Provisions for Drug Advertisement Examination

(SFDA Decree No. 27)

The Provisions for Drug Advertisement Examination, adopted by the State Food and Drug Administration and the State Administration for Industry and Commerce of the People's Republic of China, is now issued in the decree sequence number of the State Food and Drug Administration. The Provisions shall go into effect as of the date of May 1, 2007.

Shao Mingli
Commissioner
State Food and Drug Administration

Zhou Bohua
Minister
State Administration for Industry and Commerce
of the People's Republic of China

March 13, 2007

Provisions for Drug Advertisement Examination

Article 1 The Provisions are formulated for the purposes of strengthening regulation on drug advertisements and ensuring the authenticity and legality of drug advertisements in accordance with the Advertisement Law of the People's Republic of China (hereinafter referred to as Advertisement Law), the Drug Administration Law of the People's Republic of China (hereinafter referred to as Drug Administration Law), the Regulations for the Implementation of Drug Administration Law of the People's Republic of China (hereinafter referred to as Regulations for the Implementation of Drug Administration Law) and other regulations related to supervision on advertisements and drugs.

Article 2 A drug advertisement refers to any advertisement published through various media or forms containing drug name, indications (functions) or other relevant contents, and shall be examined and approved in accordance with the Provisions.

Where only the names of non-prescription drugs (including adopted names and trade names) are publicized or only the names of prescription drugs (including adopted names and trade names) are publicized in

professional medical or pharmaceutical journals, the examination is not required.

Article 3 The drug advertisement applied for examination shall be approved provided that it conforms to the following laws, regulations and related provisions:
(1) Advertisement Law;
(2) Drug Administration Law;
(3) Regulations for Implementation of Drug Administration Law;
(4) Criteria for Examining and Publishing Drug Advertisement;
(5) Other provisions of the State on advertisement regulation.

Article 4 The drug regulatory departments of the provinces, autonomous regions or municipalities directly under the Central Government are the drug advertisement examination authorities responsible for examining drug advertisements within their administrative regions. The administrative departments for industry and commerce at or above the county level are supervision and control authorities for drug advertisements.

Article 5 The State Food and Drug Administration shall guide and supervise the examination conducted by drug advertisement examination authorities and punish, in accordance with law, the examination authorities that have violated the Provisions.

Article 6 An applicant for a drug advertisement approval number must be an eligible drug manufacturer or distributor. Where the applicant is a drug distributor, the consent of the drug manufacturer is required.

An applicant may entrust an agent with the application for a drug advertisement approval number.

Article 7 An application for a drug advertisement approval number shall be submitted to the drug advertisement examination authority in the place where the drug manufacturer is located.

An application for an import drug advertisement approval number shall be submitted to the drug advertisement examination authority in the place where the agent of the import drug is located.

Article 8 Where a drug manufacturer or distributor applies for a drug advertisement approval number, it shall submit an Application Form for Drug Advertisement (Appendix 1) with sample manuscript (sample film or sample record) of which the content is consistent with that to be published attached, and an electronic document of drug advertisement application. It shall also submit the following proof documents that are authentic, legal and valid:
(1) Copy of the Business License of the applicant;
(2) Copy of the Drug Manufacturing Certificate or the Drug Supply Certificate of the applicant;
(3) Where the applicant is a drug distributor, the original document proving that the drug manufacturer authorizes the drug distributor to be the applicant shall be submitted;
(4) Where an agent submits an application for a drug advertisement approval number on behalf of the applicant, an original authorization letter given by the applicant to the agent, a copy of business license of the agent and other documents proving the subject's qualifications shall be submitted;

(5) Copies of the drug approval document (including Import Drug License or Pharmaceutical Product License), copy of approved insert sheet, and label and insert sheet used in practice;
(6) For non-prescription drug advertisement, a copy of registration certificate of non-prescription drug examination or copies of relevant certificates is required;
(7) Where an applicant applies for an import drug advertisement approval number, copies of qualification certificates of the agent of the import drug shall be submitted;
(8) Where the trade name, registered trademark and patent of the drug are involved in an advertisement, copies of the valid certificates and other relevant documents proving the authenticity of the advertisement shall be submitted.

The copy of any approval document prescribed in this Article shall be sealed by the document holder.

Article 9 An advertisement application by an enterprise for a drug shall not be accepted by the drug advertisement examination authorities under any of the following circumstances:
(1) Any of the circumstances under which the application shall be rejected as prescribed in Article 20, Article 22 and Article 23 of the Provisions;
(2) An administrative procedure to withdraw a drug advertisement approval number is in process.

Article 10 After receiving an application for drug advertisement approval number, where the dossier is complete and in conformity with statutory requirements, the drug advertisement examination authority shall issue an Acceptance Notice of Drug Advertisement; where the dossier is incomplete or not conforming to the statutory requirements, one notification on all the content to be supplemented or corrected shall be given to the applicant on the spot or within five working days; if the notification to the applicant is not issued within the timeline, the application is deemed as being accepted upon the date when the dossier is received.

Article 11 Within ten working days upon accepting an application, the drug advertisement examination authority shall check the authenticity, legality and validity of the documents submitted by the applicant, and shall examine the advertisement content in accordance with law. For the drug advertisement in conformity with statutory requirements, a drug advertisement approval number shall be issued; for those not in conformity with statutory requirements, the authority shall make a decision of not issuing a drug advertisement approval number and notify the applicant of the decision with reasons in written form and the applicant’s right to apply for administrative reconsideration or to bring an administrative suit by law.

For approved drug advertisement, the drug advertisement examination authority shall report to the State Food and Drug Administration for records and send the approved Application Form for Drug Advertisement to the authority responsible for advertisement supervision and control at the same level for records. Where there is any problem in the drug advertisement reported to the State Food and Drug Administration for records, the State Food and Drug Administration shall instruct the drug advertisement examination authority to correct it.

The drug regulatory departments shall announce the approved drug advertisement timely.

Article 12 Where a drug advertisement is to be published in the province, autonomous region or municipality directly under the Central Government other than the place where the drug manufacturer and the agent of the import drug are located (hereinafter referred to as “non-local drug advertisement”), it shall, before being published, be submitted for records to the drug advertisement examination authority in the place where the advertisement is to be published.

Article 13 The following materials for non-local drug advertisement shall be submitted for record:
(1) Copy of the Application Form for Drug Advertisement;
(2) Copy of the approved drug insert sheet;
(3) For television or audio broadcast advertisement, it is required to submit the audio tape, compact disc or other medium carrier on which the content is consistent with the approved content.

The copy of any document prescribed in this Article shall be sealed by the document holder.

Article 14 For application for putting non-local drug advertisement on record in accordance with Articles 12 and Article 13 of the Provisions, the drug advertisement examination authority shall, within five working days after accepting the application, put such drug advertisement on record, endorse the word “recorded” on the Application Form for Drug Advertisement, affix the seal specific for drug advertisement examination and send the form to the supervision and control authorities for advertisements at the same level for future reference.

Where the drug advertisement examination authority of a place where a drug advertisement is to be put on record finds that the drug advertisement is not conformed with the relevant provisions, it shall fill in the Opinion on the Record of Drug Advertisement Examination (Appendix 2), submit it to the original drug advertisement examination authority for check, and copy it to the State Food and Drug Administration.

Within five working days upon receiving the Opinion on the Record of Drug Advertisement Examination, the original drug advertisement examination authority shall give its opinions to the drug advertisement examination authority of the place where the drug advertisement is to be put on record. Where no consensus is achieved between the original drug advertisement examination authority and the drug advertisement examination authority of the place where a drug advertisement is to be put on record, the case may be submitted to the State Food and Drug Administration that shall make a final judgment.

Article 15 The valid term of a drug advertisement approval number is one year. It shall become invalid upon expiration.

Article 16 The content of an approved drug advertisement is not allowed to be changed when being published. Where any change to the drug advertisement is needed, a new drug advertisement approval number shall be obtained.

Article 17 Where an advertisement applicant publishes a drug advertisement by itself, it shall keep the original Application Form for Drug Advertisement for two years for future check.

Where an advertisement publisher or advertising operator is authorized by the applicant to publish a drug advertisement, it shall check the original Application Form for Drug Advertisement, publish the advertisement in accordance with the approved content and keep a copy of the Applicant Form for Drug Advertisement for two years for future check.

Article 18 Where there is any of the following circumstances for an approved drug advertisement, the original drug advertisement examination authority shall issue a Notice of Drug Advertisement Re-examination (Appendix 3) and conduct the re-examination. The drug advertisement may continue to be published during the re-examination.

(1) The State Food and Drug Administration finds that the content of the drug advertisement approved by the drug advertisement examination authority is not in conformity with the provisions;
(2) A supervision and control authority for advertisement at or above provincial level makes a re-examination proposal;
(3) Other circumstances where a re-examination is required by a drug advertisement examination authority.

After re-examination, where the drug advertisement is not in conformity to the statutory requirements, the Application Form for Drug Advertisement shall be taken back and the original drug advertisement approval number shall become invalid.

Article 19 Drug advertisement examination authorities shall cancel the drug advertisement approval number in any of the following circumstances:
(1) Where a Drug Manufacturing Certificate or the Drug Supply Certificate is revoked;
(2) Where a drug approval document is withdrawn or cancelled;
(3) Where the State Food and Drug Administration or the drug regulatory department of the province, autonomous region or municipality directly under the Central Government instructs to stop the production, sales and use of the drug.

Article 20 For any alteration to the approved content of a drug advertisement for false propaganda, the drug regulatory departments shall instruct to stop the publication of the advertisement immediately, revoke the drug advertisement approval number, and shall not accept any application for advertisement of the drug within one year.

Article 21 Where any illegal advertisement in which the scope of indications (functions) of the drug is expanded without authorization, the therapeutic effectiveness is exaggerated extremely, or which seriously cheats or misleads the customers, is found, the drug regulatory department at or above the provincial level shall take mandatory administrative measures to suspend the sales of the drug within their administrative area and order the enterprise that illegally publishes the drug advertisement to issue a correction notice in relevant local media.

After the enterprise that illegally publishes the drug advertisement issues a correction notice as required, the drug regulatory department at or above the provincial level shall make a decision on lifting the

mandatory administrative measures within 15 working days; where it is necessary to test the drug, the drug regulatory departments shall determine whether to lift the mandatory administrative measures within 15 days as from the day when the test report is issued.

Article 22 Where a drug advertisement application providing false materials is found by the drug advertisement examination authority during the examination, no further application of the enterprise in respect of the advertisement of the drug shall be accepted within one year.

Article 23 Where a drug advertisement with an approval number is found by the drug advertisement examination authority to have provided false materials, such drug advertisement approval number shall be revoked and no further application from the enterprise in respect of the advertisement of the drug shall be accepted within three years.

Article 24 Any drug advertisement, of which the approval number is taken back, cancelled or revoked in accordance with Article 18, Article 19, Article 20 and Article 23 of the Provisions, shall be discontinued for publication immediately; non-local drug advertisement examination authorities shall stop filing the record of the advertisement of the enterprise with the drug advertisement approval number.

Where a drug advertisement examination authority takes back, cancels or withdraws a drug advertisement approval number in accordance with Article 18, Article 19, Article 20 and Article 23 of the Provisions, it shall notify the supervision and control authority for advertisements at the same level within five working days from the day when the administrative decision on the matter is made; the supervision and control authority for advertisements shall handle it in accordance with law.

Article 25 Where a non-local drug advertisement is found not put on record in the drug advertisement examination authority of the place where it is published, the authority shall instruct to file its record within a time limit. If the record is not filed within the time limit, the drug advertisement in the above-mentioned place shall be suspended.

Article 26 The drug regulatory department at or above the county level shall monitor and check the publishing of drug advertisement that has been examined and approved. For any illegal drug advertisements, drug regulatory departments at all levels shall fill in the Notice on the Transfer of Illegal Drug Advertisement (Appendix 4) and transfer it to an supervision and control authority for advertisements at the same level together with such materials as samples of illegal drug advertisement; where the content of approved non-local drug advertisement is altered without permission, the drug advertisement examination authority of the place where the advertisement is published shall advise the original drug advertisement examination authority to revoke its approval number in accordance with Article 92 of the Drug Administration Law and Article 20 of the Provisions.

Article 27 Where an illegal drug advertisement is published and the circumstances are serious, the drug regulatory department of province, autonomous region or municipality directly under the Central Government shall announce the matter to the public and timely report it to the State Food and Drug

Administration. The State Food and Drug Administration shall summarize and release the collected information periodically.

Where any false or illegal drug advertisement is published and the circumstances are serious, it shall be announced to the public jointly by the State Administration for Industry and Commerce and the State Food and Drug Administration if necessary.

Article 28 For any drug advertisement published without approval, or the contents published inconsistent with the approved ones, the supervision and control authority for advertisements shall impose a punishment in accordance with Article 43 of the Advertisement Law; where it constitutes false advertisement or misleading propaganda, the supervision and control authorities for advertisements shall impose a punishment in accordance with Article 37 of the Advertisement Law and Article 24 of Anti-Unfair Competitions Law.

In the process of investigation of an illegal drug advertisement, where there is a need to affirm any drug technical information, the supervision and control authority for advertisements shall notify the drug regulatory department at or above the provincial level. The drug regulatory department at or above the provincial level shall give the affirmation result to the supervision and control authorities for advertisements within ten working days after receiving the notification.

Article 29 The staff members that examine and supervise drug advertisements shall be trained in such laws and regulations as the Advertisement Law and the Drug Administration Law. Where the staff members in drug advertisement examination department or in supervision and control authority for drug advertisements neglect their duty, abuse their power, or practice favoritism and commit irregularities, they shall be given an administrative sanction in accordance with law. If a crime is constituted, they shall be investigated for their criminal liabilities in accordance with law.

Article 30 A drug advertisement approval number shall be “X Yao Guang Shen (Shi) No. 0000000000", “X Yao Guang Shen (Sheng) No. 0000000000", “X Yao Guang Shen (Wen) No. 0000000000". “X” is the abbreviation for a province, autonomous region or municipality directly under the Central Government. “0000000000” is a number with ten digits, in which the first six represent year and month of the examination, and the last four represent advertisement approval sequence number. “Shi”, “Sheng” or “Wen” represents certain classification code used in advertising media.

Article 31 These Provisions shall come into force as of May 1, 2007. The Provisions for Drug Advertisement Examination issued by the State Administration for Industry and Commerce and the Ministry of Health (Decree of State Administration for Industry and Commerce No. 25) on March 22, 1995 shall be annulled therefrom.

Appendix 1

Application Form for Drug Advertisement

Drug Name：

Adopted Name in China: _____

(Trade Name) _____

Ad. Classification: Visual☐ Audio☐ Writing☐.

Drug Classification: Prescription☐ Non-prescription☐.

Applicant _____

Agent（Seal） _____

Examination Authority_____

Notes

1. Please fill in and print the electronic examination form. The form with unclear letters or incomplete entry items will not be accepted.

2. The content of the advertisement to be published is made valid only when sealed on perforation by an examination authority in “The content of the advertisement to be published” column of the form.

3. This form is in quintuplicate, including one copy for file and one to the administration for industry and commerce at the same level. After the examination and approval on the advertisement, the number of copies may be increased accordingly upon the approval of examination authority.

Applicant		Legal Representative	
Address			

Postal Code		Telephone	
E - mail		Fax	
Agent		Legal Representative	
Address			
Postal Code		Telephone	
E – mail		Fax	
Operator		Operator's Telephone	
Adopted Name in China			
Trade Name			
Production Approval No.			
Advertisement Classification (Visual/Audio/Writing)		Advertisement Duration (Visual/ Audio)	Seconds
Target Media			

No.		Supporting Documents List (documents attached to this form)
1	.	Applicant's Business License
2	.	Drug Manufacturing Certificate
3	.	Drug Supply Certificate
4	.	Letter of Approval for Drug Registration
5	.	Approved Drug Insert Sheet

6	☐	Drug Insert Sheet used in Practice
7	☐	Drug Label used in Practice
8	☐	Authorization Letter of Drug Manufacturer (if drug distributor as applicant)
9	☐	Import Drug License
10	☐	Pharmaceutical Product License
11	☐	Approval on Trade Name of Drug
12	☐	Registration Certificate of Non-prescription Drug Examination
13	☐	Trade Mark Paper
14	☐	Supporting documents for patent
15	☐	Other supporting documents proving the authenticity of drug advertisement as prescribed by laws and regulations
	(1)	
	(2)	
	(3)	
	(4)	
	(5)	
	(6)	

Notes:

1. Please tick the box before each supporting document submitted;

2. If other relevant supporting documents are provided, please list their names under Item 15; if the space allowed in any subitem is insufficient, please attach sheets as needed.

The content of the advertisement to be published (Please paste a written sample here, and enclose sample film, demo or other media)
Examination Opinions: Seal of Examining Authority Date：

Ad. Approval No.	Yao Guang Shen ( ) No.
Valid Until	year month day

Opinions of Advertisement Examination Authority in Other Places for Record:

Seal of Advertisement Examination Authority in Other Places

Date: Year Month Day

Data of Applicant for Record	Applicant			
	Address (including postal code)			
	Telephone			
	Fax			
	E - mail			
	Operator		Operator's Telephone	

Appendix 2

Letter of Opinion on the Record of Drug Advertisement Examination

（ ）No.

_____Food and Drug Administration：

The content of the advertisement __Yao Guang Shen ( ) No. ____ for record has been found with following problems:

Now forward the case to your administration.

(Affix the seal of the examination authority in the place where the record is kept)

Year Month Day

Notes: This letter has three copies, including one for record, one to the food and drug administration of the place where the advertisement is examined and approved, and one to the State Food and Drug Administration.

Appendix 3

Notice of Drug Advertisement Re-examination

（ ）No.

Ad. Applicant：_____

Ad. Agent：_____

Drug Name：_____

Drug Ad. Approval No：_____

（Reasons for reexamination as below）

(Affix the specific seal for examination authority here)

Year Month Day

Notes: This notice has two copies, one for record, and the other for the applicant or the agent.

Appendix 4

Notice on the Transfer of Illegal Drug Advertisement

（ ）Yao Guang Yi Zi（ ）No.

The Supervision and Control Authority for Advertisements of ____Administration for Industry and Commerce:

Notice is hereby given that the advertisement of (drug name) produced by (drug manufacturer's name), which was published in (the name of the media, time slot, edition) on (Year/Month/Day), is verified to be illegal. Please handle the case according to law.

XXX Food and Drug Administration

（Official Seal）

Year Month Day

Notes: This notice has three copies, one for record, one sent to the administrative department for industry and commerce at the same level, and one copied to the food and drug administration at the upper level.