td>
<td>Dark brown</td>
<td>✓</td>
</tr>
<tr>
<td>4</td>
<td>Orange</td>
<td>Dark brown</td>
<td>✓</td>
<td>11</td>
<td>Orange</td>
<td>Black</td>
<td>✓</td>
</tr>
<tr>
<td>5</td>
<td>Orange</td>
<td>Green</td>
<td>✓</td>
<td>12</td>
<td>Red</td>
<td>Blue</td>
<td>✓</td>
</tr>
</tbody>
</table>
(III) Not Recommended Pairing of Colors for Barcodes

<table>
<thead>
<tr>
<th>Serial No.</th>
<th>Gap color</th>
<th>Bar color</th>
<th>Availability</th>
<th>Serial No.</th>
<th>Gap color</th>
<th>Bar color</th>
<th>Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Green</td>
<td>Red</td>
<td>×</td>
<td>8</td>
<td>Golden</td>
<td>Black</td>
<td>×</td>
</tr>
<tr>
<td>2</td>
<td>Dark brown</td>
<td>Black</td>
<td>×</td>
<td>9</td>
<td>Blue</td>
<td>Black</td>
<td>×</td>
</tr>
<tr>
<td>3</td>
<td>Green</td>
<td>Blue</td>
<td>×</td>
<td>10</td>
<td>Green</td>
<td>Black</td>
<td>×</td>
</tr>
<tr>
<td>4</td>
<td>Light brown</td>
<td>Red</td>
<td>×</td>
<td>11</td>
<td>White</td>
<td>Red</td>
<td>×</td>
</tr>
<tr>
<td>5</td>
<td>Blue</td>
<td>Red</td>
<td>×</td>
<td>12</td>
<td>White</td>
<td>Yellow</td>
<td>×</td>
</tr>
<tr>
<td>6</td>
<td>Golden</td>
<td>Orange</td>
<td>×</td>
<td>13</td>
<td>White</td>
<td>Golden</td>
<td>×</td>
</tr>
<tr>
<td>7</td>
<td>White</td>
<td>Orange</td>
<td>×</td>
<td>14</td>
<td>White</td>
<td>Light brown</td>
<td>×</td>
</tr>
</tbody>
</table>

Note: It is recommended to apply the pairing of black and white.

(IV) Printing Positions of Drug Codes

When the drug code (Code 128C) and another barcode (e.g. product barcode, logistic code, etc.) appear together on the outer package of the same drug product, the drug code and the barcode should be printed on different planes, or should be perpendicular to each other on the same plane. See “Standard for Drug Code Attaching Positions”

(V) Printing Directions of Drug Codes
If the surface curvature and area of the product package permit, it is better that the barcode sign of the drug code be placed horizontally, and characterized identified by human be read from left to right.

If the drug barcode can not be placed horizontally, under the premises of ensuring the printing quality of the drug barcode, the drug barcode can be placed longitudinally, and characterized identified by human be read from top to bottom. It is recommended that longitudinal printing should be applied whenever printing the drug barcode on a curved surface.

When printing the drug barcode on gold and silver card paper and other reflective materials, corresponding measures should be taken to eliminate the impact of reflection. When printing the drug barcode on pyrocondensation film, the impact of deformation on the drug barcode should be sufficiently weighted, and the direction of the drug barcode should be identical to the direction of most shrinkage of the pyrocondensation.

(VI) Dimensions of Blank Area of Drug Codes

The blank area on the two sides of the drug code ≥ 10 times minimum module width (i.e. 10X).

Examples on calculation:
Example 1: If the total width of the barcode is 37mm (10mils),
=37mm÷145=0.2552mm, 10X=0.2552mm x 10=2.552mm

That is to say, the minimum width of the blank area on the left
and on the right of the barcode should not be less than 2.552mm.

Example 2: If the total width of the barcode is 28mm (7mils),
X=28mm÷145=0.1931mm, 10X=0.1931mm x 10=1.931mm

That is to say, the minimum width of the blank area on the left
and on the right of the barcode should not be less than 1.931mm.

VI. Quality Inspection and Judgment Criteria

(I) Quality Inspection Methods for Drug Codes

The GB/T 14258 2003 Standard Testing Method is adopted as
the quality inspection level standard for drug codes. If a barcode
verifier with grading and inspection functions is used for inspection
and regulation, the barcode quality level should be above Class C
(1.5).

The GB/T 14258 2003 Standard Testing Method analyzes
various quality parameters according to the “scan reflectance
profile” derived from scan of the barcodes, and classify the barcodes
into five quality levels of “A” -“F”, with “A” being the best, “D”
being the worst and “F” being disqualified.

Class A: the barcode can be easily identified, which applies for
occasions of only scanning once and along one line.
**Class B:** the performance of the barcode in the identification is not as good as Class A, which applies for occasions of only scanning along one line but permitting repeated scan.

**Class C:** the barcode may need several times of repeated scan, which usually requires scanning devices capable of repeated scan and having several scanning lines to achieve a good identification.

**Class D:** the barcode may not be identified by some devices, which requires scanning devices capable of repeated scan and having several scanning lines to achieve a good identification.

**Class F:** the barcode is disqualified and can not be used.

The quality classification of barcodes in the GB/T 14258 2003 Standard Testing Method represents the printing qualities of the barcodes and the occasions of their application.

**(II) Inspection criteria**

1. Environmental criteria:

   The temperature of the laboratory should be within 20 °C ±5 °C and humidity within 35% ~ 65%.

2. Inspection devices:
An overall characteristic measuring device should be applied in the inspection.

An overall characteristic measuring device should have the capability of measuring reflectance of barcode symbols, giving scanning reflectance curves, or giving the overall characteristic data of barcode symbols according to the analysis on scanning reflectance curves.

3. Wavelength of measuring light

The peak wavelength of the measuring light should be specified in the standard for application of barcodes. If the peak wavelength of the measuring light is not specified in the standard for application, its should be close to the wavelength used in the scan. See GB/T 14258 – 2003 for methods for choosing wavelengths.

4. Diameter of measuring aperture

The nominal diameter of the measuring aperture should be specified according to relevant standards and specifications applicable for the barcode being measured. See GB/T 14258 – 2003.

5. Measuring light path

The optical axis should be at a 45-degree angle toward the normal of the surface being measured, and should be within a plane perpendicular to the measuring reticle and parallel to the bar of the barcode. The optical axis of the light path used to collect reflected
light should be perpendicular to the measuring surface. The collection of reflected light should be done within a cone-shape scope with a vertex angle of 15 degrees, and a central axis vertical to the surface being measured and crossing the center of the sampling area. See GB/T 14258 – 2003.

6. Benchmark for reflectance

The value of reflectance should be presented in the form of percentage. The benchmark for reflectance should be barium sulfate or magnesium oxide standard samples meeting the standard requirements of ISO7724. The reflectance of such standard samples is considered to be 100 %. Reflecting plates corrected by a state-approved standard laboratory and with a certificate issued may also be used as the benchmark for reflectance. In such a benchmark, the incidence angle of illumination is 45 degrees, the receiving angle is perpendicular to the surface of the object, and the receiving optical signal is diffuse reflection light.

7. Tested samples

During the inspection, the status of the tested drug code symbols should be identical to the scanning and identification status routinely used for the drug codes as far as possible. As for samples which can not be tested in packages, and for drug code samples on labeling tags, labeling paper and package materials, appropriate
handling should be done to make the samples smooth and the sizes appropriate for inspection. As for print media with an opacity of less than 0.85, a dark surface of reflectance less than 5% should be placed under the bottom of the barcode symbols during the inspection. See Appendix d of GB/T 14258 – 2003.

(III) Inspection items

The inspection items should include:

1. Quality class of the barcode symbol
2. Evaluation parameters for scanning reflectance curve
3. Correctness of decoding
4. Minimum reflectance
5. Symbol contrast
6. Minimum edge contrast
7. Modulation radio
8. Defects
9. Decodability
10. Blank area

(IV) Inspection methods

1. General requirements
(1) Inspection zone
The inspection zone is the area crossing the barcode symbol and perpendicular to the height of the barcode symbol. The distance from the bottom of this area to the bottom of the bar of the barcode equals to the distance from the top of this area to the top of the bar of the barcode, which takes the value of 10% of the height of the barcode symbol or the diameter of the measuring aperture, whichever is greater. The blank area of the barcode symbol should be included in the direction of the width of the inspection zone (See GB/T 14258 – 2003).

(2) Times of Scanning measurement

Given the difference in the performance of the symbol among different bar heights, several times of scanning should be done on the barcode symbol at different bar heights in the specified inspection zone, appropriate measuring aperture and light source should be chosen, and the width of the whole symbol including the blank area should be scanned. The scanning lines should be basically equidistant in the direction of the height of the inspection zone. The minimum times of scanning for each symbol is 10 or the quotient (taking the integer) derived from the height of the inspection zone divided by the measuring aperture, whichever is smaller.

2. Scanning measurement
According to this Standard, the devices used to evaluate the quality of barcode symbols should be capable of measuring and analysing the change of diffuse reflectance of barcode symbols on printing media, scanning with multiple paths, limiting the scanning paths within the specified measurement zone, and covering the whole area including the blank area in the direction of the width of the barcode symbols.

3. Evaluation parameters of scanning reflectance curve

(1) Determination of Units

In order to distinguish between the bar units and the blank units, an overall threshold (gt) should be determined, which equals to one half of the sum of the highest reflectance and the lowest reflectance.

The various areas above the overall threshold is deemed as blank, and the highest reflectance of each blank area is defined as the reflectance of such blank area (r3), and the lowest reflectance of each bar area is defined as the reflectance of such bar area (rb).

(2) Determination of Edges

The edge of the unit is at the point of the intermediate value of the reflectance of the blank area (r3) and the reflectance of the bar area (rb) of adjacent units on the scanning reflectance curve, i.e. \((r3 + rb) / 2\). If more than one point between the adjacent units meet this condition, it will be impossible to determine the position of the
edge and the width of the unit, so that the scanning reflectance curve will not satisfy the requirements, which causes the failure in decoding.

(3) Correctness of Decoding

For the scanning reflectance curve measured, the edges of each unit should be determined according to the specified method for determining unit edges. The scanning reflectance curve should be decoded using the standard encoding algorithm in the coding specifications.

The correctness of decoding is an indicator used to describe the correctness of decoding of the scanning reflectance curve.

(4) Symbol Contrast

Symbol contrast refers to the contrast of the highest and the lowest reflectance on the reflectance curve.

(5) Lowest reflectance

The lowest reflectance is the minimum value of reflectance on the reflectance curve. The lowest reflectance should not be higher than the highest reflectance, so it can be ensured that the lowest reflectance will not be too high, especially in contrast to the highest reflectance, and that there is sufficient contrast between the reflectance of the blank area and the reflectance of the bar area.

(6) Minimum edge contrast
Edge contrast refers to the contrast of the reflectance of the adjacent blank units (including the blank area) and the reflectance of the bar area on the scanning reflectance curve, and the minimum edge contrast is the minimum value of all edge contrasts.

(7) Modulation radio

Modulation radio is the ratio of minimum edge contrast to symbol contrast.

(8) Defects

Defects is the nonuniformity of the reflectance curve within the units and the blank areas.

The the nonuniformity of the reflectance curve of a unit is represented by the difference between the peak reflectance and the valley reflectance within a unit or a blank area. If there is no peak reflectance within the bar unit or there is no valley within the blank unit, the nonuniformity of the reflectance curve of the unit is 0.

(9) Decodability

The decodability is an indicator for evaluating printing accuracy using applicable standard decoding algorithms as the benchmark. It is smoother for the barcode scanning devices to identify symbols with high decodability than those with low decodability.
The decodability of the scanning reflectance curve reflects the admissible error which has not been used during the printing and left for scanning.

(10) Blank area inspection

For the minimum admissible value for the width of the blank area, see the specific standards for barcode symbols (GB/T 18347-2001).

**Quality Class of Drug Code Symbols**

In practical application, due to the difference in the types of barcode identification devices and the difference in the surrounding barcodes of the barcode being identified, and in order to achieve an acceptable performance level, there will be different requirements for the quality levels of the barcode symbols. Therefore, the requirements for the quality levels of the barcode symbols should be applied according to such standard, and the levels of the symbols should be the arithmetic mean value of the levels of all scanning reflectance curve.

If the same barcode symbol generates different encoding data in two scans, regardless of the level of the individual scanning reflectance curves, the symbol level of the barcode should be 0.

1. Correctness of Decoding
Decodable drug code symbols should comply with standards regarding character encoding, start character, stop character, check character of symbol, blank area and space among characters (if any). If the scanning reflectance curve can not be decoded according the standard decoding algorithm, the correctness of decoding is incorrect, and the quality level of such parameter is 0, otherwise, the correctness of decoding is correct, and the quality level of such parameter is 4. Normally, the reason for failure of decoding can be derived from the analysis on the scanning reflectance curve.

2. Determination of quality levels

The quality levels of drug codes can be divided into 4 to 0, with 4 being the highest and 0 being the lowest;

Assuming the times of scanning measurements on a drug code is n, n is normally 10;

If one decoding error occurs in the n times of measurements, the symbol level of the barcode being tested is 0;

If there is no decoding error occurring in the n times of measurements (not decoding is allowed), the arithmetic mean value of the level of the scanning reflectance curve by n times of measurements should be taken as the level value derived from the scanning reflectance curve of the barcode being tested;
The final quality level of a drug code is the quality level of the standard for barcode symbols and the additional requirements for the application standard, or the barcode symbol quality level calculated from the above only based on the scanning reflectance curve of the barcode, whichever is smaller.

3. Quality of drug barcode symbols

(1) The identifiers represented by the drug barcode symbols (Code 128C) should be the same as the characters read by human.

(2) If a barcode verifier with grading and inspection functions is used for inspection of the barcode, the barcode quality level should be above Class C (1.5).

(3) Compliance with relevant requirements specified in the “Printing Standard for Drug Supervision Codes”.

(4) Visual inspection: there is no stripping, stain, longitudinal break in the printing of the barcode; the edges of the bars are clear, without obvious blurring, virtual Halo or curving.
VII Standard for administration coding position

(I) The Selection Criteria of Position of Medicine Electronic Administration Code Symbol

7.1.1 Fundamental Principles
The selection of position of Medicine Electronic Administration Code Symbol should be oriented by the relatively uniform symbol position, non-deforming symbols, easy scan operation and read.

7.1.2 The Best Position
The best position of Medicine Electronic Administration Code Symbol is within the right lower region of the back of drug packages.

7.1.3 Other Selections
When the Medicine Electronic Administration Code Symbols are not suitable to put on the back of drug package, it’s selective to place the Medicine Electronic Administration Code Symbols on the right lower region of proper side, and for the drugs which are bulky or heavy, the Medicine Electronic Administration Code Symbol should not be put on the bottom of the drug package.

7.1.4 The Marginal Principle
The space between Medicine Electronic Administration Code Symbol and the place closed to an edge of drug package should be not too tight to avoid scanning failure due to the errors such as package printing, die cutting and so on.

7.1.5 The Directionality Principle
In general, the Medicine Electronic Administration Code Symbol on the drug package is appropriate to be held horizontally, as shown in Figure 1A. When held horizontally, the human-readable characters (Arabic numerals) of the Medicine Electronic Administration Code Symbol should be read from left to right, if it’s impossible to ensure the direction and quality of printing and the curvature of drug package’s surface, the Medicine Electronic Administration Code Symbol could be held vertically, as shown in Figure 1B. When held vertically, the human-readable
characters (Arabic numerals) of the Medicine Electronic Administration Code Symbol should be in accordance with other graphics and text around the bar code symbol.

7.1.6 The Direction of the Medicine Electronic Administration Code Symbol on the Curved Surface

When the Medicine Electronic Administration Code Symbol strip is held on the curved surface of drug package to make the strip of Medicine Electronic Administration Code Symbol in parallel with the generatrix of the surface, the curvature of the surface (θ) should not exceed 30 degrees, as shown in Figure 2.
1. The outer edge of the first strip
2. The middle of the Medicine Electronic Administration Code Symbol
3. The outer edge of the last strip
4. The outer edge of blank spaces on the right side and left side
5. The Medicine Electronic Administration Code Symbol
6. The surface of the drug package
7. The generatrix of the curved surface
8. The surface curvature of the Medicine Electronic Administration Code Symbol

Figure 2 The schematic of surface curvature of the Medicine Electronic Administration Code Symbol

The maximum magnification factor of the available Medicine Electronic Administration Code Symbol is related to the diameter of curved surface, and the strip of the Medicine Electronic Administration Code Symbol should be perpendicular to the generatrix of the curved surface as the surface curvature of the Medicine Electronic Administration Code Symbol exceeds 30 degrees, as shown in Figure 3.
7.1.7 The Position Which Should be Avoidable Choice

1) The Medicine Electronic Administration Code Symbol should not be put in the places with perforation, punch, openings, binding nails, drawbench, juncture, fold, edgefold, overlap, ripple, apophysis, wrinkle, other graphic and text, as well as rough-textured places.

2) The Medicine Electronic Administration Code Symbol should not be put on the corner or the places where the surface curvature is too big.

3) The Medicine Electronic Administration Code Symbol should not be put on the edgefold of the drug package or below the overhang.


7.2.1 Cardboard Folding Box-Type Package (Box-Shaped Package)

For the drugs with box-shaped package, The Medicine Electronic Administration
Code Symbol is suitable to be printed on the bottom right region of the front of package, near to the edge, as shown in Figure 4A; secondly, it could be printed on the bottom right region of the side of package, as shown in Figure 4B; it should not be placed at the bottom and top of the box, and the distance from edge should be in accordance with the marginal principle.

Figure 4 The Example of the tagging the drugs with box-shaped package

7.2.2 The Package of The Bottle of Medicine

The Medicine Electronic Administration Code Symbol is suitable to be printed on the bottom right region of the back or front of package, as shown in Figure 5. It should not be put on the bottom or top of the bottle.
7.2.3 Can-Shaped and Tube-Shaped Package

The Medicine Electronic Administration Code Symbol is suitable to be printed on the bottom right region of the back or front of package, as shown in Figure 6. It should not be put on the places with ripple, juncture and rise.

Figure 5 The Example of tagging the drug electronic supervision code for the bottle of medicine
Figure 6 The Example of tagging the drug electronic supervision code for the medicine packed in cans and tubes

7.2.4 Basin-Shaped and Barrel-Shaped Packages
The Medicine Electronic Administration Code Symbol is suitable to be printed on the bottom right region of the back or front of package, as shown in Figure 7A, Figure 7B. When the Medicine Electronic Administration Code Symbol is not suitable to be put on the back, front or side, it could be put on the cap of the package, as shown in Figure 7C.

A）Preferred position  B）Optional position  C）Optional position

Figure 7 The Example of tagging the Medicine Electronic Administration Code for the medicine packed in Basins and barrels

7.2.5 Bag-Shaped Package
The Medicine Electronic Administration Code Symbol is suitable to be printed on the bottom right region of the back or front of package as close to the middle of the bag as possible, as shown in Figure 8. It should not place the Medicine Electronic Administration Code Symbol at the seam or below the frilled edge.

A）Preferred position  B）Optional position
7.2.6 The Intermediate Package of the Medicine (Secondary-Level Package)

If it is possible to use the intermediate package of the medicine and external package as independent sales package in circulation, the drug-producing enterprises should tag the secondary-level package and establish relations (tagging the intermediate package).

When the intermediate package is tagged, the placement of the Medicine Electronic Administration Code Symbol could be based on the shapes of the intermediate package; if non-transparent box-type package is adopted, the placement of the drug electronic administration code could be selected according to the statement of “box-shaped package”; when the transparent heat shrinking film is used as the intermediate package, the drug electronic administration code on the intermediate package can not overlap with the drug electronic administration code on small package, should be placed on another surface, as shown in Figure 9.

Figure 8 The Example of tagging the drug electronic supervision code on the bottle of the medicine packed in bags

Figure 9 The example of tagging the drug electronic supervision code on the
7.2.7 The Carton Package of Medicine (Third-Level Package)

For the carton package of medicine (third-level package), in order to facilitate to scan the medicine electronic administration code in circulation of medicine, there are at least two different surfaces which must use two identical Medicine Electronic Administration Code Symbols on the same outer package, put on the upper right region on the opposite sides of the outer package, as shown in Figure 10. Also, the Medicine Electronic Administration Code Symbols could be put on the corner between the upper right region of the two adjacent sides (two identical medicine electronic administration code), as shown in Figure 11.

Don’t put the Medicine Electronic Administration Code Symbol on the top and the bottom of the outer package.

The medicine electronic administration codes on the same box must maintain data consistency. It is the only visible medicine electronic administration code on scans after the outer boxes of medicine are stacked, avoid repeat operations, and paste the medicine electronic administration code on the same surface to the drug batch number.

For ease of scan operations, the size of the medicine electronic administration code label on the outer package of medicine should be magnified in proportion, and the recommended density of the Medicine Electronic Administration Code Symbol was ≥15 mils.

In order to avoid scanning failures due to the wear-out of medicine electronic administration code label in circulation, it’s suggested that the enterprise put the same medicine electronic administration code label into the box (pasted on inner box or the packing list), and when the code on the outer box couldn’t be identified, open the package to scan the medicine electronic administration code on inner box.
中国药品电子监管码：China Drug Electronic Supervision Code

电话查询：Query Hotline:

短信查询：Query Message:

网站查询：Query Network:

Figure 10 The example of tagging the medicine electronic supervision code on our box
Figure 11 The example of dual Medicine electronic administration code label

(III) Additional Instruction

Put other bar codes on the different surfaces from medicine electronic administration code as the medicine electronic administration code together with the bar code of the products or other logistics codes used within an enterprise appear on the same outer box of medicine.

VIII. References

GB 12904—2003 The Barcode of the products
GB/T 14258—2003 Information Technology, Automatic Identification and Data Collection Technology, Quality Inspection of All Barcodes Printed
GB/T 16986—2003 EAN·UCC System Identifier
GB/T 18347—2001 128 Barcodes
GB/T 18805—2002 The Printability Trial of Commercial Barcode
GB12905 Generic Terms of Barcode System, Generic Terms of Barcode Symbol
GB/T 14257 Generic Position of Commercial Barcode Symbol
YBX-2001-2009 The Folding Carton Used for Drug Package
ISO 7724-2: 1984 Colour and glazing - Colorimetry – Section 2: Color measurement