Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice is issued under section 10(a)(1) and (a)(2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: December 16, 1996.

Michael A. Friedman,

*Deputy Commissioner for Operations.*

[FR Doc. 96–32427 Filed 12–20–96; 8:45 am]

**BILLING CODE 4160–01–F**

## Memorandum of Understanding Between the Food and Drug Administration and the Republic of Belarus

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the Republic of Belarus. The purpose of the MOU is to exchange information on drugs and biological products and to facilitate the development of the Belarus health care sector by establishing in Belarus a streamlined registration procedure for U.S. drugs and biological products.

**DATES:** The agreement became effective March 25, 1996.

**FOR FURTHER INFORMATION CONTACT:** Bradford W. Williams, Office of Compliance, Center for Drug Evaluation and Research (HFD–310), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–594–0165.

**SUPPLEMENTARY INFORMATION:** In accordance with 21 CFR 20.108(c), which states 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.*

224–96–4004

Memorandum of Understanding Between the Food and Drug Administration of the Department of Health and Human Services of the United States of America and the Ministry of Health of the Republic of Belarus on Cooperation and Information Exchange for Facilitating the Introduction of Drugs and Biological Products into the Republic of Belarus

The Food and Drug Administration (FDA), of the Department of Health and Human Services of the United States of America, on the one hand; and the Ministry of Health of the Republic of Belarus, on the other hand, hereinafter referred to as the parties,

Guided by principles recorded in the Agreement between the Government of the United States of America and the Government of the Republic of Belarus on Science and Technology Cooperation, signed in Minsk on January 14, 1994, and

Strengthening the bonds of friendship between the parties, Have reached an understanding on matters of cooperation:

I

The goals of the parties are:

1. To exchange information on drugs and biological products and on requirements applicable to them (including standardization, registration, quality control, and side effects), and prompt exchange of information on the removal of drugs and biological products from the market or restrictions on their use.
2. To facilitate the development of the Belarusian health care sector by establishing in Belarus a streamlined registration procedure for United States drugs and biological products that are manufactured and marketed in the United States under the jurisdiction of the FDA as provided in the Annexes to this Memorandum of Understanding. The Belarusian party should use the streamlined procedure for such products.

The parties confirm that it would be mutually beneficial for the parties to work together to streamline the process for registering in Belarus drugs and biological products when these products are permitted by the FDA to be marketed in the United States. The effect of the parties joint endeavors under this Memorandum of Understanding should be to extend to Belarusian users access to the same United States drugs and biological products as are available to United States users of such products, which possess a high degree of safety, effectiveness, and quality .

II

This Memorandum of Understanding covers drugs and biological products manufactured and marketed in the United States under the jurisdiction of the FDA including:

1. Drugs: articles that meet the definition of a drug under the United States Federal

Food, Drug and Cosmetic Act. Drugs include both prescription drugs and non prescription drugs (Over-the-Counter, ''OTC'' products). This Memorandum of Understanding does not apply to homeopathic drugs or to vitamins, mineral or herbal products, or any other dietary supplements.

2. Biological products: products that are regulated as biological products under the United States Public Health Service Act.

III

1. The Belarusian party should identify the streamlined registration requirements for those drugs and biological products that are manufactured and marketed in the United States under the jurisdiction of the FDA.
2. For drugs and biological products that are manufactured and marketed in the United States under the jurisdiction of the FDA, the Belarusian party intends to accept the FDA's decisions and regulations on premarket approval, licensing, monographs, and related documentation, as well as FDA's quality standards and enforcement of manufacturing controls and other requirements.
3. In addition to any requirements for registration as drugs, any products that can be defined as a controlled substance or highly addictive must receive the additional approval of the appropriate Belarusian bodies under the laws and regulations of the Belarus. Products for which this approval will be necessary should be further explained in an exchange of letters between the participants.

This Memorandum of Understanding should apply equally to pharmaceutical or biological products manufactured and marketed in the United States under the jurisdiction of the FDA which require prescription prior to sale and those which are sold directly ''Over-the-Counter'' (OTC) without prescription. It is understood that marketing status in the Republic of Belarus will be in accordance with Belarusian laws and regulations, notwithstanding United States marketing status.

4. This Memorandum of Understanding lists, in Annexes, the information which the United States firms should provide to the Belarusian party on drugs and biological products that are manufactured and marketed in the United States under the jurisdiction of the FDA, in order to obtain permission for them to be marketed in the Republic of Belarus. Upon submission of information as listed in the Annexes, the Belarusian party intends not to require, as a condition of registration or importation, the conduct of any additional clinical or analytical review or testing, or any other medical, scientific, quality, or other related requirements. Registration should take no more than 60 days after the submission to the appropriate Belarusian party of all of the information required in the Annexes and payment of any fee(s) required by Belarus.

Upon submission of a request for registration of vaccines and sera, the Ministry of Health of the Republic of Belarus may require additional documentation which will meet the requirements of the Republic of Belarus. In cases when additional documentation is necessary, the Belarusian party should notify the firm seeking registration within the 60 day period.

5. Upon request of the Belarusian party, the FDA should provide access to information on the compliance status of drugs and biological products and manufacturers that are eligible for Belarusian registration under this Memorandum, to the extent the information is permitted by United States laws. The FDA should also respond to inquiries from the Belarusian party about information submitted in accordance with the Annexes with respect to such matters as the marketing status of any drug or biological product. The parties intend to share information about all drugs and biological products that present a significant risk to users.
6. Upon request of the FDA, the Belarusian party will consider confidential any information provided to it by the FDA if it is not public information. Similarly, at the request of the Belarusian party, the FDA will respect the confidentiality of information provided by the Belarusian party to the FDA, to the extent permitted by law.
7. Under this Memorandum of Understanding, subject to availability of resources, the parties plan to share knowledge and provide assistance and information to one another when necessary.
8. The FDA should provide the Belarusian party with up-to-date copies of laws, regulations, provisions, and procedures used to ensure the level of quality of drugs and biological products, necessary for public health. The Belarusian party should provide the FDA with up-to-date copies of the laws, regulations, provisions, and procedures for registration of a given product imported into the Republic of Belarus from other countries and, in particular, from the United States. The Annexes to this Memorandum of Understanding should contain the sole procedure and list of requirements applicable to those products manufactured and marketed in the United States under the jurisdiction of the FDA.
9. The parties should consult periodically, subject to the availability of funds, in order to promote cooperation and to facilitate implementation of this Memorandum of Understanding. As the need arises, the parties should develop and agree on a specific plan of cooperation.
10. Subject to the availability of funds, the parties may establish a coordinating committee and one or more technical committees, including representatives of each party with knowledge in regulation of drugs and biological products, in order to facilitate implementation of this Memorandum of Understanding.

IV

The following offices are designated as liaison offices for the parties:

A. For the FDA:

Director
(currently Bradford W. Williams)
Division of Drug Labeling and Nonprescription Drug Compliance
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
7520 Standish Place
Rockville, Maryland 20855
USA

B. For the Ministry of Health:

Director of the Administration of Pharmacy, Medical Equipment, and Regulations
Ministry of Health
39 Myasnikov Street
220097 Minsk
Republic of Belarus

Activities under this Memorandum of Understanding will begin on the last date of signature by all parties and will last for a period of three years. Activities under this Memorandum of Understanding may be extended or amended by mutual written consent. They may be terminated by any party by a sixty day advance written notice to the other parties done at Minsk, Belarus, in duplicate, in the English and Russian languages, this 27th day of March, 1996.

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

Mary Pendergast
Deputy Commissioner/
Senior Advisor to the Commissioner

For the Ministry of Health of the Republic of Belarus:

Inessa M. Drobishevkaia
Minister

Annex I

*Application Procedures and Information Which the United States Firm Must Provide to Belarusian Authorities for Registration and/or Re-registration in the Republic of Belarus of Drugs and Biological Products Manufactured and Marketed in the United States Under the Jurisdiction of the Food and Drug Administration (FDA)*

1. The manufacturing firm or their authorized representative shall submit one (1) English language and three (3) Russian language copies of an application which includes the following information to:

   Chief of the Pharmacy Department,
   Department for Pharmacy, Medical Equipment and Regulations
   Ministry of Health
   39 Myasnikov Street
   220097 Minsk
   Republic of Belarus

2. Information on the manufacturing firm and/or their authorized representative including:

a. Name of registering firm

b. Name of manufacturing firm, if applicable (if representing another firm, a notarized letter authorizing the registering firm to register the products in Belarus)
c. Address, telephone and facsimile numbers of registering and/or manufacturing firm
d. Name, title and signature of the authorized responsible representative(s)
e. Certification that the drugs or biological products are manufactured in the United States.
3. The FDA Letter of Approval, or, For products subject to an FDA Over-the-Counter (OTC) monograph, copies of the relevant sections of the Final Monograph or Tentative Final Monograph with a certification by the manufacturing firm and/or its authorized representative that the product conforms in all respects to the Final Monograph or Tentative Final Monograph.
4. The FDA approved product package insert (information and instruction sheet), labels and labeling. The information provided must include the following:
a. Name: trade, generic, and chemical
b. Description: chemical and pharmacological group
c. Clinical pharmacology/mechanism of action
d. Indications and instructions for usage
e. Contraindications
f. Observations
g. Precautionary measures
h. Adverse reactions and toxicity data
i. Information on overdose
j. Dosage and methods of administration
k. How medical product is supplied, including dosages and product strength
l. Information on storage conditions and expiration.
m. Other information contained in the insert.
5. For the registration of prescription drugs (New Molecular Entities) manufactured in the United States and covered by an approved New Drug Application:
a. 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:
i. Pharmacological report (specifications) supporting all indications for usage as stated in the instructions, including summary of the pivotal clinical trials(s)
ii. Toxicology report (acute, subacute, subchronic, and chronic toxicology)
iii. Specific activity report related to the following: side effects, birth defects, allergies, skin irritations
b. 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.
c. A short summary of information about side effects of the pharmaceutical and any adverse experiences with the pharmaceutical learned since FDA approval.
6. For the registration of generic drug products manufactured in the United States under the jurisdiction of the FDA:
a. A summary bioequivalence study and results.
7. Requirements for the registration of pharmaceutical substances manufactured and marketed in the United States:
a. Certificate of Analysis for the substance from the manufacturing company (original copy or notarized copy).
b. Information on the product(s) which will be manufactured in the Belarus using the substance.
8. Methods of analysis and release specifications. Guidelines on documentation required are contained in Annex II.
9. The manufacturing firm and/or its authorized responsible representative shall sign and submit a statement that the firm meets the current Good Manufacturing Practice (GMP) requirements.
10. The manufacturing firm and/or its authorized representative shall provide a copy of the most recent FD–483, FDA Notice of Inspection Observations, that is relevant to the drug or biological product for which registration is sought.
11. The manufacturing firm and/or its authorized responsible representative shall sign and submit a statement that all information submitted is truthful, accurate, and complete.
12. In case of any change of information provided in the original application, including any FDA-approved changes in the package insert, labels or labeling, the manufacturing firm and/or its authorized representative shall provide notification of these changes within 30 days.
13. The manufacturing firm and/or its authorized representative shall provide samples of the product in the packaged form in which the product is offered for registration.
14. For re-registration of pharmaceutical or biological preparations manufactured and marketed in the United States:
a. Copy of the original registration certificate issued by the Ministry of Public Health
b. Complete information on changes in the composition or manufacturing process since the original registration
c. Summary of information concerning side effects, adverse effects and complaints received by the firm during the previous 5 years.

Annex II

*Addendum 1*

Supplemental Guidelines for Submission of Methods of Analysis and Release Specifications in Applications for Synthetic Chemical Compounds (substances) for Registration in the Republic of Belarus

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 Guidelines for the Submission of Methods for Analysis and Release Specifications in Applications for Liquid Injection Dosage Form Products for Registration in the Republic of Belarus

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 Republic of Belarus

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 (include weight tested)
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 Guidelines for the Submission of Methods for Analysis and Release Specifications in Applications for Liquid Ophthalmic Dosage Form Products for Registration in the Republic of Belarus

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 Guidelines 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 Republic of Belarus

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 Guidelines for the Submission of Methods for Analysis and Release Specifications in Applications for Aerosol Dosage Forms for Registration in the Republic of Belarus

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 Guidelines for the Submission of Methods for Analysis and Release Specifications in Applications for Tablets and Dragee Dosage Form Products for Registration in the Republic of Belarus

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)

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''Requirement no. 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 Guidelines for the Submission of Methods for Analysis and Release Specifications in Applications for Solid Oral Capsule Dosage Form Products for Registration in the Republic of Belarus

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/or
5. Dissolution test, or release rate test
6. Uniformity of dosage units test/content uniformity
7. Solubility test
8. Assay
9. Microbiology purity test
10. Impurity(ies) test(s) (Chromatographic Profile)

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Requirements 6 and 7 apply to capsules in which proportion of active ingredient per one capsule amounts to 50 mg. or less.

Annex II

*Addendum 9*

Supplemental Guidelines for the Submission of Methods for Analysis and Release Specifications in Applications for Suppository Products for Registration in the Republic of Belarus

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)

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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 Guidelines for the Submission of Methods for Analysis and Release Specifications in Applications for Topical Solid Products for External Use for Registration in the Republic of Belarus

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)

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Requirement 6 shall apply in accordance with the type of ointment

Annex II

*Addendum 11*

Supplemental Guidelines for the Submission of Methods for Analysis and Release Specifications in Applications for Tincture and Extract products for Registration in the Republic of Belarus

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

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

Medicinal Plants and Teas are not covered under this Memorandum of Understanding.

[FR Doc. 96–32424 Filed 12–20–96; 8:45 am]

BILLING CODE 4160–01–F