SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and memoranda of cooperation between FDA and others shall be published in the Federal Register, the agency is publishing notice of this memorandum of cooperation.

Dated: December 11, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination

Memorandum of Cooperation Between the Food and Drug Administration (FDA) Department of Health and Human Services of the United States of America and Servicio Nacional de Pesca (SERNAP) the Economy, Development and Reconstruction Ministry of Chile Concerning an Exchange of Information and Technical Cooperation With Regard to Food Control Practices to Protect Public Health and to Facilitate Trade in Fish and Fishery Products

In keeping with a mutual desire of the Governments of the United States and Chile to facilitate the trade of safe and wholesome fish and fishery products, and

Desiring to strengthen the bonds of cooperation between the two governments, and

Recognizing that both countries wish to ensure the public health and the wholesomeness of foodstuffs consumed by their citizens, and

Noting that increasing global trade of foodstuffs and the related global trade agreements provide an incentive for countries to harmonize food safety control measures and sanitary practices to facilitate trade without compromising food safety, sanitation and wholesomeness, and

Recognizing that the existing Memorandum of Understanding between the United States and Chile regarding the safety and wholesomeness of shellfish remains in place, and that shellfish are separate and apart form the fish and fishery products considered in this Memorandum of Cooperation,

FDA of the Department of Health and Human Services of the United States and SERNAP, of the Economy, Development and Reconstruction Ministry of Chile, have reached the following general understanding to guide their cooperation:

I. Objectives

The objectives of this Memorandum of Cooperation are to:

A. Exchange information about food laws, regulations, standards, food inspection and the enforcement practices that comprise the fish and fishery products control procedures and practices of each country.

B. Determine whether there exist appropriate food safety laws, regulations, guidelines, and an inspection infra-structure for exported fish and fishery products that will, at a minimum, provide assurances that these products meet the same level of protection as for the domestic fishery products of the trading partner, or meet other stipulated standards. Particular areas of interest include: Laboratories and analytical methodologies and standards, use of Hazard Analysis Critical Control Point (HACCP) controls, extent and provisions for HACCP training, permitted food and color additives, permitted drugs and allowable drug residues in aquacultured fishery products.

C. Determine whether each country is prepared to adhere to the principle of ''transparency'' (the continuing open exchange of regulatory and compliance information or changes therein) as described in the World Trade Organization agreement on Sanitary and Phytosanitary Measures.

D. Provide confidence in the ability of government agencies or government sanctioned agencies to effectively oversee the compliance of the fish and fishery products industry with acceptable sanitary and food safety practices, and thereby provide a foundation for future agreements on measures to facilitate the unencumbered trade of these products between the United States and Chile.

E. Discuss the development of a framework for the resolution of issues of mutual concern related to differences in regulations or practices that may have an effect on the level of protection afforded consumers with regard to the safety, sanitary processing methods, identification of species, and the wholesomeness of exported fish and fishery products.

II. Implementation

Both sides will seek to:

A. Establish a procedure for the exchange of information and documents as permitted by law, as may be deemed necessary by either participant, that establish, support, or explain fish and fishery products safety, sanitation, and enforcement procedures used by either country, and the level of public health protection afforded by them. All information and documents exchanged under this Memorandum may not be further disclosed by the receiving participant without the written consent of the other participant.

B. Discuss, explain, and promote an understanding of how these legal and regulatory provisions work in practice, identify the government departments or authorities that are responsible for ensuring their effectiveness (identification of the competent authorities), and explain their operations, with particular regard for their role in the import and export of fishery products and the oversight of HACCP control measures.

C. Facilitate visits by representatives of the competent authorities of each country, at their own expense, to an agreed-upon number of facilities in the other country that process fish and fishery products for export, to evaluate inspection methods and other regulatory practices in these facilities.

D. Establish procedures to discuss emerging issues and promote cooperation in carrying out these objectives. The discussions should alternate between countries and be held on mutually agreeable dates and at mutually agreeable places. The host country should designate a Chairperson for the discussions who should develop an agenda and circulate appropriate information and materials to participants prior to the talks. Agenda topics and briefing papers should be identified as items for active discussion or information requests. In addition, the Chairperson will obtain agreement on the minutes of the talks.

III. Records

A. The working language and the draft minutes of discussions will be in Spanish and English. The Chairperson should obtain interpreters for the talks, as may be necessary.

B. Each participant to this Memorandum should name a contact person to implement the decisions reached during the discussions.

Cooperation under this Memorandum will begin on the last date of signature of the participants. After five years the participants plan to evaluate the Memorandum and may mutually consent in writing to additional five year periods. It may be amended by mutual written consent of both participants and may be terminated by either participant upon thirty days written notice to the other participant.

For the Servicio Nacional de Pesca of the Economy, Development and Reconstruction Ministry of Chile:
By: Juan Rusque Alcaino
Title: Director Nacional de Pesca
Date: May 13, 1996
Place: Washington, DC

For the Food and Drug Administration, Department of Health and Human Services of the United States of America:
By: William B. Schultz
Title: Deputy Commissioner for Policy
Date: May 13, 1996
Place: Washington, DC

[FR Doc. 96–32187 Filed 12–18–96; 8:45 am]

BILLING CODE 4160–01–F

Memorandum of Understanding Revised Annex Between the Food and Drug Administration and the Russian Federation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a Revised Annex to a Memorandum of Understanding Between the FDA and the Russian Federation. The purpose of the Revised Annex is to reaffirm their cooperation under the principles of cooperation established in the MOU initially

effective February 15, 1994, and to clarify and expand the procedures for registration under this MOU. The purpose of the initial MOU is to exchange information on drugs and biological products and to facilitate the development of the Russian health care sector by establishing in Russia a streamlined registration procedure for U.S. drugs and biological products.

DATES: The agreement became effective January 30, 1996.

FOR FURTHER INFORMATION CONTACT: Philip M. Budashewitz, Office of Health Affairs (HFY–50), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which state that all written agreements and memoranda of understanding between FDA and others shall be published in the Federal Register, the agency is publishing notice of this memorandum of understanding.

Dated: December 11, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

Statement on the Revised Annex to the Memorandum of Understanding Between the Food and Drug Administration Department of Health and Human Services and the Ministry of Health and Medical Industry of the Russian Federation and the State Committee for Sanitary and Epidemiological Surveillance of the Russian Federation Concerning Cooperation and Information Exchange on Drugs and Biological Products Facilitating Importation

In order to reaffirm their cooperation under the principles of cooperation established in the Memorandum of Understanding (MOU) between the parties initially effective on February 15, 1994, and to clarify and expand the procedures for registration under this MOU, the following revisions are agreed to and become effective upon signature by representatives of the parties.

The following revised Annex I is incorporated into the Memorandum of Understanding and replaces the original Annex I. This revised Annex I is the authoritative description of the procedures and requirements for the registration in the Russian Federation of products and substances manufactured in the United States under the jurisdiction of the U.S. Food and Drug Administration.

The additional Annex II constitutes guidelines from the Pharmacopeial Committee of the Ministry of Health and Medical Industries relating the types of information expected to be submitted by firms in the Methods of Analysis and Specifications section of the Application described in Addendum 2 of Annex I.

These Annexes will be made available to firms covered by this Memorandum for their guidance from the Ministry of Health and Medical Industries of the Russian Federation, the U.S. Food and Drug Administration, and the U.S. and Foreign Commercial Service, Moscow.

Points of Contact for Annexes I and II

In order to facilitate the registration of pharmaceuticals and substances, the following additional contacts under the Memorandum of Understanding are adopted and appended to those specified in the original documents effective in February, 1994.

For the Food and Drug Administration

Director
Division of Drug Labeling and Nonprescription Drug Compliance
Center for Drug Evaluation and Research (HFD–310)
(Currently Bradford W. Williams)
Food and Drug Administration
7520 Standish Place
Rockville, MD 20855
U.S.A.
Telephone: 301–594–0063
Fax: 301–594–0165

For the Ministry of Health and Medical Industry

Chief of Inspection
State Control Inspection of Pharmaceuticals and Medical Technology
(Currently Ramil U. Khabriev)
Ministry of Health and Medical Industry of the Russian Federation
Rakhmanovsky per. 3
101431 Moscow
Russian Federation
Telephone: 7095–927–2875
Fax: 7095–925–0128

Done at Washington, D.C. on the 30th of January, 1996

For the Department of Health and Human Services of the United States of America:

Donna E. Shalala

For the Food and Drug Administration of the United States of America:

Mary Pendergast

For the Ministry of Health and Medical Industry of the Russian Federation:

Alexander Tsaregorodtsev

For the State Committee for Sanitary and Epidemiological Surveillance of the Russian Federation:

Gennady Onischenko

Revised Annex I

Instructions and Requirements for Registration in the Russian Federation of Pharmaceuticals and Substances Produced in the United States under the Jurisdiction of the U.S. Food and Drug Administration

The following instructions establish the system and organization for registration in the Russian Federation of pharmaceuticals and substances (active substances) produced in the United States of America under the jurisdiction of the U.S. Food and Drug Administration (hereinafter referred to as the ''FDA'') in accordance with the Memorandum of Understanding between the parties.

Registration

These instructions are mandatory for manufacturers and/or their authorized representatives seeking registration or re-registration of pharmaceuticals and substances produced in the U.S. under the jurisdiction of the FDA.

All pharmaceuticals and substances registered in the Russian Federation must be registered in the name of their manufacturer and/or in the name of their authorized representative. In addition, the pharmaceutical or substance must be registered and listed with the FDA by the manufacturer.

The registration will be conducted in accordance with the form specified in addenda 1 and 2.

1. General Regulations

According to the existing laws of the Russian Federation, all pharmaceuticals (substances) may only be purchased for medical purposes after they have been registered in accordance with the established system of the Ministry of Health and Medical Industries of the Russian Federation.

2. Procedure for the Evaluation of Applications for Registration of Pharmaceuticals and Substances Produced in the U.S. under the Jurisdiction of the U.S. Food and Drug Administration.

2.1 A manufacturer (applicant), hereinafter referred to as ''Company'', that wishes to register a pharmaceutical (substance) in the Russian Federation must submit one (1) copy of a package in English and three (3) copies of the same package in the Russian language consisting of the following: a letter of intent (see Addendum 1), an application (see Addendum 2), and the appropriate documentation (specified in Addendum 1) for the pharmaceutical (or substance) to the Chief of Inspection, State Control Inspection of Medicaments and Medical Technology, hereinafter referred to as ''Inspection on State Control.''

2.2 Inspection on State Control will then forward the documents to:

- the Bureau of Registration of Pharmaceuticals, Medical Technology, and Medical Substances, hereinafter referred to as ''Bureau of Registration'' one copy of the complete application in Russian and the English copy (file);
- the State Pharmacological Committee, hereinafter referred to as ''Pharmacological Committee'': one complete copy of the application in Russian and one sample of the pharmaceutical;
- the State Pharmacopeial Committee, hereinafter referred to as the ''Pharmacopeial Committee'': one complete copy of the application in Russian and one sample of the pharmaceutical.

2.3 The Pharmacological Committee will make a preliminary evaluation of the application and will meet within thirty (30) days of its receipt of the documents.

2.4 The Pharmacological Committee or its Presidium will meet on the application

and the minutes of the meeting of the Pharmacological Committee or its Presidium will be signed by the Chairman of the Committee and the Academic Secretary; the decision will be confirmed by the Head of the Inspection on State Control. Copies of the minutes will be signed by the Chairman of the Pharmacological Committee or the Academic Secretary and forwarded to the Inspection on State Control, the Company and the Pharmacopoeial Committee within five (5) days of the confirmation of the minutes. The Pharmacological Committee and the Inspection for State Control will complete the step described in 2.3 and 2.4 within thirty five (35) days from the submission of the application to the Inspection on State Control by the Company.

2.5 The Pharmacopoeial Committee will complete its evaluation of the application for the pharmaceutical (or substance) within thirty (30) days of its receipt of the documents.

2.6 Recommendations for registration will be made by the Presidium of the Pharmacopoeial Committee and a Declaration of the decision will be issued.

2.7 This Declaration will be signed by the Chairman of the Pharmacopoeial Committee and the Academic Secretary; the decision will be confirmed by the Head of the Inspection on State Control within five (5) days after the meeting of the Pharmacopoeial Committee. The Pharmacopoeial Committee and the Inspection for State Control will complete the step described in 2.6 and 2.7 within thirty five (35) days from the submission of the application to the Inspection on State Control by the Company.

2.8 The Inspection on State Control cannot guarantee timeless in regard to the evaluation of documents, if the documents are not complete or in accordance with the appropriate list.

2.9 The Inspection on State Control has the right to suspend consideration of the application for registration of the pharmaceutical (substance) if the Company does not answer questions of the Pharmacological Committee or the Pharmacopeial Committee due to an incomplete application within ninety (90) days. In this case, the documentation provided by the Company and any registration fee(s) will not be returned to the Company. The Company will be notified of this suspension in writing within ten (10) days of the decision.

2.10 All decision to be made by the Pharmacological Committee, Pharmacopeia Committee, and the Inspection on State Control will be in accordance with the terms of the Memorandum of Understanding between the parties.

3. Procedure for the Registration of Pharmaceuticals and Substances produced in the United States under the Jurisdiction of the U.S. Food and Drug Administration.

3.1 The Bureau of Registration will, on the basis of the authorization of the Inspection on State Control, within five (5) days, issue an official Certificate of Registration (see Addendum 7) for manufacturers or Certificate of Registration and forward it to the Head of the Inspection on State Control for signature.

3.2 The Bureau of Registration will send the issued Certificate of Registration to the Company and simultaneously will send copies to the Inspection on State Control, the Pharmacological Committee, and the Pharmacopeial Committee. The Bureau of Registration will send the Certificate of Registration to the Company within ninety (90) days of the submission of the application to the Inspection on State Control by the Company.

3.3 The Certificate of Registration is valid for five (5) years with the option for re-registration (as provided in section 5 below) when the term has expired.

3.4 The Pharmacopoeial Committee shall distribute the normative documents to the State Scientific Research Institute within ten (10) days after registration and to all other organizations who implement quality control of medical preparations and substances within sixty (60) days after registration.

4. The System of Changing and Supplementing the Application

4.1 In order to change or supplement an application, the Company must send a supplemental application (see Addenda 7 and 9) describing the change being made and confirming the necessity to change or supplement the documentation. These supplemental applications should be provided as follows: three (3) copies in Russian and one (1) copy in English.

4.2 The Inspection on State Control will then forward the documents to:

- the Bureau of Registration - one (1) Russian language Copy and one (1) English language copy
- the Pharmacological Committee - one (1) Russian language copy
- the Pharmacopoeial Committee - one (1) Russian language copy

4.3 The Pharmacological and Pharmacopoeial Committees will within sixty (60) days, according to the established system of the meetings of their Presidiums, decide on the expediency of the changes and supplements and will in turn inform the Inspection on State Control of their decisions any changes or supplements which have been approved by the FDA will be accepted according to the terms of the MOU.

4.4 The Inspection on State Control will inform the Company and the Bureau of Registration of the accepted decision in writing with in ninety (90) day of the submission of the application of the application to the Inspection on State Control by the Company.

5. The System of Re-Registering Pharmaceuticals (Substances).

5.1 The re-registration of pharmaceuticals (substances) is undertaken when the validity of the registration has expired after five (5) years. For re-registration of the pharmaceutical, the Company should submit a written letter of intent (see Addendum 1) and documentation in accordance with Addendum 8 or 9.

5.2 Re-registration is undertaken according to sections 4.2, 4.3 and 4.4 of the present instructions.

5.3 A document confirming the re-registration (Addendum 11) is sent to the Company within ninety (90) days of the submission of the re-registration application to the Inspection on State Control by the Company.

Revised Annex I

Addendum I

Letter of Intent/Application for Pharmaceutical (Substances) under the Jurisdiction of the FDA

Chief of Inspection,
State Control Inspection of Pharmaceuticals and Medical Technology
Ministry of Health and Medical Industry of the Russian Federation
3, Rakhmanovsky per.
Moscow, 101431, Russian Federation

With the present letter, the company _____ informs of its intent to register/re-register in the Russian Federation a pharmaceutical (or substance), produced by the company _____. The given pharmaceutical (or substance) is _____ (include form). The above pharmaceutical (or substance) is produced in the United States of America and is subject to the jurisdiction of the U.S. Food and Drug Administration, is freely marketed in the United States, and is manufactured in accordance with all U.S. Current Good Manufacturing Practice regulations. All information provided in this application is truthful, accurate and complete to the best of our knowledge.

This letter contains the following attachments:

1.1 The Application (Addendum 2) for the registration/re-registration of the pharmaceutical (or substance)-three (3) copies in Russian and one (1) copy in English;

1.2 One copy in English of the letter of approval from the Food and Drug Administration and a Russian translation (3 copies); *OR*

For products subject to an FDA Over-the-Counter (OTC) monograph, one (1) copy in English and three (3) copies of a Russian translation of the relevant sections of the Final Monograph or Tentative Final Monograph with a Certification by the firm (in Russian) that the product conforms in all respects to the Final Monograph or Tentative Final Monograph.

1.3 For each type of pharmaceutical, additional information as provided in the Addenda specified:
- For drug products subject to a U.S. New Drug Application approved by FDA: Addendum 3.
- For Prescription Generic Drug Products approved by the FDA: Addendum 4
- For Substances: Addendum 5
- To supplement to report changes: Addendum 7
- To re-register when no changes have occurred: Addendum 8
- To re-register when changes have occurred: Addendum 9

1.4 Samples of the pharmaceutical in the proposed packaging form: five (5) samples for pharmaceuticals, two (2) for substances.

Signature
Corporate Seal

(This letter should accompany each pharmaceutical or substance with the signature of the authorized official of the Company).

Revised Annex I

Addendum 2

Application

Application for the Registration of Pharmaceutical Products and Substances under the Jurisdiction of the FDA

1. Manufacturing Company and address of the manufacturing facility
2. Holder of the patent(s), if any exist, Expiration Date of the patent(s)
3. Name of the pharmaceutical preparation
4. International non-proprietary name (INN)
5. Main synonyms of the preparation
6. Composition of the preparation
7. Therapeutic class
8. Medical form
9. Dosage of the preparation (quantitative)
10. Route of administration (oral, injectable, etc.)
11. Authorized indications and instructions for use
12. Shelf life (expiration dating) and storage requirements
13. Description of standard package form, including copies of all labels and labeling
14. For a substance, the product(s) in which it is to be used
15. Methods of analysis and release specifications: Guidelines on documentation are contained in Annex II.
16. Most recent FDA–483 Notice of Investigational Observations.
17. The name, address, telephone number, facsimile number, and the internet e-mail address (if any) of firm's authorized representative(s) AND IN THE CASE OF A DISTRIBUTOR REPRESENTING A MANUFACTURER:
18. Notarized Letter from Manufacturing Company under corporate seal authorizing distribution company to distribute and register products (substances) in the Russian Federation.
19. Complete labels and labeling for distributor shall be submitted if different than that of the manufacturer. In all cases, Distributor's labels and labeling must bear names and addresses of both manufacturing and distributing firms in the form ''Distributed by _____'', ''Manufactured by _____''

Signature
Corporate Seal
NOTE: For substances, items 8, 9, 10 and 12 do not apply.

Revised Annex I

Addendum 3

Documents Necessary for the Registration of New Pharmaceuticals under the Jurisdiction of the U.S. Food and Drug Administration

1. A Summary (expert report) of results of pre-clinical and clinical studies of the pharmaceutical. This report must include a collection of general information concerning the pharmaceutical made up of short summaries of each of the following points:
   A. Pharmacological report (specifications) supporting all indications for usage as stated in the instructions, including summary of the pivotal clinical trial(s)
   B. Toxicology report (acute, subacute, subchronic, and chronic toxicology)
   C. Specific activity report related to the following: side effects, birth defects, allergies, skin irritations
2. In a short summary of information on use of the pharmaceutical in clinical conditions and after FDA approval. A copy of any scientific publications concerning the pharmaceutical should be submitted.
3. A short summary of information about side effects of the pharmaceutical and any adverse experiences with the pharmaceutical learned since FDA approval.

Revised Annex I

Addendum 4

Documentation Necessary for the Registration of Generic Pharmaceuticals under the Jurisdiction of the U.S. Food and Drug Administration

1. A summary of bioequivalence study and results.

Revised Annex I

Addendum 5

Documentation Necessary for the Registration of Substances under the Jurisdiction of the U.S. Food and Drug Administration

1. Certificate of Analysis for the substance from the manufacturing company (original copy or notarized copy).

Revised Annex I

Addendum 6

Sample Registration Certificate for Pharmaceuticals (Substances) under the Jurisdiction of the FDA

Ministry of Health Care and Medical Industries of the Russian Federation

Registration Certificate

No. _____

This certificate has been issued to _____ (*company-producer, country*) and testifies that in accordance to the regulations for registration of pharmaceuticals in the Russian Federation _____ (*name of pharmaceutical (substance)*) in the medical form _____ has been registered in the Russian Federation.
This certificate is valid for five (5) years and does not serve as an obligation to purchase the above mentioned pharmaceutical.

_____
Date of Registration

Head of the Inspection on State Control or Pharmaceuticals and Medical Equipment

Bureau of Registration of Pharmaceuticals, Medical Equipment, and Products with Medicinal Value

Revised Annex I

Addendum 7

Supplemental Application to Report Changes for Pharmaceuticals (Substances) under the Jurisdiction of the FDA

A special supplemental application is necessary to report any changes to the original registration application within 30 days of occurrence of the changes.

1. Letter from Manufacturer (''Company''), under corporate seal, submitting information on any changes in the information submitted at the last registration, including any changes in FDA approved labels or labeling.

Revised Annex I

Addendum 8

Application for Re-registration (Renewal) of Pharmaceuticals (Substances) Subject to the Jurisdiction of the U.S. Food and Drug Administration when No Changes Have Been Made Since the Original Registration.

1. Letter of Intent to Re-register - see Addendum 1.
2. Letter from Manufacturer (''Company'') certifying that no changes in ingredients, labeling or Good Manufacturing Practice status have occurred since the time of the last registration.

Signature
Corporate Seal

Revised Annex I

Addendum 9

Application for Re-registration (Renewal) of Pharmaceuticals (Substances) Subject to the Jurisdiction of the U.S. Food and Drug Administration to Report Concomitant Changes

1. Company-applicant
2. Name of the pharmaceutical preparation
3. Main synonyms of the preparation
4. Composition of the preparation
5. If changes have occurred in the ingredients or manufacturing procedure since the time of the original registration, indicate changes
6. Medical forms
7. Dosage of the preparations
8. Administration (oral, injectable, etc.)
9. Main indications for administration

10. Shelf Life (expiration dating) and storage requirements
11. Description of standard package form and copies of all labeling

Signature
Corporate Seal

Revised Annex I

Addendum 10

Sample Re-registration Certificate for Pharmaceutical (Substances) under the Jurisdiction of the FDA

Confirmation of the Re-registration of a Pharmaceutical(Substance)

The Inspection on State Control of Pharmaceuticals and Medical Equipment confirms that: _____ (*name of pharmaceutical(substance)*) has been registered as of _____ (*date of registration*) as number _____ (*reg.number*) and retains its registration number until the next routine re-registration. In the event that the company-producer changes the composition of the pharmaceutical, the indications and warnings for usage or the methods of control and technological production, the company-producer is obliged to inform the Inspection on State Control of Pharmaceuticals and Medical Equipment of such changes.
No. _____ (*registration number*)
_____ (*date of registration*)

Head of the Inspection on State Control of Pharmaceuticals and Medical Equipment

Bureau of Registration of Pharmaceuticals, Medical Equipment, and Products with Medicinal Value

Annex II

Addendum 1

Supplemental Requirements when Appropriate for Submission of Methods of Analysis and Release Specifications in Applications for Synthetic Chemical Compounds (substances) for Registration in the Russian Federation

Where appropriate for the substance submitted:

1. Description of material (appearance)
2. Identification test(s)
3. Solubility
4. Flash point/evaporation point
5. Melting point and Boiling point
6. Specific gravity/density
7. Specific rotation
8. Absorbance test (Specific Absorbance)
9. Refractive index
10. Clarity and color of solution
11. Impurity(ies) test(s) (Chromatographic Profile)
12. pH test
13. Chlorides test
14. Sulphates test
15. Loss on drying
16. Water contents assessed by Carl Fisher titration (include weight tested)
17. Residual solvents test
18. Heavy metals test
19. Assay
20. Microbiological tests
21. Residue on Ignition

Annex II

Addendum 2

Supplemental Requirements when Appropriate for the Submission of Methods for Analysis and Release Specifications in Applications for Liquid Injection Dosage Form Products for Registration in the Russian Federation

Where appropriate for the product submitted:

1. Description (appearance)
2. Identification test
3. Transmittance/Absorbance test
4. Particle size (in cases of suspension, emulsion)
5. Solution pH
6. Specific rotation
7. Specific gravity/density
8. Impurity(ies) test(s) (Chromatographic Profile)
9. Net contents test/Deliverable Volume
10. Pyrogen test(L.A.L. test)
11. Sterility testing
12. Completeness of solution and particulate test
13. Clarity and color of solution
14. Assay

Annex II

Addendum 3

Guidelines on Information Appropriate for Submission of Methods for Analysis and Release Specifications in Applications for Solid Dosage Forms for Preparation of Injections and Antibiotics for Registration in the Russian Federation

Where appropriate for the product submitted:

1. Description (appearance)
2. Solubility
3. Net contents test
4. Identification test
5. Melting range
6. Specific rotation
7. Specific absorbance
8. Completeness of solution and particulate test
9. Impurity(ies) test(s) (Chromatographic Profile)
10. pH test
11. Chlorides test
12. Sulphates test
13. Loss on drying
14. Water test determined using Carl Fisher titration
15. Heavy metals
16. Pyrogenicity tests (chemical test)
17. Test for sterility
18. Assay
19. Uniformity of Dosage Units
20. Clarity and color of solution

Annex II

Addendum 4

Supplemental Requirements when Appropriate for the Submission of Methods for Analysis and Release Specifications in Applications for Liquid Ophthalmic Dosage Form Products for Registration in the Russian Federation

Where appropriate for the product submitted:

1. Description (appearance, color, clarity, particulate matter)
2. Identification test
3. Impurity(ies) test(s) (Chromatographic Profile)
4. Transmittance/Absorbance test
5. Viscosity (for solutions containing methyl cellulose or similar substances)
6. pH test
7. Determination of fill volume (method and allowable deviations)
8. Sterility test
9. Assay
10. Particulates count- clear liquids
11. Particle size- suspensions

Annex II

Addendum 5

Supplemental Requirements when Appropriate for the Submission of Methods for Analysis and Release Specifications in Applications for Liquid Dosage Forms for Internal and External Use Products for Registration in the Russian Federation

Where appropriate for the product submitted:

1. Description (appearance, color)
2. Identification test
3. pH test
4. Specific gravity/density
5. Viscosity
6. Particle size test (in cases of suspension, emulsion)
7. Net contents test
8. Assay
9. Microbiological purity test(s)
10. Impurity(ies) test(s) (Chromatographic Profile)

Annex II

Addendum 6

Supplemental Requirements when Appropriate for the Submission of Methods for Analysis and Release Specifications in Applications for Aerosol Dosage Forms for Registration in the Russian Federation

Where appropriate for the product submitted:

1. Description
2. Container integrity test
3. Pressure test
4. Assay
5. Uniformity of delivered dose
6. Net contents test and number of doses in container (for dosed aerosols)
7. Percent total volume delivered
8. Aerosol particle size test
9. Identification test
10. Water content test (method and allowable limits)
11. Impurity(ies) test(s) (Chromatographic Profile)
12. Microbiology purity (description of test or reference to Pharmacopeia)

Annex II

Addendum 7

Supplemental Requirements when Appropriate for the Submission of Methods for Analysis and Release Specifications in Applications for Tablets and Dragee Dosage Form Products for Registration in the Russian Federation

Where appropriate for the product submitted:

1. Description (appearance, color of tablets, appearance in fracture, size of tablets, diameter and height, strength)
2. Average mass of tablets, method, allowable deviations
3. Identification test
4. Impurity(ies) test(s) (Chromatographic Profile)
5. Insoluble Ash test (HCl)
6. Disintegration test (method)
   AND/OR
7. Dissolution test
   OR
   Release rate test
8. Uniformity of Dosage Units test/Content uniformity test
9. Assay
10. Microbiology purity test(s)

''Requirement #8 shall apply for tablets in which proportion of active ingredient in one tablet amounts to 50 mg or less.

Annex II

Addendum 8

Supplemental Requirements when Appropriate for the Submission of Methods for Analysis and Release Specifications in Applications for Solid Oral Capsule Dosage Form Products for Registration in the Russian Federation

Where appropriate for the product submitted:

1. Description of capsule and its contents (appearance, form, color)
2. Identification test
3. Average weight of capsule contents/ weight variation test (method and allowable deviations)
4. Disintegration test (method and norms)
   AND/OR
   Dissolution test
   OR
   Rate of Release test
5. Uniformity of Dosage Units test/Content uniformity
6. Solubility test
7. Assay
8. Microbiology purity test
9. Impurity(ies) test(s) (Chromatographic Profile)

Requirements 5 and 6 apply to capsules in which proportion of active ingredient per one capsule amounts to 50 mg. or less.

Annex II

Addendum 9

Supplemental Requirements when Appropriate for the Submission of Methods for Analysis and Release Specifications in Applications for Suppository Products for Registration in the Russian Federation

Where appropriate for the product submitted:

1. Description (appearance, color, form, diameter, homogeneity)
2. Average weight of dosage unit test
3. Identification test
4. Melting point or measuring full deformation time (lipophilic bases)
5. Dissolution time (hydrophilic bases)
6. Test for Uniformity of Dosage Units (Content Uniformity)
7. Assay
8. Microbiology purity test(s)
9. Impurity(ies) test(s) (Chromatographic Profile)

Requirement 5 shall be observed for suppositories where proportion of active ingredient in one suppository amounts to 50 mg. or less.

Annex II

Addendum 10

Supplemental Requirements when Appropriate for the Submission of Methods for Analysis and Release Specifications in Applications for Topical Solid Products for External Use for Registration in the Russian Federation

Where appropriate for the product submitted:

1. Description (appearance, color)
2. Identification test
3. Net Contents test
4. pH of aqueous extraction solution
5. Uniformity of Dosage Unit test
6. Particle size test (Size determination of drug particles)
7. Sterility test(for eye ointments)
8. Assay
9. Microbiological purity tests
10. Impurity(ies) test(s) (Chromatographic Profile)

Requirement 6 shall apply in accordance with the type of ointment.

Annex II

Addendum 11

Supplemental Requirements when Appropriate for the Submission of Methods for Analysis and Release Specifications in Applications for Tincture and Extract products for Registration in the Russian Federation

Where appropriate for the product submitted:

1. Alcohol test
2. Description (appearance, color)
3. Identification test
4. Heavy metals
5. Specific gravity/density.
6. Residue on drying
7. Net contents test
8. Assay
9. Moisture content test

NOTE: This Applies only to tincture and extract regulated as drug products.

Medicinal Plants and Teas are not covered under this MOU.

[FR Doc. 96–32188 Filed 12–18–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[BPD–849–FN]

Medicare Program; Recognition of the Ambulatory Surgical Center Standards of the Joint Commission on the Accreditation of Healthcare Organizations and the Accreditation Association for Ambulatory Health Care

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final notice.

SUMMARY: This notice grants deemed status to two organizations, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) and the Accreditation Association for Ambulatory Health Care (AAAHC), for their accredited ambulatory surgical centers (ASCs) that request Medicare certification. We believe that accreditation of ASCs by either organization demonstrates that all Medicare ASC conditions are met or exceeded, and, thus, we grant deemed status to each organization.

EFFECTIVE DATE: The provisions of this notice are effective beginning on December 19, 1996 through December 19, 2002.

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