DECISION OF THE GOVERNMENT OF THE RUSSIAN FEDERATION NO. 415 OF JULY 6, 2006 ON THE APPROVAL OF THE REGULATIONS ON LICENSING THE MANUFACTURE OF MEDICAMENTS (with the Amendments and Additions of July 19, 2007)

In accordance with the Federal Law on Licensing Certain Types of Activity, the Government of the Russian Federation resolves the following:

1. To approve the annexed Regulations on Licensing the Manufacture of Medicaments.

2. To invalidate:

Decision of the Government of the Russian Federation No. 500 of July 4, 2002 on the Approval of the Regulations on the Licensing of the Manufacture of Medicaments (Sobraniye Zakonodatelstva Rossiyskoy Federatsii, 2002, No. 27, item 2711);

Item 99 of the Amendments Introduced into the Decisions of the Council of Ministers of the RSFSR, the Government of the RSFSR and the Government of the Russian Federation Concerning the State Registration of Juridical Persons approved by Decision of the Government of the Russian Federation No. 731 of October 3, 2002 (Sobraniye Zakonodatelstva Rossiyskoy Federatsii, 2002, No. 41, item 3983).

Chairman of the Government of the Russian Federation

Mikhail Fradkov

Regulations on Licensing the Manufacture of Medicaments (approved by Decision of the Government of the Russian Federation No. 415 of July 6, 2006) (with the Amendments and Additions of July 19, 2007)

1. These Regulations shall determine the procedure for the licensing of the manufacture of medicaments carried out by juridical persons.

2. The production of medicines shall be licensed by the Federal Service for Supervision in the Area of Public Health and Social Development and by the Federal Service for Veterinary and Phytosanitary Supervision (hereinafter referred to as the licensing body), including by:

- the Federal Service for Supervision in the Area of Public Health and Social Development - as concerns the production of medicines, intended for the medical application;
- the Federal Service for Veterinary and Phytosanitary Supervision - as concerns the production of medicines, intended for animals.

3. A licence for the carrying out of the manufacture of medicaments shall be granted for five years. The validity of a licence may be prolonged in the procedure stipulated for redrawing up a licence.

4. The licensing requirements and conditions for carrying out the manufacture of medicaments shall be:

a) that the licence seeker (licensee) has buildings, premises and equipment belonging to him by the right of ownership or other legal ground that are necessary for the carrying out of the activity being licensed, or the presence of legal grounds for the use of premises and equipment or of only equipment belonging to organisations manufacturing medicaments;

b) the observance by the licensee of the rules for the organisation of the manufacture of and control over the quality of medicaments in medicinal forms permitted for manufacture, said rules being approved in accordance with Article 13 of the Federal Law on Medicaments;

c) that the licence seeker (licensee) has legal grounds for the manufacture of patented and/or original medicaments and their sale in accordance with the patent legislation of the Russian Federation and with the Law of the Russian Federation on Trademarks, Service Marks and Names of the Places of Origin of Goods;

d) the observance by the licensee of the requirements on the prohibition of the sale of medicaments that have become unfit for use, medicaments with an expired period of fitness, falsified medicaments and medicaments that are illegal copies of medicaments registered in the Russian Federation, and also on the destruction of such medicaments in accordance with Article 31 of the Federal Law on Medicaments;

e) the presence on the staff of the licence seeker (licensee) of specialists, responsible for the manufacture, quality and stamping of medicaments, having higher or middle special education (chemical-technological, biotechnological, pharmaceutical or medical - for medicines, intended for the medical application, or the chemical and technological, biotechnological, pharmaceutical, biological, veterinary or medical - for medicines, intended for animals) and a length of work in the profession of not less than three years;

f) professional improvement, at least once every five years, for specialists responsible for the manufacture, quality and stamping of medicaments.

5. The carrying out of the licensed activity in gross violation of the licensing requirements and conditions shall entail the responsibility established by the legislation of the Russian Federation. In this

case, gross violation shall be understood as non-fulfilment by a licensee of the requirements and conditions stipulated by Subitems (a) to (d) of Item 4 of these Regulations.

6. To obtain a licence for the manufacture of medicaments, the licence seeker shall send or submit to the licensing body an application and the documents (copies of the documents) mentioned in Item 1 of Article 9 of the Federal Law on Licensing Certain Types of Activity, as well as the following documents:

a) a list of medicaments that the licence seeker is willing to manufacture;

b) a description of the main technological processes ensuring the quality of the medicaments;

c) the consent of the local self-government bodies to the placement of the manufacture of the medicaments on the relevant territory;

d) copies of the patents of the Russian Federation and/or of the licensing agreements permitting the manufacture and sale of patented and/or original medicaments;

e) copies of documents showing that the licence seeker (licensee) has buildings, premises and equipment, belonging to him by the right of ownership or other legal grounds, necessary for the carrying out of the activity being licensed, or of documents confirming the presence of legal grounds for the use of premises and equipment or of only equipment belonging to organisations manufacturing medicaments;

f) copies of the sanitary-and-epidemiologic opinion, issued in the established procedure, on the conformity of the manufacture of the medicaments to the requirements of the sanitary rules;

g) copies of documents confirming the qualifications, conforming to the licensing requirements and conditions, of specialists responsible for the manufacture, quality and stamping of the medicaments.

7. Unnotarised copies of documents shall be submitted with presentation of the original.

The licensing body shall not have the right to request from a licence seeker the submission of any documents other than those listed in these Regulations.

8. When considering an application for the granting of a licence, the licensing body shall check the fullness and reliability of the information about the licence seeker contained in the application and documents submitted in accordance with Item 6 of these Regulations and shall also check whether the licence seeker can fulfil the licensing requirements and conditions.

The check of the fullness and reliability of such information shall be carried out by comparing the information contained in the documents submitted by the licence seeker with the information contained in the Unified State Register of Juridical Persons, which is furnished to the licensing body by the Federal Tax Service in the procedure established by the Government of the Russian Federation.

The check of whether a licence seeker can fulfil the licensing requirements and conditions shall be carried out by the licensing body in accordance with the requirements established for the organisation of checks by the Federal Law on the Protection of the Rights of Juridical Persons and Individual Businessmen in the Conduct of State Control (Supervision).

9. In the case of the loss of a document confirming the presence of a licence, the licensee shall have the right to obtain a duplicate.

A licensee shall have the right to obtain copies, attested by the licensing body, of a document confirming the presence of a licence.

The duplicate or a copy of the document confirming the presence of a licence shall be granted to the licensee within ten days from the date of the receipt by the licensing body of the relevant written application.

The duplicate of the document confirming the presence of a licence shall be drawn up with a note "duplicate" in two copies, one of which shall be handed over to the licensee and the other shall be kept in the licensing file of the licensing body.

10. Information referring to the carrying out of licensed activity and stipulated by Item 2 of Article 6 and Item 1 of Article 14 of the Federal Law on Licensing Certain Types of Activity shall be placed in the official electronic or print media of the licensing body and also on the information stands in the premises of the licensing body within ten days from the date of:

a) the official publication of the normative legal acts establishing the obligatory requirements for the licensed activity;

b) the adoption by the licensing body of a decision on the granting or redrawing up of a licence, the suspension or renewal of its validity, or on annulling a licence;

c) the receipt from the Federal Tax Service of information about the liquidation of a juridical person or about the termination of its activity as a result of reorganisation.

d) the entry into force of a court decision on annulling a licence.

11. The licensing control over the observance by a licensee of the licensing requirements and conditions shall be exercised in the procedure stipulated by the Federal Law on the Protection of the Rights of Juridical Persons and Individual Businessmen in the Conduct of State Control (Supervision).

12. The adoption by the licensing body of a decision on the granting of a licence (on refusal to grant a licence) or redrawing it; suspension or renewal of its validity, or on annulling a licence, and also the keeping of a register of licences and the furnishing of information contained in the register of licences

shall be carried out in the procedure established by the Federal Law on Licensing Certain Types of Activity.

13. For the consideration by the licensing body of an application for a licence, for its granting or redrawing up, a state duty shall be paid in the amounts and procedure established by the legislation of the Russian Federation on taxes and fees.