

Measures for the Examination of Drug Advertisements

Promulgation date: 03-13-2007

Effective date: 05-01-2007

Department: STATE FOOD AND DRUG ADMINISTRATION
STATE ADMINISTRATION FOR INDUSTRY & COMMERCE

Subject: PHARMACEUTICS & HEALTH

Order of the State Food and Drug Administration and the State Administration of Industry and Commerce

(No.27)

The Measures for the Examination of Drug Advertisements, which were deliberated and adopted by the State Food and Drug Administration and the State Administration of Industry and Commerce of the People's Republic of China, are hereby promulgated by the sequence number of the order of the State Food and Drug Administration, and shall come into force as of May 1st, 2007.

People's Republic of China People's Republic of China

State Food and Drug Administration State Administration of Industry and Commerce

Director: Shao Mingli Director: Zhou Bohua

March 13th, 2007

Measures for the Examination of Drug Advertisements

Article 1 For the purpose of strengthening the administration of drug advertisements (hereinafter referred to as drug ads) and guaranteeing the authenticity and legality of drug ads, these measures are formulated in accordance with the Advertising Law of the People's Republic of China (hereinafter referred to as Advertising Law), the Pharmaceutical Administration Law of the People's Republic of China (hereinafter referred to as Pharmaceutical Administration Law), the Rules for the Implementation of the Pharmaceutical Administration Law of the People's Republic of China (hereinafter referred to as Rules for the Implementation of the Pharmaceutical Administration Law) and other relevant state provisions on the supervision and administration of ads and drugs.

Article 2 The term "drug ads" refers to all the ads which are published through various mediums or in various forms and contain drug names, applicable diseases (functions and indications) or other drug-related content. All drug ads shall be examined in accordance with these Measures.

It is not required to examine a nonprescription drug ad which only publicizes the name of the drug (including the general name and commodity name of the drug) or a prescription drug ad which only publicizes the name of the drug (including the general name and commodity name of the drug) on designated professional publications of medicine science and pharmacy.

Article 3 A drug ad for which an application is filed for examination may not pass the examination unless it conforms to the following laws, regulations and relevant provisions:

- (1) Advertising Law;
- (2) Pharmaceutical Administration Law;
- (3) Rules for the Implementation of the Pharmaceutical Administration Law;
- (4) Standards for the Examination and Issuance of Drug Ads;
- (5) Other state provisions on the administration of ads.

Article 4 The drug administrative departments of the provinces, autonomous regions and municipalities directly under the Central Government shall be the examination organs of drug ads, which shall be responsible for examining the drug ads within their respective administrative regions. The administrative departments of industry and commerce at or above the county level shall be the supervisory and administrative organs of drug ads.

Article 5 The State Food and Drug Administration shall guide and supervise the examination work of drug ads conducted by the examination organs of drug ads, and punish the examination organs which have committed any violation of these Measures according to law.

Article 6 An applicant for a drug ad license number shall be a qualified manufacturing or trading enterprise of the drug. Where the applicant is a trading enterprise of the drug, it must obtain the consent of the manufacturing enterprise of the drug.

An applicant may entrust an agent to handle the application issues for a drug ad license number on behalf of it.

Article 7 An application for a drug ad license number shall be sent to the examination organ of drug ads of the place where the manufacturing enterprise of the drug is located.

An application for the ad license number of an import drug shall be sent to the examination organ of drug ads of the place where the agency of the import drug is located.

Article 8 To apply for a drug ad license number, an applicant shall submit a Drug Ad Examination Form (Attached List 1), which shall be attached with the electronic document of the sample manuscript (film or tape) whose content is identical with the content to be published and that of the application form for drug ad, and, at the same time, submit the following authentic, legal and effective documentary evidences:

- (1) Photocopy of the applicant's Business License;
- (2) Photocopy of the applicant's Drug Manufacturing License or Drug Trading License;
- (3) Original documentary evidence on the fact that the manufacturing enterprise of the drug agrees to its status as applicant in case the applicant is a trading enterprise of the drug;
- (4) In case the applicant entrusts an agent to apply for a drug ad license number, the original letter of authorization produced by the applicant and the photocopy of the agent's business license and other documentary evidences on the agent's subject qualification shall be submitted;
- (5) Photocopies of the drug approval certificates (including Import Drug Registration Certificate

and Medical Product Registration Certificate), photocopy of the approved drug instructions and the label and instructions that are actually used;

(6) As for a nonprescription drug ad, a photocopy of the examination and registration certificate of the nonprescription drug and photocopies of the relevant documentary evidences shall be submitted;

(7) To apply for the ad license number of an import drug, the photocopies of the relevant documentary evidences on the qualification of the agency of the import drug shall be submitted;

(8) Where the ad involves such content as the commodity name of the drug, the registered trademark or patent, etc, the photocopies of the relevant valid documentary evidences and other documentary evidences confirming the authenticity of the content of the ad shall be submitted.

The photocopy of any documentary evidence to be submitted as prescribed in this Article shall be affixed with the seal of the entity holding it.

Article 9 In the case of any of the following circumstances, an examination organ of drug ads may not accept an enterprise's application for drug ad:

(1) Any of the circumstances under which the application shall be rejected as prescribed in Article 20, 22 and 23 of these Measures;

(2) The administrative procedure for canceling the drug ad license number is under implementation.

Article 10 An examination organ of drug ads shall, after receiving an application for a drug ad license number, issue a Notice of Drug Ad Acceptance if the application materials are complete and satisfy the statutory requirements, and, if the application materials are not complete or fail to satisfy the statutory requirements, notify the applicant of the content to be corrected once and for all on the spot or within 5 workdays; if it fails to do so within the prescribed time limit, the day when the application materials are received shall be deemed as the day of acceptance.

Article 11 An examination organ of drug ads shall, within 10 workdays since the day of acceptance of an application, examine the authenticity, legality and validity of the documentary evidences submitted by the applicant and examine the content of the ad according to law. If the drug ad passes the examination, it shall issue a drug ad license number; otherwise, it shall make a decision on not issuing a drug ad license number, notify the applicant of the decision in written form and give reasons, and, at the same time, notify the applicant of its right to apply for an administrative review or bring an administrative lawsuit according to law.

As for an approved drug ad, the examination organ of drug ads shall report it to the State Food and Drug Administration for record and send the approved Drug Ad Examination Form to the ad supervisory and administrative organ of the same level for record. Where there is any problem in the drug ad reported to the State Food and Drug Administration for record, the State Food and Drug Administration shall order the examination organ of drug ads to correct.

The drug supervisory and administrative departments shall publicize the approved drug ads to the society in a timely manner.

Article 12 Where a drug ad is to be published in any province, autonomous region, or municipality directly under the Central Government other than the place where the manufacturing enterprise of the drug or the import drug agency is located (hereinafter referred to as publishing drug ad in any other place), the archive-filing formalities shall be handled beforehand at the examination organ of drug ads of the place where the ad is to be published.

Article 13 To publish any drug ad in any other place, the following materials shall be submitted:

- (1) Photocopy of the Drug Ad Examination Form;
- (2) Photocopy of the approved instructions of the drug;
- (3) A tape, CD or any other medium carrier whose content is identical with the content passing the examination as for a TV or radio ad;

The photocopy of any documentary evidence to be submitted as prescribed in this Article shall be affixed with the seal of the entity holding it.

Article 14 As for an application for the archive-filing of a drug ad published in any other place submitted in accordance with the provisions of Article 12 and Article 13 of these Measures, the examination organ of drug ads shall, within 5 workdays since the day when the archive-filing application is accepted, put it on record, endorse the word "Filed" on the Drug Ad Examination Form, affix the special seal for the examination of drug ads and send a copy of the Form to the ad supervisory and administrative organ of the same level for future reference.

In case the examination organ of drug ads of the place where a drug ad is to be put on record believes that the drug ad fails to conform to the relevant provisions, it shall fill in the Opinion on the Archive-filing of Drug Ads (Attached List 2), send the opinion to the original examination organ of drug ads which examines and approves the drug ad for recheck and send a copy to the State Food and Drug Administration.

The original examination organ of drug ads which examines and approves the drug ad shall, within 5 workdays since the day when it receives the Opinion on the Archive-filing of Drug Ads, notify the examination organ of drug ads of the place where the drug ad is to be put on record of its opinion. If the two examination organs of drug ads can't reach a consensus, they may invite the State Food and Drug Administration to make a ruling thereon.

Article 15 The valid period of a drug ad license number shall be one year, and the license number shall become invalid once the period expires.

Article 16 When an approved drug ad is published, no content of the ad may be changed. Where it is necessary to change any content of the drug ad, the drug ad license number shall be reapplied.

Article 17 A drug ad applicant publishing the drug ad by itself shall keep the original Drug Ad Examination Form for two years for future reference.

An ad publisher or operator entrusted by a drug ad applicant to act as an agent or publish the drug ad shall check the original Drug Ad Examination Form, publish the drug ad in accordance with the content examined and approved, and keep the photocopy of the Drug Ad Examination Form for two years for future reference.

Article 18 In case an approved drug ad is under any of the following circumstances, the original examination organ of drug ads which examines and approves the drug ad shall send a Notice on the Reexamination of Drug Ads (Attached List 3) to the applicant of the drug ad and reexamine the drug ad according to law. During the reexamination period, the drug ad may be continually published:

- (1) The State Food and Drug Administration believes that the content of the approved drug ad fails to conform to the relevant provisions;
- (2) An ad supervisory and administrative organ at or above the provincial level suggests reexamining the drug ad;
- (3) Any other circumstances under which the examination organ of drug ads believes it necessary to conduct reexamination.

If, upon reexamination, the examination organ of drug ads believes that the drug ad fails to satisfy the statutory requirements, it shall take back the Drug Ad Examination Form, and the original drug ad license number shall be invalidated.

Article 19 In the case of any of the following circumstances, the examination organ of drug ads shall write-off the drug ad license number:

- (1) The Drug Manufacturing License or Drug Trading License has been revoked;
- (2) The approval certificates on the drug have been cancelled or written-off;
- (3) The production, distribution and use of the drug have been suspended as ordered by the State Food and Drug Administration or the drug supervisory and administrative department of the province, autonomous region, or municipality directly under the Central Government.

Article 20 Where false publicity is conducted by altering the content of an approved drug ad without authorization, the drug supervisory and administrative department shall order to stop publishing the drug ad immediately, cancel the ad license number of such drug and not accept the application for examining and approving any ad on such drug within one year.

Article 21 As for an illegal drug ad which willfully enlarges the scope of applicable diseases (functions and indications) of the drug, exaggerates the curative effects of the drug by using absolute words and seriously befools and misleads the consumers, once it is found, the drug supervisory and administrative department at or above the provincial level shall adopt an administrative coercive measure to suspend the distribution of such drug within its jurisdiction and, at the same time, order the enterprise which illegally publishes the drug ad to publish a notice of correction on the corresponding local medium. After the notice is published, the drug supervisory and administrative department at or above the provincial level shall make a decision on releasing the administrative coercive measure within 15 workdays; where it is necessary to check the drug, the drug supervisory and administrative department shall make a decision on whether to release

the administrative coercive measure or not within 15 days since the day when the written check report is sent.

Article 22 As for an enterprise submitting any false application material for the examination and approval of a drug ad, once it is found out by the examination organ of drug ads in the process of acceptance or examination, the examination organ shall not accept this enterprise's application for the examination and approval of any ad on such drug within one year.

Article 23 Where an enterprise obtains a drug ad license number by providing false application materials for examination and approval, once it is found out, the examination organ of drug ads shall cancel the drug ad license number and may not accept this enterprise's application for the examination and approval of any ad on such drug within three years.

Article 24 The publication of a drug ad the license number of which has been taken back, written-off or cancelled in accordance with Article 18, 19, 20 or 23 of these Measures shall be stopped immediately; the examination organ of drug ads of any other place shall stop accepting such enterprise's application for the archive-filing of such drug ad.

Where an examination organ of drug ads decides to take back, write-off or cancel a drug ad license number in accordance with Article 18, 19, 20 or 23 of these Measures, it shall, within 5 workdays since the day when it makes the administrative handling decision, notify the ad supervisory and administrative organ of the same level, which shall handle it according to law.

Article 25 Where an enterprise publishing a drug ad in any other place fails to send an archive-filing application to the examination organ of drug ads of the place where the drug ad is to be published, once it is found out, the examination organ shall order it to handle the formalities for archive-filing within a prescribed period, if it fails to do so, the examination organ shall suspend the publishing activities of such drug ad in that place.

Article 26 The drug supervisory and administrative departments at or above the county level shall supervise and check the publication of the examined and approved drug ads. As for the illegally published drug ads, the drug supervisory and administrative departments at various levels shall fill in the Notice on the Transfer of Illegal Drug Ads (Attached List 4) and transfer them to the ad supervisory and administrative organs of the corresponding levels together with such materials as the sample pieces of these illegal drug ads; where a drug ad is published in any other place and the approved content is altered without authorization, the examination organ of drug ads of the place where the drug ad is to be published shall propose a suggestion on canceling the license number of the drug ad to the original examination organ of drug ads which examines and approves the drug ad in accordance with Article 92 of the Pharmaceutical Administration Law and Article 20 of these Measures.

Article 27 Where any entity publishes any illegal drug ad and the circumstance is serious, the drug supervisory and administrative department of the province, autonomous region, or municipality directly under the Central Government shall publish an announcement thereon and report it to the

State Food and Drug Administration, which shall publish such reports on a consolidated and regular basis.

Where any entity publishes any false or illegal drug ad and the circumstance is serious, the State Administration of Industry and Commerce and the State Food and Drug Administration shall jointly publish an announcement thereon when necessary.

Article 28 Where a drug ad without being examined and approved is published or the content of a drug ad published is inconsistent with the content examined and approved, the ad supervisory and administrative organ shall impose punishment in accordance with the provision of Article 43 of the Advertising Law; where it constitutes a false ad or makes false and misleading publicity, the ad supervisory and administrative organ shall impose punishment in accordance with the provision of Article 37 of the Advertising Law and the provision of Article 24 of the Anti-Unfair Competition Law.

When investigating and punishing a case of illegal drug ad, where it is necessary to determine certain professional technical content as involved in the case, the ad supervisory and administrative organ shall send a written notice on the content to be determined to the drug supervisory and administrative department at or above the provincial level, which shall feed back the determination result to the ad supervisory and administrative organ within 10 workdays since the day when the notice is received.

Article 29 The working personnel engaging in the examination and supervision of drug ads shall accept the training on the Advertising Law, the Pharmaceutical Administration Law and other relevant laws and regulations. Any working personnel of the examination organs of drug ads and the supervisory and administrative organs of drug ads who neglects his duties, misuses his authority or conducts any self-seeking misconduct shall be imposed upon of administrative punishment. If any crime is constituted, he shall be subject to criminal liabilities according to law.

Article 30 A drug ad license number shall be “No. 0000000000 of X Drug Ad Examination (Video)”, “No. 0000000000 of X Drug Ad Examination (Audio)” or “No. 0000000000 of X Drug Ad Examination (Words)”, of which, “X” refers to the abbreviation of a province, autonomous region, or municipality directly under the Central Government, “0” is composed of 10 digits, the first 6 digits shall be the date when the examination is carried out and the last 4 digits shall be the serial number of the approved ad. “Video”, “Audio” and “Words” refers to the codes of the classified mediums for publishing ads.

Article 31 These Measure shall come into force as of May 1st, 2007. The Measures for the Examination of Drug Ads (No. 25 of the State Administration of Industry and Commerce) promulgated by the State Administration of Industry and Commerce and the Ministry of Health on March 22nd, 1995 shall be abolished simultaneously.