

**MINISTRY OF PUBLIC HEALTH AND SOCIAL DEVELOPMENT
OF THE RUSSIAN FEDERATION**

ORDER

October 30, 2006.

N 736

**ON APPROVAL OF ADMINISTRATIVE REGULATIONS
OF FEDERAL SERVICE FOR THE SUPERVISION OF PUBLIC HEALTH
AND SOCIAL DEVELOPMENT ON EXECUTION OF THE STATE DUTY
OF DRUG REGISTRATION**

In accordance with Regulation of Government of the Russian Federation of November 11, 2005 N 679 "On order of development and approval of administrative regulations for rendering of state service" (Code of Laws of the Russian Federation, 2005, N 47, clause 4933) and Statement of Ministry of Public Health and Social Development of the Russian Federation approved by Regulation of Government of the Russian Federation of June 30, 2004 N 321 "On approval of Regulations of Ministry of Public Health and Social Development of the Russian Federation" (Code of Laws of the Russian Federation, 2004, N 28, clause 2898; 2005, it is hereby ordered:

1. To approve the attached Administrative Regulations of Federal Service for the Supervision of Public Health and Social Development on execution of the state duty of drug registration.

2. Federal Service for the Supervision of Public Health and Social Development (R.U.Khabriev) to provide state drug registration in accordance with Administrative regulations approved by the present Order.

3. To accept as expired Order of Ministry of Public Health of the Russian Federation of November 20, 2002, N 352 "On approval of Regulations of compact procedure of drugs registration" (registered by Ministry of Justice of Russia at December 6, 2002, N 4007).

4. To delegate the control over the present Order execution to the Minister of Public Health and Social Development of the Russian Federation V.I. Starodubov.

Minister
M.Ju.ZURABOV

APPROVED BY
Order
of Ministry of Public Health
and Social Development
of the Russian Federation
of October 30, 2006, N 736

**OF ADMINISTRATIVE REGULATIONS
OF FEDERAL SERVICE FOR THE SUPERVISION OF PUBLIC HEALTH
AND SOCIAL DEVELOPMENT ON EXECUTION OF THE STATE DUTY
OF DRUG REGISTRATION**

I. General Provisions

1.1. The Administrative Regulations of Federal Service for the Supervision of Public Health and Social Development on Execution of the State Duty of Drug Registration (hereinafter referred to as Regulations) are worked out on the basis of clause 19 of Federal Law of 22.06.1998 N 86-ФЗ "On drugs" (Code of Laws of the Russian Federation, 1998, N 26, clause 3006), in accordance with Regulation of Government of the Russian Federation of 11.11.2005 N 679 "On order of development and approval of administrative regulations of state service" (Code of Laws of the Russian Federation, 21.11.2005, N 47,

clause 4933) and within the bounds of authority constituted in Statement on Federal Service for the Supervision of Public Health and Social Development approved by Regulation of Government of the Russian Federation of 30.06.2004 N 323 (Code of Laws of the Russian Federation, 2004, N 28, clause 2900).

1.2. State registration of drugs is a state control and supervisory function executed by Federal Service of Oversight in Public Health and Social Development for the purpose of authorization for manufacturing, importation, selling and usage of drugs within the territory of the Russian Federation.

1.3. The following items are subject to state registration:

- 1) new drugs;
- 2) new combinations of drugs registered earlier;
- 3) drug registered earlier but manufactured in other pharmaceutical dosage forms, with new dosage or other additives;
- 4) reproduced drugs.

1.4. State registration of drugs shall be executed in the name of legal entity indicated in the statement of state registration which is filed to Federal Service for the Supervision of Public Health and Social Development by the drug development center of other legal entity on behalf of the drug development center.

1.5. State registration of Russian and foreign drugs is executed in accordance with the same requirements.

1.6. During execution of the state duty of drugs registration the following administrative procedures shall be implemented:

- 1) consideration of documents and making a decision about state registration of drugs. The basis is clause 19 of Federal Law of 22.06.98 N 86-ФЗ "On drugs";
- 2) Alteration of registration documentation of the drugs.
- 3) taking into account the facts and circumstances that threaten life and health of people in case of the drugs application. The basis is clause 41 of Constitution of the Russian Federation;
- 4) maintenance of a state registry of drugs. The basis is clause 19 of Federal Law of 22.06.98 N 86-ФЗ "On drugs"; p. 5.6.1. of "Regulations of Federal Service for the Supervision of Public Health and Social Development" approved by Regulation of Government of the Russian Federation of 30.06.2004 N 323.

II. Execution order requirements to state duty

2.1. Order of informing about state duty of state drugs registration.

2.1.1. A registration certificate is the document certifying the fact of state registration of a drug. The registration certificate is valid provided that all recited information about the drug and about the organization to which name the drugs is registered is unamended. Term of validity of registration certificate is unlimited.

2.1.2. The documents and data for state drugs registration and (or) for alteration of registration documentation for drugs as well as registration certificates issuance shall be sent to the following address:

Federal Service for the Supervision of Public Health and Social Development, Department executing registration of drugs: 109074, house 4, building 1, Slavanskaya Ploshchad, Moscow. House of service: on weekdays from 09:00 a.m. to 06:00 p.m.

The place for documentation reception necessary for state duty execution for state drugs registration shall be equipped with a telephone, a computer with Internet connection and with the present text of the Regulations.

Telephones for information and preregistration: +7(495) 298-5342; +7(495) 298-3534.

E-mail: drugregistration@roszdravnadzor.ru

General inquiry service: +7(495) 298-4628.

The information about the filed applications for state registration, about the course of documents consideration which are given to organizations for state registration of drugs or for alteration of registration documentation as well as about the decisions made in accordance with p. 2.2. of the present Regulations shall be available for the applicants and on the official web-site: www.roszdravnadzor.ru.

Information about the registered drug shall be published by Federal Service for the Supervision of Public Health and Social Development on monthly basis on the official web-site: www.roszdravnadzor.ru.

2.1.3. Lists of documents which shall be filed for the state registration of drugs or for alteration of registration documentation and requirements for such documents are given in the corresponding sections of administrative procedures of the present Regulations.

2.2. Terms and conditions of state duty execution of state medicines registration are indicated in the present Regulations in corresponding sections of administrative procedures.

Consideration of documents and data shall be executed in the order of their arrival for the state registration. The Head of Federal Service for the Supervision of Public Health and Social Development has the right to issue a written direction about other order of the consideration and decision making about state registration for the following groups of drugs:

- 1) drugs meant for treatment of orphan diseases;
- 2) drugs meant for treatment of some epidemically dangerous diseases;
- 3) drugs meant for treatment of diseases with high death or disability rate.

The Head of Federal Service for the Supervision of Public Health and Social Development has the right to issue a written direction about suspension of consideration and decision making process of state registration for the period necessary for the appealed organization to give an answer for the inquiry about additional information in the cases when such information is needed for a better informed decision about authorization of the drug for legal distribution within the territory of the Russian Federation.

2.3. Reasons of refusal to consider the documents or to register drugs are listed in the corresponding sections of administrative procedures of the present Regulations.

2.4. The amount and order of payment for the state drugs registration shall be approved in accordance with p. 2 of clause 6 of Federal Law of 22.06.98 N 86-ФЗ "О лекарственных средствах".

2.5. Action or inaction of Federal Service for the Supervision of Public Health and Social Development connected with state registration of drugs can be appealed against in accordance with established order. Minister of Ministry of Public Health and Social Development of the Russian Federation shall terminate the decisions of Federal Service for the Supervision of Public Health and Social Development that contradict federal laws if any other order of termination is not defined by federal law.

III. Administrative procedures

3.1. The structure and correlation of administrative procedures executed in state registration of drugs are given in the Scheme (Addendum 1).

3.2. Unit managers of Federal Service for the Supervision of Public Health and Social Development being in charge of state registration of drugs in accordance with the present Regulations shall organize documentary registration of each stage of administrative procedure execution indicating the date of its execution and with the responsible person's signature. Information about the course of documents consideration and the data presented by organization for state registration of drug or about alterations of registration documentation shall be available for the applicants.

3.3. Administrative procedure "Documents consideration and making decision about drugs state registration" shall be executed in connection with the set of documents and data for state registration of a drug received from the organization according to the following order (the scheme for administrative procedure execution is given in Addendum 2):

3.3.1. Documents consideration and decision making about state registration of a drug shall be executed within 6 months from the date of receipt of the complete set of documents and data, which is defined in the present Regulations, by Federal Service for the Supervision of Public Health and Social Development.

In case the differences of the drug being registered from the drug that has been registered earlier are only in the additives and manufacturing technology and such differences do not influence the quality, effectiveness and safety of the drug an accelerated prosecution shall be used for documents consideration and decision making about state registration. The accelerated prosecution shall be provided by Federal Service for the Supervision of Public Health and Social Development within 3 months from the date of receipt of the complete set of documents and data, which is defined in the present Regulations, by Federal Service for the Supervision of Public Health and Social Development.

3.3.2. Documents and data received from organization for state registration of a drug shall be registered within 1 working day from the date of their receipt. The set of documents may be mailed as a registered letter (in a small parcel) with a list of contents and a return receipt. Maintaining of records about received documents shall be controlled by head of department of state drug registration.

3.3.3. Organization shall provide Federal Service for the Supervision of Public Health and Social Development with the following documents and data for creation of a registration file for state registration of a drug in accordance with p. 9 of clause 19 of Federal Law of 22.06.98 N 86-ФЗ "On drugs":

- 1) application for state registration of the drug;
- 2) receipt of payment for the state registration of the drug;
- 3) legal address of the drug producer;
- 4) the drug name including international nonproprietary name, scientific name in Latin, the main synonyms;
- 5) original name of the drug if it is registered as a commercial label in accordance with legislation of the Russian Federation on commercial labels, service marks and appellation of origin;
- 6) list of components of the drug, their quantity;
- 7) therapeutic drug management which corresponds requirements of clause 16 of Federal Law of 22.06.98 N 86-ФЗ "On drugs";

- 8) Drug quality certificate;
- 9) information about the drug manufacturing, the initial text of pharmacopeia (a normative document)
- 10) drug quality control methods;
- 11) results of preclinical research of the drug;
- 12) results of pharmacological and toxicological research of the drug;
- 13) results of clinical research of the drug;
- 14) the drug samples for its quality examination;
- 15) suggestions on the drug price;
- 16) documents evidencing of the drug registration if it is registered out of the Russian Federation.

All documents and data for state registration of drug shall be executed in Russian or have a notarized translation into Russian.

Content of the necessary documents and data which provide a possibility of quality, effectiveness and safety examination of the drug is given in Addendum 3.

To undergo an accelerated prosecution for state registration the documents indicated in subsection 11-13 of section 3.3.3. of the present Regulations shall be executed in the form of references to bare sources of literature and in the form of report about research of bioequivalence carried on taking into account requirements of Addendum 1 to such data.

3.3.4. Head of department of state drug registration shall within 4 calendar days from the date of documents and data receipt designate the officers from the department of the executive in charge of the documents and data consideration for state registration of the drug. Full name of the responsible person, his/her place of work and phone number shall be communicated to the organization in accordance with its written or oral request.

Head of Department of Federal Service of State Drug Registration taking into account the present Regulations shall make decision about application or non-application for an accelerated prosecution for documents consideration.

3.3.5. The responsible person shall within 20 calendar days from the date of his/her appointment check the completeness and content of submitted documents and data to define:

- whether the set of documents and data defined in p. 3.3.3. of the present Regulations is complete;
- consistency of information and data in the separate documents of the submitted set;
- reliability of documents and data signed by an authorized person representing the appealed organization on each document;
- correspondence of content, detailing and probative level of the submitted information with sections topics in the documents and data presented for state registration;
- competence of application for state registration taking into account the applicable statutory requirements of Federal Law of 22.06.1998 N 86-ФЗ "On drugs" (Code of Laws of the Russian Federation 1998, N 26, clause 3006) presented to subjects of drugs circulation on the territory of the Russian Federation.

In case of incompleteness, not complete set of documents and data or in case of incompetence of the application for state registration there shall be a refusal prepared to receive and consider the documents and data indicating reasons for the refusal, the refusal shall be signed by the head of Federal Service for the Supervision of Public Health and Social Development and sent to the appealed organization.

3.3.6. The responsible person shall within 10 calendar days from the completion date of check of completeness and content of documents and data submitted for state drug registration define the necessity of additional information and (or) examination of quality, effectiveness and safety of the drug. The necessity of examination of quality and (or) effectiveness and (or) safety of drugs shall be defined on the following basis:

- in the absence of enough expert opinions about the drug manufacturing, methods of the drug quality control, preclinical data, clinical research results;
- in case of deficient foundation and (or) ambiguous character of the drug quality control, preclinical data, clinical research results in the submitted documents and data;
- if the expert opinions contradict each other (in this case it is mandatory to carry out an additional examination).

If there is enough reason the examination shall be carried out in accordance with administrative regulations of Federal Service for the Supervision of Public Health and Social Development "Organization of drugs quality, effectiveness and safety examination (during state registration)" within the period not exceeding 130 calendar days from the date of determination of such examination necessity.

3.3.7. Within 10 calendar days from the date of conclusion of the examination receipt or, if there is no necessity in examination, from the date of completion of completeness and content of submitted for state drug registration documents and data check, the responsible person shall prepare a conclusion about state registration of the drug taking into account the following:

- results of documentary verification of documents and data set submitted for state registration of the drug;

- materials of the carried out examinations of quality, effectiveness and safety of the drug;
- additional information from the appealed organization.

In case of positive conclusion a project of order on state registration and a registration certificate shall be prepared which are to be signed by the head of Federal Service for the Supervision of Public Health and Social Development.

In case of negative conclusion a notice of objection to state registration shall be prepared indicating the reasons for refusal which is to be signed by the head of Federal Service for the Supervision of Public Health and Social Development and sent to the appealed organization.

3.3.8. The reason for objection to state drug registration are the following:

1) incompleteness, not complete set of documents and data submitted by appealed organization or if the application of state drug registration is incompetent and it is hereupon impossible to carry out examination of quality, effectiveness and safety of the drug (for state registration);

2) the fact of contradiction of quality and quantity of the drug samples with the data adduced in the registration file;

3) receipt of expert opinion about unsafeness, inefficacy or about failure to prove safety and effectiveness of the drug, if it is received from at least two experts independent from each other and is indicative of the following:

- risk of the drug usage is higher than expected benefit;
- insufficient evidence of effectiveness;
- contradiction of information stated in registration file with the actual condition.

3.3.9. Within 5 calendar days from the date of order and registration certificate signature the responsible person shall notify the appealed organization of readiness of the registration certificate.

3.3.10. Within 10 working days from the date of order and registration certificate signature the responsible person shall submit information about the state registration for alteration of the state drug register and for archiving.

3.3.11. Federal Service for the Supervision of Public Health and Social Development shall issue duplicates of drug registration certificate upon application of the organization for which it is registered within 1 month from the date of such application receipt.

3.3.12. The documents and data submitted for state drug registration irrespectively of the fact whether the drug has been registered or not are subject to storage in Federal Service for the Supervision of Public Health and Social Development together with corresponding expert opinions, copies of orders on state registration and register certificates observing requirements of information confidentiality within the whole period of the state registration validity and within 5 years after its expiration.

3.4. Administrative procedure "Alteration of drug registration documentation" shall be executed in connection with receipt from the organization named in the registration certificate (or from its legal successor) a set of documents and data for alteration of registration documentation or in connection with revelation by Federal Service for the Supervision of Public Health and Social Development of data concerning quality, effectiveness or safety of the drug in accordance with the following order (the scheme of administrative procedure is given in Addendum 4):

3.4.1. Alteration of drug registration documentation concerning quality or effectiveness of the drug shall be carried out by Federal Service for the Supervision of Public Health and Social Development within the time indicated in p. 3.3.1. of the present Regulations.

In all other cases including the ones connected with inclusion of data about new adverse reaction or restrictions of administration, changes of rights for the drug, trade name, package, alterations of drug registration documentation shall be made within period not exceeding 1 month from the day of corresponding set of documents and data receipt.

3.4.2. Documents and data supporting the alterations of registration documentation received from the organization shall be registered within 1 working day from the date of receipt. The set of documents may be mailed as a registered letter (in a small parcel) with a list of contents and a return receipt. Maintaining of records about received documents shall be controlled by head of department of state drug registration.

All documents for alteration of registration documentation of a drug shall be executed in Russian or have a notarized translation into Russian.

3.4.3. Head of department of state drug registration shall within 4 calendar days from the date of documents and data receipt from appealed organization or in connection with new data about quality, effectiveness and safety of the drug revealed by Federal Service for the Supervision of Public Health and Social Development appoint a responsible person of the department's officials to conduct consideration of the question. Full name of the responsible person, his/her place of work and telephone number shall be communicated to the appealed organization in accordance with its written or oral request.

3.4.4. The responsible person shall within 10 calendar days from the date of his/her appointment check the completeness and content of submitted documents and data to define:

- consistency of information and data in the separate documents of the submitted set;
- reliability of documents and data signed by an authorized person representing the appealed organization;
- correspondence of content, detailing and probative level of the submitted information with sections topics in the documents and data presented for alteration of registration documentation.

3.4.5. The responsible person shall within 5 calendar days from the completion date of check of completeness and content of documents and data submitted define the necessity of additional information and (or) examination of quality, effectiveness and safety of the drug. The necessity of examination of quality and (or) effectiveness and (or) safety of drugs shall be defined on the following basis:

- in the absence of enough expert opinions about the drug manufacturing and (or) methods of the drug quality control and (or) preclinical data and (or) results of pharmacological and toxicological research of the drug and (or) clinical research results (taking into account the reasons of alteration of the registration documentation);
- in case of deficient foundation and (or) ambiguous character of the drug quality, effectiveness and safety control in the submitted documents and data;
- if the expert opinions contradict each other (in this case it is mandatory to carry out an additional examination).

In case the alteration is connected with the name, address or the business form or connected with transfer of rights for the drug under condition of invariance of its manufacturing place or if it is connected with information of new adverse reaction or restrictions of administration, change of trade name or package, the examination of quality, effectiveness and safety of the drug shall not be carried out.

If there is enough reason the examination shall be carried out in accordance with administrative regulations of Federal Service for the Supervision of Public Health and Social Development "Organization of drugs quality, effectiveness and safety examination (during state registration)" within the period not exceeding 130 calendar days from the date of determination of such examination necessity.

3.4.6. Within 5 calendar days from the date of conclusion of the examination receipt or, if there is no necessity in examination, from the date of completion of completeness and content of submitted documents and data check, the responsible person shall prepare a conclusion about alteration of registration documents for the drug taking into account the following:

- results of documentary verification of documents and data set submitted for alteration of drug registration documents;
- materials of the carried out examinations of quality, effectiveness and safety of the drug (if any);
- additional information from the appealed organization.

In case of positive conclusion a project of order on alteration of drug registration documentation and a registration certificate shall be prepared which are to be signed by the head of Federal Service for the Supervision of Public Health and Social Development.

In case of negative conclusion a notice of objection to alteration of drug registration documentation shall be prepared indicating the reasons for refusal which is to be signed by the head of Federal Service for the Supervision of Public Health and Social Development and sent to the appealed organization.

3.4.7. The reasons for objection to alteration of drug registration documentation are the following:

- 1) non-submission or not complete set of documents and data submitted for support of alteration of registration documentation by appealed organization
- 2) the fact of contradiction of quality and quantity of the drug samples with the data adduced in the registration file;
- 3) receipt of expert opinion about possible degradation of quality, effectiveness and safety of the drug in case of alteration of registration documentation;
- 4) there are reasons for objection to alteration of drug name: if the suggested name does not meet the requirements for drug names or is identical or similar to confusion with a name protected by a trade mark of other registered drug.

3.4.8. Alteration of registration documentation can not be objected if:

- 1) the alteration concerns the name, address or business form of the appealed organization;
- 2) the alteration concerns transfer of rights for the drug under condition of invariance of its manufacturing place;
- 3) the alteration concerns the fact of determination of new drug side effects, its interaction with other drugs, new contraindications or additional precautions in handling with the drug;
- 4) the appealed organization determines more strict quality parameters for the drug;
- 5) the alteration concerns the necessity to fulfill the conditions defined by legislation of the Russian Federation.

3.4.9. Within 5 calendar days from the date of order and registration certificate signature the responsible person shall notify the appealed organization of readiness of the registration certificate.

3.4.10. Within 10 calendar days from the date of order and registration certificate signature the responsible person shall submit information about the alterations in the drug registration documentation for alteration of the state drug register and for archiving.

3.4.11. Federal Service for the Supervision of Public Health and Social Development shall issue duplicates of drug registration certificate under application of the organization for which it is registered within 1 month from the date of such application receipt.

3.4.12. The documents and data submitted for alteration of drug registration documentation irrespectively of the fact whether the alteration has had place or not are subject to storage in Federal Service for the Supervision of Public Health and Social Development together with corresponding expert opinions, copies of orders on state registration and register certificates observing requirements of information confidentiality within the whole period of the state registration validity and within 5 years after its expiration.

3.5. 3.4. Administrative procedure "Consideration of facts and circumstances threatening life and health of people on application of drugs" shall be executed in connection with revelation during execution of administrative procedure "Collection and analysis of information about drug side effects" of administrative regulations of Federal Service for the Supervision of Public Health and Social Development on execution of the state duty of quality, effectiveness and safety examination organization of the drugs and circumstances endangering life and health of people on application of drugs as a result of severe and (or) unexpected side effects of their action in accordance with the following order (the scheme of administrative procedure is given in Addendum 5):

3.5.1. In revealing the facts and circumstances threatening life and health of people on application of drugs including any unfavorable clinical presentations which independently of the drug dose lead to death, constitute a menace for life, require hospitalization or its prolongation, lead to persistent or expressed disablement and (or) disability, or bring on abnormal reproductive effects (hereinafter – severe side effects), as well as including such side effects, character or severity of which do not conform with existing information about the drug (hereinafter – unexpected side effects), head of department of state drug registration shall within 5 working days from the date of reveal of such circumstances prepare a corresponding memorandum directed to the head of Federal Service for the Supervision of Public Health and Social Development.

If the reason of such circumstances is in features of mechanism of drug-induced action the present administrative procedure's force shall cover all drugs containing similar components.

3.5.2. Within 5 working days from the date of such memorandum or additional information about revealed facts and circumstances receipt the head of Federal Service for the Supervision of Public Health and Social Development has the right to make the following decisions:

- 1) to order about organization of additional information collection about revealed severe and (or) unexpected side effects of the drug action;
- 2) to order about carrying out of additional examination of the drug quality, effectiveness and safety taking into account the revealed severe and (or) unexpected side effects of its action;
- 3) to consider alteration of the drug registration documentation;
- 4) to keep in abeyance decision of Federal Service for the Supervision of Public Health and Social Development on state registration of a drug;
- 5) to withdraw the drug registration certificate;
- 6) not to take any additional measures in case the revealed severe and (or) unexpected side effects of the drug occur at random.

3.5.3. Collection of additional information about revealed severe and (or) unexpected side effects of the drug-induced action shall be executed in accordance with administrative procedure "Collection and analysis of information about drug side effects" of administrative regulations of Federal Service for the Supervision of Public Health and Social Development "Organization of drugs quality, effectiveness and safety examination" within the terms defined by the head of Federal Service for the Supervision of Public Health and Social Development.

3.5.4. Carrying out of additional examination of quality, effectiveness and safety of a drug subject to revealed severe and (or) unexpected side effects of its action shall be organized in accordance with administrative procedure "Organization of drugs quality, effectiveness and safety examination (during state registration)" of administrative regulations of Federal Service for the Supervision of Public Health and Social Development "Organization of drugs quality, effectiveness and safety examination" within the terms defined by the head of Federal Service for the Supervision of Public Health and Social Development.

3.5.5. Examination of question about alteration of registration documentation in connection with revelation of severe and (or) unexpected side effects of a drug shall be executed in accordance with administrative procedure "Alteration of drug registration documentation" of the present Regulations.

3.5.6. Federal Service for the Supervision of Public Health and Social Development shall keep in abeyance action of decision about drug state registration for the purpose of affording to the organization named in the drug registration certificate an opportunity to carry out additional preclinical and (or) clinical research of the drug in accordance with regulations of laboratorial and clinical practice being in force in the Russian Federation in connection with the revealed severe and (or) unexpected side effects. License

to carry out clinical research of drugs shall be issued by Federal Service for the Supervision of Public Health and Social Development in accordance with the established procedure.

In case the organization named in registration certificate refuses to carry out additional preclinical and (or) clinical research of the drug in accordance with the established procedure as well as in case of confirmation in additional examination of quality, effectiveness and safety of the drug of severe and (or) unexpected side effects of the drug-induced actions Federal Service for the Supervision of Public Health and Social Development shall withdraw the registration certificate. Information about the registration certificate withdrawal shall be entered in the state drug register.

3.6. Administrative procedure "Maintenance of state drug registry" shall be executed in connection with execution of administrative procedures "Рассмотрение документов и принятие решения о государственной регистрации лекарственных средств", "Внесение изменений в регистрационную документацию на лекарственное средство", "Рассмотрение фактов и обстоятельств, создающих угрозу для жизни и здоровья людей при применении зарегистрированных лекарственных средств" of the present Regulations in accordance with the following order (the scheme of administrative procedure is given in Addendum 6):

3.6.1. Within 5 working days from the date of the corresponding decision making the head of department of state drug registration or a person appointed by him (responsible person) shall enter the information in an electronic filing.

3.6.2. Within 1 working day from the date of information entry into the electronic filing the responsible person shall create a note, enters information about the corresponding decision of the head of Federal Service for the Supervision of Public Health and Social Development, enters information about issued registration certificates, special conditions of state registration and archives the electronic filing.

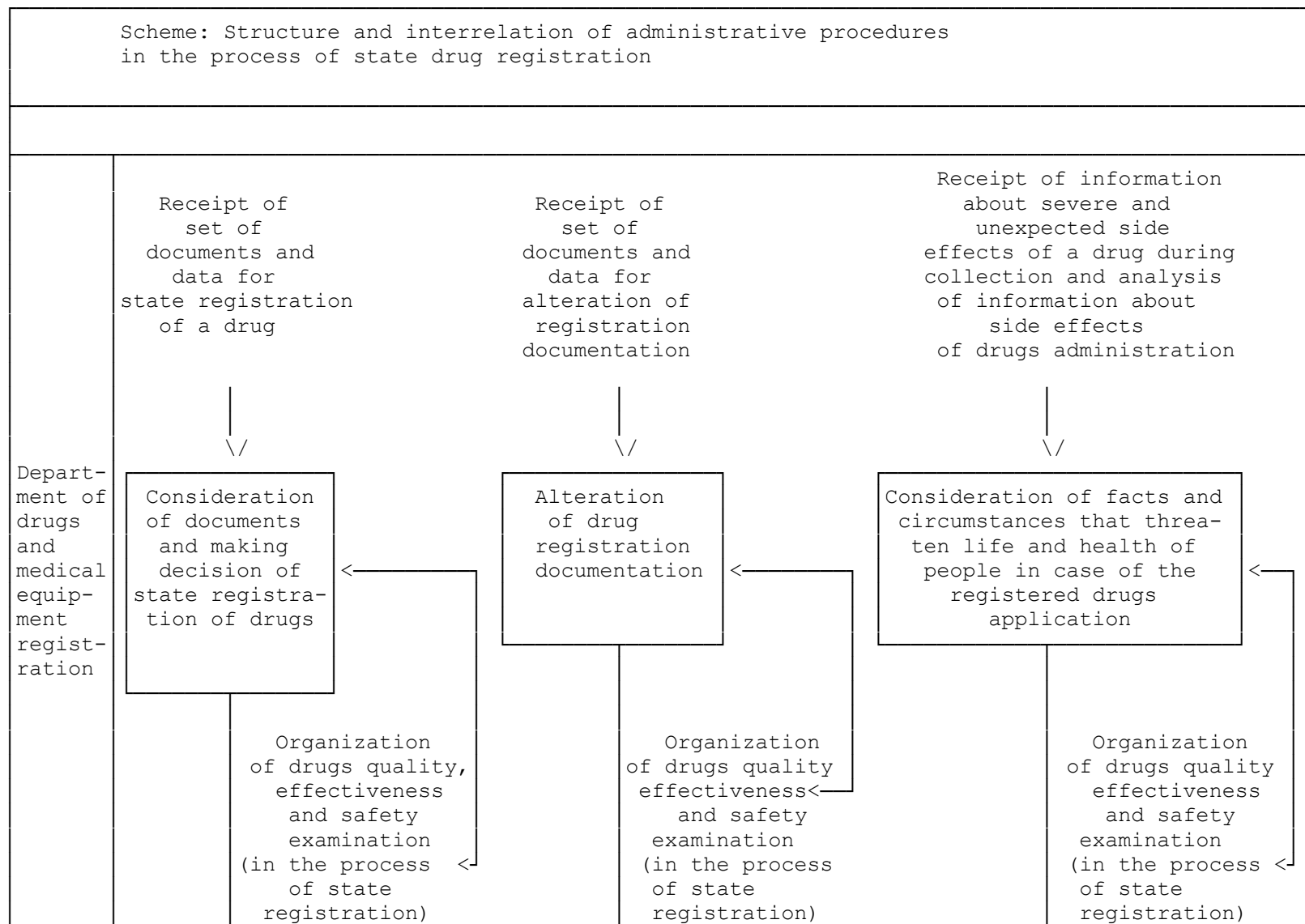
Database of the state drug register consists of electronic archive on hard disks and includes the following information modules, directories and document copies:

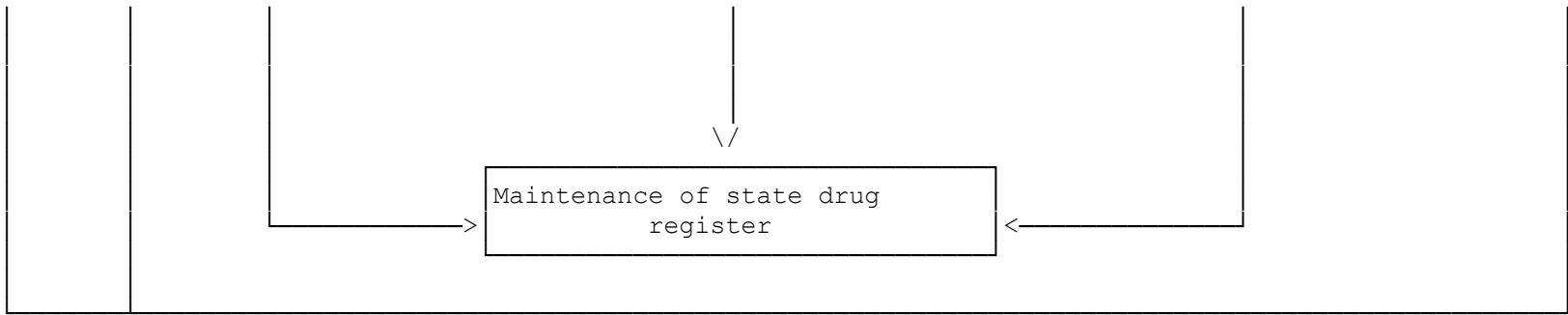
- 1) Documents and data of electronic documentation.
- 2) Decisions of the head of Roszdravnadzor:
 - a) of state registration;
 - б) of alteration of registration certificate;
 - в) of termination or suspension of state registration;
 - г) of special conditions of registration.
- 2) Registration certificates and attachments.
- 3) Documents on drug quality control (normative documentation or text of pharmacopeia).
- 4) Medical application instructions (Instructions).
- 5) List of international nonproprietary names (INN) (of the World Health Organization).
- 6) The Anatomical, Therapeutic, Chemical classification system (codes ATC).

3.6.3. The reports and certificates in accordance with the database of state drug register shall be prepared by the responsible representative within 5 working days from the date of corresponding request receipt.

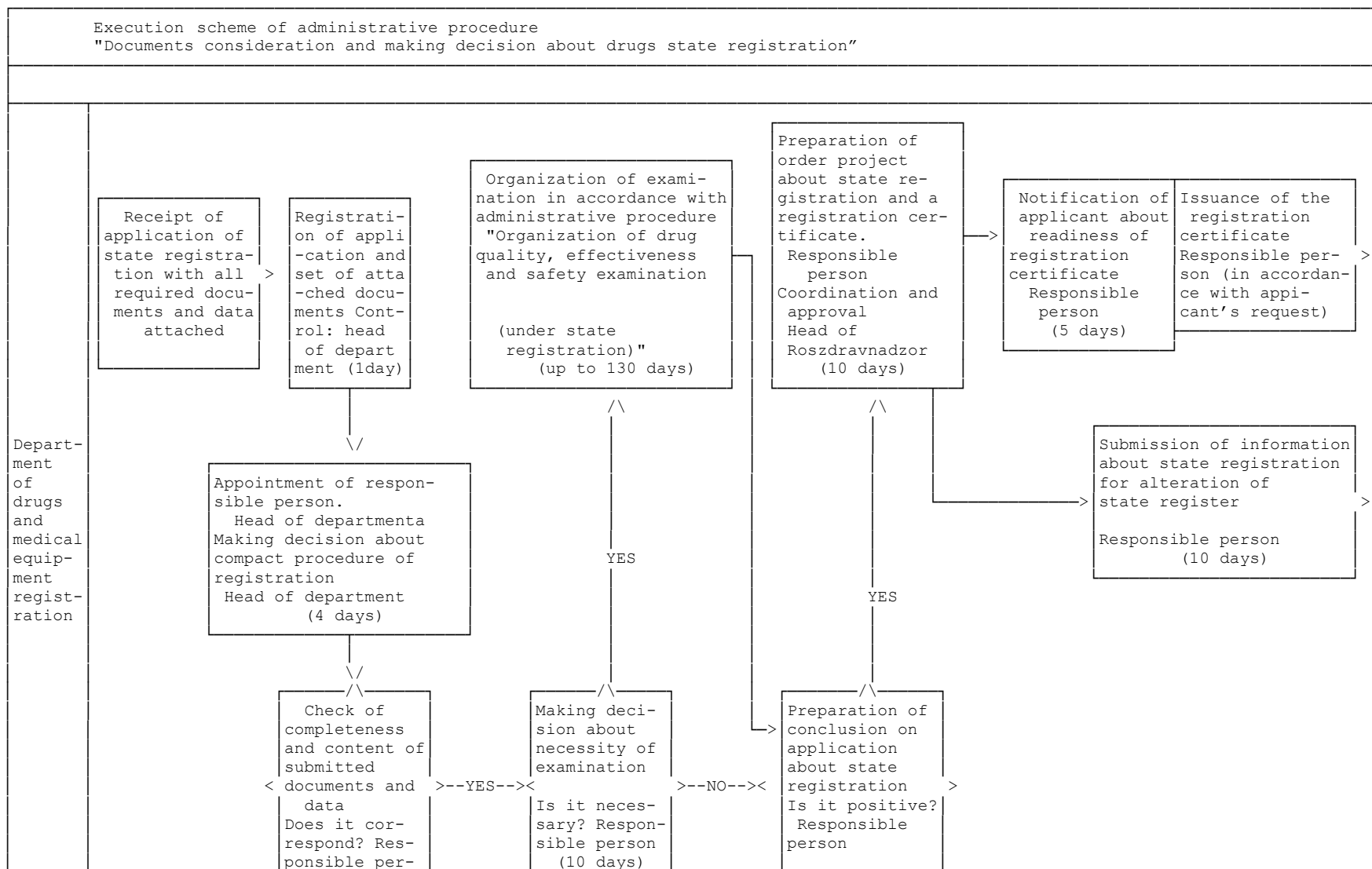
3.6.4. Control over maintenance of the state drug register shall be carried out by the head of department of state drug registration.

To Administrative Regulations of federal service on execution of the state duty of drug registration





to Administrative Regulations of federal service on execution of the state duty of drug registration



[son (20 days)]

[]

[]

NO
V/

(Refusal in)
(state)
(registration)
(The head of)
(Roszdravnadzor)

-----NO-----

CONTENT OF INFORMATION GIVING POSSIBILITY
TO CARRY OUT EXAMINATION OF DRUG QUALITY,
EFFECTIVENESS AND SAFETY

A. Information about the drug components, ways of production and quality control of the drug, quality factors of the drug

Active substance (reactant)

General information

Nomenclatural name (IUPAC); structure; description; general characteristics; admixtures.

Manufacturing

A place (places) of manufacturing; summary of manufacturing process layout and intraproductive control; control of initial substances and materials; intraproductive control of production stages and intermediate products; validation and/or qualification of the process; experimental-industrial justification.

Quality control

Analytical procedures; validation of analytical procedures; analysis by series; basis for specification.

Standards and materials of comparison

Package (initial, secondary)

Stability

Results of stability research in the claimed type of package.

Ready medication

Drug description and content

Description of pharmaceutical characteristics

Drug components; active substance; additives; drug product (content of the main acting substances and additives; permissible limits of deviation; physical-and-chemical and biological characteristics); basis for manufacturing and packaging (initial and secondary); microbiologic characteristics.

Manufacturing

A place (places) of manufacturing; material balance; summary of manufacturing process layout and methods of the process control; control of manufacturing stages and intermediate products; validation and/or qualification of the process.

Control of specialties

Specifications; analytical procedures; validation of analytical procedures; analysis by series; admixtures characteristics; basis for specifications; project of the text of pharmacopeia (normative document)

Standards or materials of comparison

Package (initial, secondary)

Stability

Results of stability research in the claimed types of initial package.

B. Information about results of preclinical pharmacological and toxicological drug research

Introductory abstract of carried out preclinical research

Reports of carried out research:

Pharmacology

Results of research confirming the drug pharmacological activity.

Pharmacokinetics

Absorption; distribution; metabolism; excretion; drug interaction.

Toxicology

General toxicity, specific toxicity.

Bibliography cited.

C. Information about results of clinical drug research

Overview of earlier clinical researches

Reports about carried out researches:

Generalized analysis of results research of drug effectiveness and safety

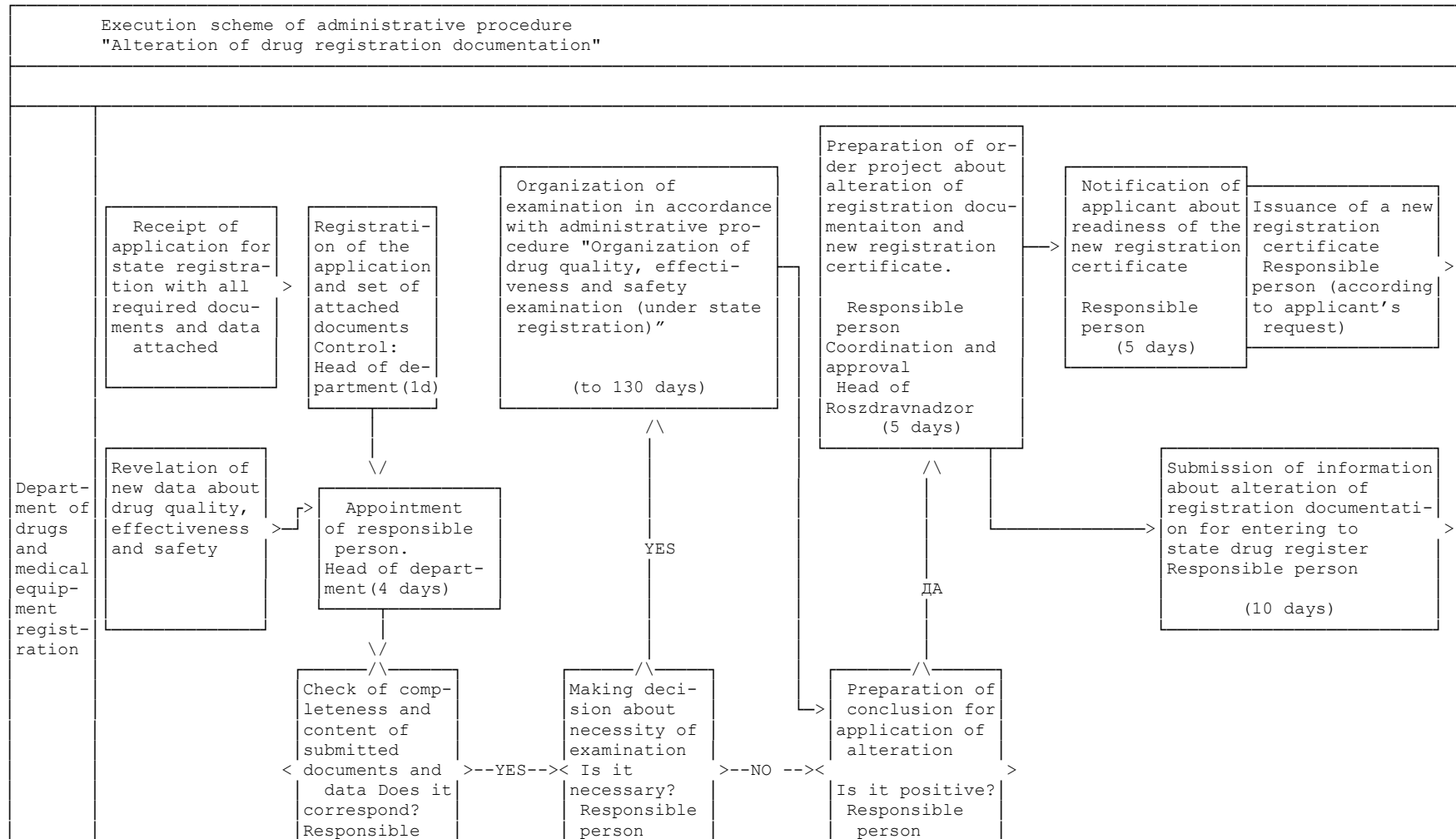
Generalized results of separate researches; comparative analysis of results of separate researches; studies populations; comparison of effectiveness results received in different researches; comparison of results of different groups of patients; analysis of results of recommended dosage regimen research.

Generalized analysis of safety results

Methods of safety assessment; character and frequency of unwanted effects; clinically significant changes of laboratorial values; drug interaction; "withdrawal syndrome"

Bibliography cited.

Addendum N 4
to Administrative Regulations
of federal service on execution
of the state duty
of drug registration



person
(10 days)

(5 days)

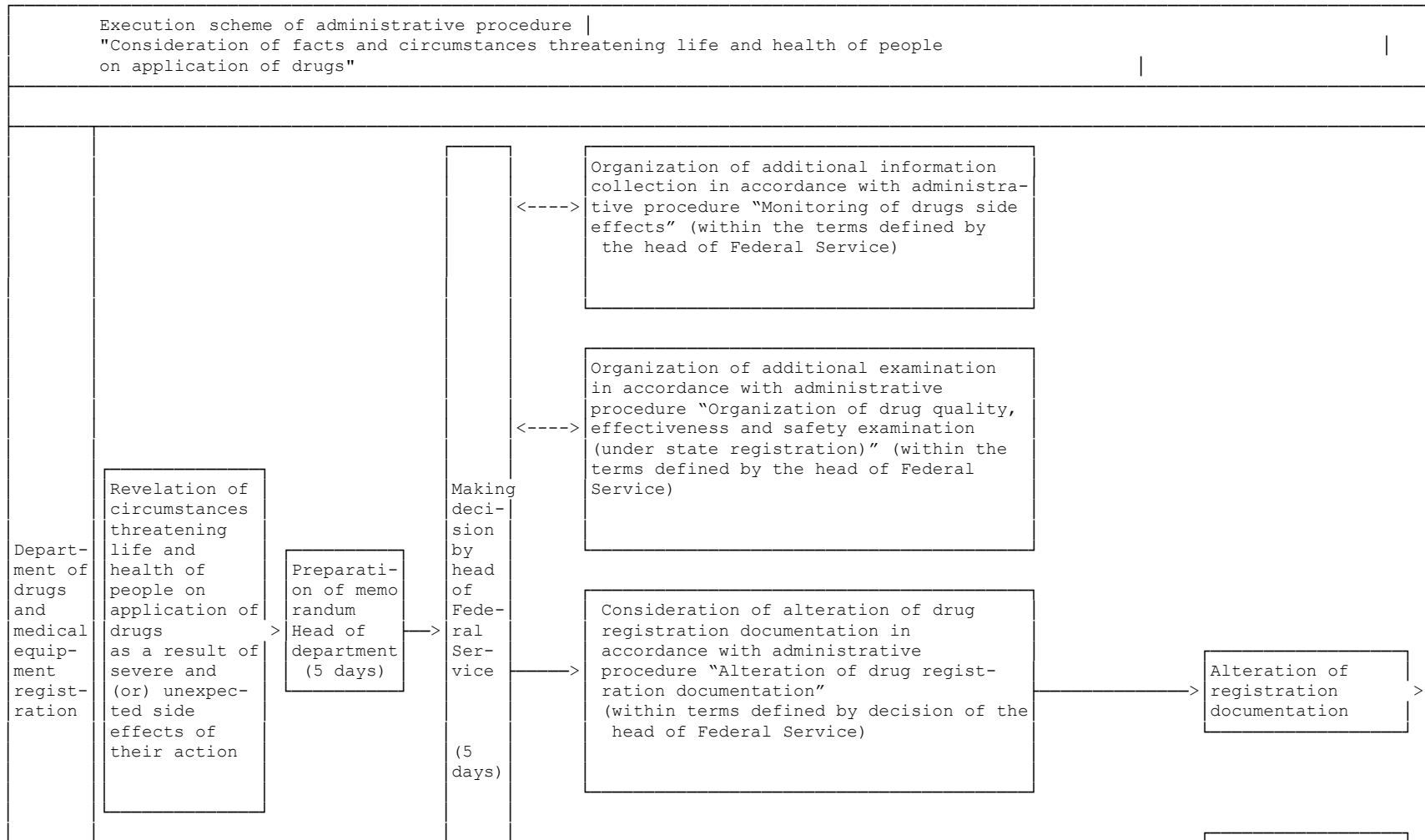
NO
↓

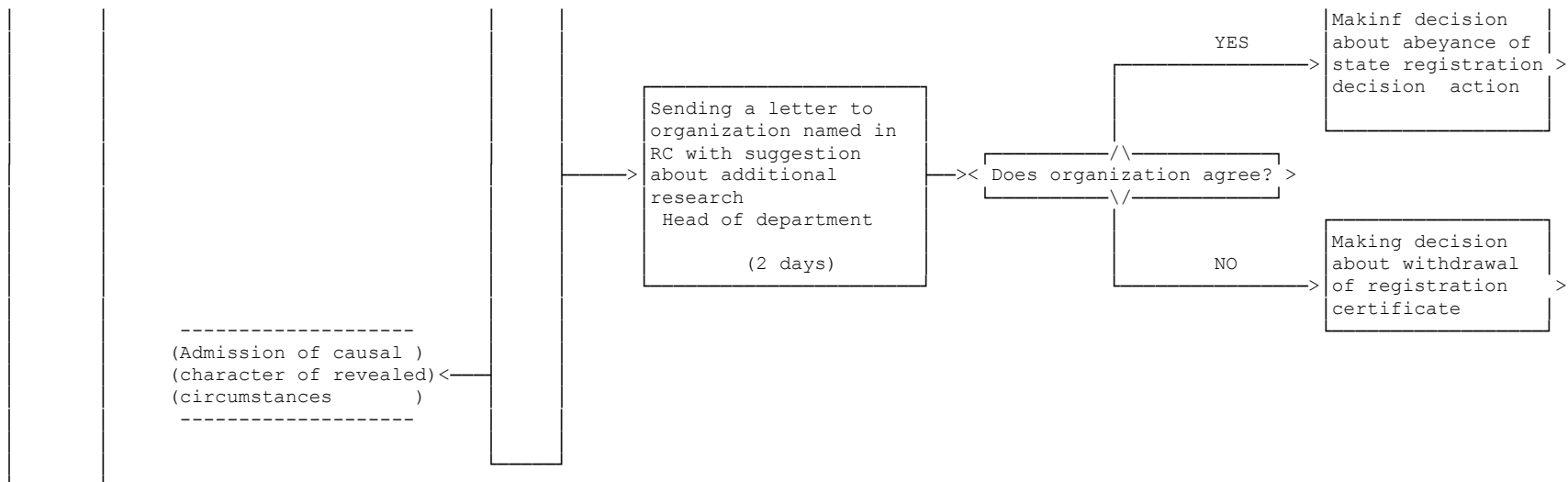
(Refusal to)
(make alteration)
(to state)
(registration)
(documentation)
(Head of)
(Roszdravnadzor)

-----NO-----

↓

Addendum N 5
to Administrative Regulations
of federal service on execution
of the state duty
of drug registration





Addendum N 6
to Administrative Regulations
of federal service on execution
of the state duty
of drug registration

