AGREEMENT ON MUTUAL RECOGNITION BETWEEN THE SWISS CONFEDERATION AND THE UNITED STATES OF AMERICA RELATING TO PHARMACEUTICAL GOOD MANUFACTURING PRACTICE

The Swiss Confederation ("Switzerland") and the United States of America ("the United States") (individually a "Party" and collectively the "Parties"),

CONSIDERING the traditional links of friendship that exist between Switzerland and the United States;

RECOGNIZING the U.S. Food and Drug Administration's (FDA) mission to protect the public health by ensuring the safety, efficacy, and security of human drugs and biological products and veterinary drugs;

RECOGNIZING the Swiss Agency for Therapeutic Products' (Swissmedic) mission to protect the public health by ensuring the safety, efficacy, and security of therapeutic products;

DESIRING to facilitate bilateral trade between the Parties;

RECOGNIZING the importance of continued and enhanced collaboration between Swissmedic and FDA to advance protection of public health;

RECOGNIZING that mutual recognition of pharmaceutical good manufacturing practice inspections can be an important means of enhancing public health outcomes in both Parties;

RECOGNIZING that an agreement providing for mutual recognition is of particular interest to small- and medium-sized businesses, and their workers, of both Parties;

RECOGNIZING that any such mutual recognition depends on the confidence in the continued reliability of inspection procedures and practices of each Party; and

RECOGNIZING the importance of maintaining the high levels of health, safety, environmental, and consumer protection in each Party,

HAVE AGREED as follows:

Section A: Pharmaceutical Inspections

Article 1: Definitions

For purposes of this Agreement:

Assessment[1] means:

(a) for Switzerland, an equivalence assessment done by Swissmedic; and

(b) for the United States, a capability assessment done by FDA;

Authority means:

(a) For Swissmedic, an equivalent authority; and

(b) For FDA, a capable authority;

Capable Authority means an Authority that FDA has determined is capable according to the criteria and procedures specified in Annex 3 and referred to in the U.S. laws and regulations listed in Annex 1. For greater certainty a finding that a regulatory authority is "capable" does not require that the authority maintain procedures for conducting inspections and overseeing manufacturing facilities that are identical to the FDA's procedures;

Equivalence means that the regulatory system under which an authority operates is sufficiently comparable to assure that the process of inspection and the ensuing official Good Manufacturing Practice documents will provide adequate information to determine whether respective statutory and regulatory requirements of the authorities have been fulfilled. For greater certainty, "equivalence" does not require that the respective regulatory systems have identical procedures;

Equivalent Authority means an Authority in respect of which Swissmedic has made a positive equivalence determination according to the criteria and procedures specified in Annex 3 and as referred to in the Switzerland laws and regulations listed in Annex 1;

Good Manufacturing Practice (GMP) means systems that assure proper design, monitoring, and control of manufacturing processes and facilities, the adherence to which assures the identity, strength, quality, and purity of pharmaceuticals. GMP includes strong quality management systems, obtaining appropriate quality raw

[1] For greater certainty, an "assessment" for purposes of this Agreement includes any reassessment.

materials (including starting materials) and packaging materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories;

GMP inspection means an inspection of manufacturing facilities, including processing, packaging, testing, and sterilizing facilities, and contract facilities performing these functions, during the marketing of products for compliance with GMP;

Inspection means an on-site evaluation of a manufacturing facility to determine whether the manufacturing facility is operating in compliance with GMP, its commitments made as part of the approval to market a product, or both;

Inspection Report means a report written by an investigator or inspector of an Authority concerning an inspection of a manufacturing facility that the investigator or inspector conducted that describes the purpose, scope, and details concerning the coverage of an inspection and includes written observations or factual findings bearing on the manufacturing facility's conformance to applicable GMP requirements set out in the laws and regulations listed in Annex 1 and any commitments made as part of the approval to market a product;

Official GMP document means a document issued by an Authority following an inspection of a manufacturing facility. Examples of official GMP documents include: inspection reports; certificates issued by an authority attesting the compliance of a manufacturing facility with GMP; GMP non-compliance statements issued by Swissmedic and notices of observation, untitled letters, warning letters, and import alerts issued by FDA;

Post-approval inspection means an inspection of a manufacturing facility specific to an approved application; and

Pre-approval inspection means an inspection of a manufacturing facility carried out as part of the review of an application before a marketing approval is granted.

Article 2: Purpose

This Agreement facilitates the exchange of official GMP documents between the Authorities and reliance on the factual findings contained in those documents.[2] This

[2] Pursuant to 21 U.S.C. § 384e, FDA has the authority to enter into agreements to recognize pharmaceutical inspections conducted by foreign regulatory authorities, including relying upon information from such inspections, if FDA determines those authorities are capable of conducting inspections that meet U.S. requirements.

Agreement seeks to benefit public health and facilitate trade by allowing each Authority to leverage and to reallocate its inspection resources, including by avoiding duplication of inspections, so as to improve each Authority's oversight of manufacturing facilities overall and better address quality risk and prevent adverse health consequences.

Article 3: Scope of the Agreement

1. The provisions of this Agreement apply to:

   (a) pre-approval, post-approval, and GMP inspections of manufacturing facilities conducted within the territory of a Party by an Authority; and

   (b) pre-approval, post-approval, and GMP inspections of manufacturing facilities conducted in territories of non-Parties by an Authority to the extent provided for in paragraphs 3 and 4 of Article 5.

2. The provisions of this Agreement apply to inspections with respect to those products described in Annex 2.

3. Annex 1 lists the laws and regulations governing inspections and the GMP requirements.

Article 4: Recognition of Authorities

1. For the purposes of this Agreement, the United States recognizes Swissmedic as a Capable Authority according to the criteria and procedure specified in Annex 3.

2. For the purposes of this Agreement, Switzerland recognizes the FDA as an Equivalent Authority according to the criteria and procedure specified in Annex 3.

Article 5: Acceptance of Official GMP Documents

1. Except as provided for in paragraph 2, with regard to manufacturing facilities located in the territory of a Party, the Authority of the other Party shall recognize pharmaceutical inspections and accept the official GMP documents of an inspection of a manufacturing facility conducted by the other Authority.

2. In specific circumstances, an Authority may decide not to accept an official GMP document as provided for in paragraph 1. Examples of such circumstances

include the indication of material inconsistencies or inadequacies in an inspection report, quality defects identified in the post-market surveillance, or other specific evidence of serious concern in relation to product quality or consumer safety.

3. Each Authority may accept official GMP documents issued by the Authority of the other Party for manufacturing facilities located outside the territory of the Party of the issuing Authority.

4. Each Authority may determine the terms and conditions under which it accepts official GMP documents under paragraph 3.

5. For purposes of this Agreement, to accept an official GMP document means to rely on the factual findings in such document and to take the conclusions of the issuing Authority into account.

Article 6: Transmission of Official GMP Documents

1. If an Authority requests an official GMP document from the Authority of the other Party, the requested Authority shall transmit the requested document within 21 calendar days of the request or of the requested document being finalized, whichever is later.

2. The Authority that decides not to accept an official GMP document shall notify the issuing Authority of the reasons for non-acceptance and may request clarification from that issuing Authority. The issuing Authority shall respond to a request for clarification in a timely manner and shall normally base its response on input from one or more members of the inspection team.

3. If, based on an official GMP document, the requesting Authority determines that another inspection of the manufacturing facility is needed, the requesting Authority may request:

(a) the Authority of the other Party to conduct an inspection in accordance with Article 7; or

(b) additional inspection reports from the other Authority.

Article 7: Requests for Pre-approval, Post-approval, and GMP Inspections

1. Each Authority may request in writing, after assessing the official GMP documents of the other Party, if available, and concluding that another inspection is

necessary, that the Authority of the other Party conduct a pre-approval, post-approval, or GMP inspection of a manufacturing facility. The written request shall include the reason for the request and identify the precise issues to be addressed in the inspection and the requested timeline for completing the inspection and transmitting the official GMP documents.

2. Within 15 calendar days of receipt of the request, the requested Authority shall acknowledge receipt and confirm whether it will conduct the inspection in accordance with the requested timelines. If the requested Authority considers that final official GMP documents relevant to the request are available, it shall notify the requesting Authority and transmit any final official GMP documents upon request.

Article 8: Safeguard Clause

1. Each Party recognizes that the importing Party has a right to fulfill its legal responsibilities by taking actions necessary to ensure the protection of human and animal health at the level of protection it deems appropriate.

2. Further to paragraph 1, each Authority has the right consistent with the other Party's applicable laws, to conduct its own inspection of a manufacturing facility in the territory of the other Party, including when the Authority of the other Party has declined to conduct its own inspection.

3. An Authority conducting its own inspection of a manufacturing facility in the territory of the other Party should be an exception from the normal practice.

4. An Authority conducting its own inspection of a manufacturing facility in the territory of the other Party shall notify in writing the Authority of the other Party prior to conducting the inspection. The written notification shall include the reason for the inspection and identify the issues to be addressed in the inspection and the requested timeline for the inspection.

5. In the event that an Authority conducts an inspection referred to in paragraph 4, the requested Authority of the other Party may join that inspection.

Article 9: Suspension of an Authority

1. Each Authority has the right to suspend recognition of the Authority of the other Party. This right shall be exercised in an objective and reasoned manner.

2. If an Authority suspends the recognition of the Authority of the other Party, it shall, without undue delay, notify the suspended Authority of the reasons for the suspension and provide sufficient detail to allow the suspended Authority to understand corrective measures that must be taken to lift the suspension. The Joint Committee of the Parties shall be informed thereof.

3. An Authority is not obligated to accept an official GMP document issued after the date of suspension from the suspended Authority.

4. A suspension shall remain in effect until the Authority lifts the suspension based on a positive determination of recognition made pursuant to a reassessment in accordance with the criteria specified in Annex 3.

5. An Authority suspending the recognition of the Authority of the other Party shall, upon request, promptly discuss in the Joint Committee of the Authorities:

(a) the reason for the suspension; and

(b) the corrective actions that would need to be taken for the suspension to be lifted.

The Joint Committee of the Authorities shall endeavor to discuss within three months of the suspension the appropriate timeframe and exact steps to be taken to lift the suspension based on a positive determination of recognition made pursuant to a reassessment in accordance with the criteria specified in Annex 3.

Article 10: Exchange of Information

The Authorities of each Party shall establish appropriate arrangements, including access to relevant databases, for the exchange of:

(a) official GMP documents;

(b) other appropriate information related to the inspection of a manufacturing facility; or

(c) any information concerning confirmed problem reports, corrective actions, recalls, rejected import consignments, and other regulatory and enforcement problems for products covered by this Agreement.

Article 11: Alert System

Each Authority shall maintain an alert system that permits the Authority of the other Party to be made aware, proactively and with the appropriate speed, of:

(a) quality defects as outlined in the Pharmaceutical Inspection Convention/Scheme (PIC/S) Procedure for Handling Rapid Alerts and Recalls Arising from Quality Defects Standard Operating Procedure dated 1 July 2017, as amended;

(b) recalls as outlined in the PIC/S Procedure for Handling Rapid Alerts and Recalls Arising from Quality Defects Standard Operating Procedure dated 1 July 2017, as amended;

(c) counterfeit or falsified products as outlined in the PIC/S Procedure for Handling Rapid Alerts and Recalls Arising from Quality Defects Standard Operating Procedure dated 1 July 2017, as amended; or

(d) potential serious shortages and other problems concerning quality or non-compliance with GMP that could necessitate additional controls or suspension of the distribution of the affected products.

Article 12: Transitory Provisions

1. No later than 12 months following the entry into force of this Agreement, the Joint Committee of the Authorities shall review experience gained, including timelines for sharing GMP documents, in order to consider whether the provisions on pre- and post-approval inspections provided in this Agreement shall be reviewed. The Joint Committee of the Authorities may decide to postpone this review.

2. No later than three years following the entry into force of this Agreement, the Joint Committee of the Authorities shall consider whether to include vaccines for human use within the product coverage of this Agreement.

3. Without prejudice to the consideration identified in paragraph 1 and 2, as of the entry into force date of this Agreement, an Authority shall notify the Authority of the other Party in advance of conducting a pre-approval, post-approval, or GMP inspection of a manufacturing facility of vaccines for human use located in the territory of the Party and give the Authority of that Party the option of joining the inspection. In order to support the inclusion of vaccines for human use within the product coverage of this Agreement, the Joint Committee of the Authorities shall take into account, in particular, the experience gained through such inspections.

4. Either at the time of the initial consideration identified in paragraph 2, or thereafter, the Joint Committee of the Authorities may decide to include vaccines for human use within the product coverage of this Agreement. If the Joint Committee of the Authorities makes such a decision, it will promptly refer the matter to the Joint Committee of the Parties with a view to amend Annex 2 in accordance with Article 17.

5. In the event that Annex 2 is amended pursuant to paragraph 4, the respective Authorities shall, without undue delay, make the amended text publicly available on their respective websites.

Section B: Administration and Enhancement of the Agreement

Article 13: Changes to Laws, Regulations, and Criteria

1. Each Party shall notify the other Party of a change to its laws related to this Agreement, including those laws listed in Annex 1, as soon as practicable. Annex 1 shall be amended accordingly, if necessary.

2. Each Party shall notify the other Party of a change to its regulations related to this Agreement, including those regulations listed in Annex 1, at least 60 days before the change enters into force. If considerations of safety, health, or environmental protection require more urgent action, the Party shall notify the other Party of the change as soon as practicable. Annex 1 shall be amended accordingly, if necessary.

3. Each Party shall notify the other Party of any significant changes that may have an impact on the criteria for recognition as soon as practicable.

Article 14: Joint Committee of the Authorities

1. The Parties hereby establish a Joint Committee of the Authorities to facilitate communication between Authorities and the effective operation of the Agreement.

2. The Joint Committee of the Authorities shall be co-chaired by representatives from the Authority of each Party. The Joint Committee of the Authorities shall make its decisions by unanimous consent. The Joint Committee of the Authorities shall determine its own rules and procedures.

3. The Joint Committee of the Authorities shall provide a forum to discuss any issue relating to the operation of this Agreement, and its functions shall include the following:

(a) providing a forum to discuss issues regarding recognition or suspension and timelines for completing assessments or reassessments according to the criteria specified in Annex 3;

(b) adopting, where necessary, appropriate complementary technical and administrative measures for the effective implementation of this Agreement;

(c) resolving issues that may arise concerning the implementation of this Agreement;

(d) considering ways to enhance the operation of this Agreement; and

(e) considering whether to amend this Agreement.

4. The Joint Committee of the Authorities shall meet at the request of one of the Authorities with respect to disagreements between the Authorities, including determinations of recognition or suspension, at such times as this committee may agree.

5. The Joint Committee of the Authorities may meet in person or by other means as agreed to by this committee.

Article 15: Joint Committee of the Parties ("Joint Committee")

1. The Parties hereby establish a Joint Committee.

2. The Joint Committee shall be composed of government representatives of each Party, including representatives from each Authority. It shall be co-chaired by both Parties. The Joint Committee shall make its decisions by unanimous consent. It shall determine its own rules and procedures.

3. The Joint Committee may consider any matter relating to this Agreement. In particular, its functions shall include the following:

(a) considering any matter referred by the Joint Committee of the Authorities, as listed under paragraph 3 of Article 14;

(b) considering trade facilitating measures and the impact on small- and medium-sized businesses;

(c) resolving issues that may arise concerning the implementation of this Agreement;

(d) noting decisions of the Joint Committee established under Article 14 of the *Agreement on mutual recognition between the European Community and the United States of America* with respect to matters that relate to this Agreement; and

(e) considering whether to amend or terminate the Agreement, including any Annexes.

4. The Joint Committee may meet in person or by other means as agreed to by this committee

Article 16: Other Agreements

1. Except where there is written agreement between the Parties, obligations contained in a mutual recognition agreement or any other agreement between a Party and a non-Party shall have no effect with regard to the other Party.

2. This Agreement shall not affect the rights and obligations of the Parties under any other international agreement.

Article 17: Entry into Force, Amendment, and Termination

1. Each Party shall notify the other Party, in writing, once its Authority has:

   (a) completed the assessments according to the criteria and procedure specified in Annex 3; and

   (b) positively recognized the Authority of the other Party pursuant to Article 4,

and the Party has completed the internal procedures required for the entry into force of this Agreement.

2. This Agreement shall enter into force the day following the last notification.

3. This Agreement may be amended by written agreement of the Parties.

4. Annexes of this Agreement shall form an integral part thereof. The Joint Committee of the Parties may decide to amend an Annex.

5. Either Party may terminate this Agreement by providing the other Party six months' notice in writing.

6. The Parties shall continue, after termination of this Agreement, to recognize official GMP documents issued in accordance with, and prior to the expiry of, this Agreement, provided that the GMP documents were issued before the notice of termination was provided.

IN WITNESS WHEREOF, the undersigned, being duly authorized by their respective Governments, have signed this Agreement in duplicate, in English and German languages, both texts being equally authentic.

DONE at Washington DC, in duplicate, this 12 of January, 2023.

FOR THE GOVERNMENT OF THE UNITED STATES OF AMERICA	**FOR THE GOVERNMENT OF THE SWISS CONFEDERATION**
United States Trade Representative	State Secretariat for Economic Affairs
United States Food and Drug Administration	Swiss Agency for Therapeutic Products

ANNEX 1

Applicable Laws and Regulations

The applicable laws and regulations for each Party are as follows:

(a) For Switzerland:

(i) Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA, SR 812.21). Of particular relevance: Chapter 2 (Medicinal Products) Section 1 (Manufacture) Art. 5, 6, 7; Section 3 (Imports, Exports and Foreign Trade) Art.18 et seqq.; Chapter 4 (Common Provisions on Medicinal Products and Medical Devices), Section 3 (Market Surveillance and Inspection Procedures) Art. 58, 60;

(ii) Ordinance on Licencing in the Medicinal Products Sector (Medicinal Products Licencing Ordinance, MPLO, SR 812.212.1). Of particular relevance: Chapter 2 (Establishment Licences) Section 1 (Manufacturing Licence) Art. 3 et seqq.; Chapter 3 (Licensing Procedure) Art. 39 et seqq.; Chapter 6 (Implementation) Section 1 (Inspections) Art. 56 et seqq.; Section 2 (Collaboration between Swissmedic and Other Authorities) Art. 64; Annex 1 (International rules of Good Manufacturing Practice);

(b) For the United States:

(i) Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq. Of particular relevance: 21 U.S.C. 351(a)(2)(B) (drug adulterated if not manufactured in conformance with current good manufacturing practice); 21 U.S.C. 355(d)(3); 21 U.S.C. 355(j)(4)(A) (approval of human drug contingent on adequacy of methods, facilities, and controls for manufacturing, processing, and packing to preserve the identity, strength, quality, and purity of drug); 21 U.S.C. 360b(c)(2)(A)(i) and 360b(d)(l)(C) (approval of animal drug contingent on adequacy of methods, facilities, and controls for manufacturing, processing, and packing to preserve the identity, strength, quality, and purity of drug); 21 U.S.C. 374 (inspection authority); and 21 U.S.C. 384e (recognition of foreign government inspections);

(ii) Public Health Service Act Section 351, 42 U.S.C. 262. Of particular relevance: 42 U.S.C. 262(a)(2)(C)(i)(II) (licensing of biologic contingent on demonstration that the facility in which it is manufactured, processed, packed, or held meets standards designed to assure that the product continues to be safe, pure, and potent); and 42 U.S.C. 262(j) (Federal Food, Drug, and Cosmetic Act applies to biologic products);

(iii) 21 C.F.R. Part 210 (Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding of Drugs; General);

(iv) 21 C.F.R. Part 211 (Current Good Manufacturing Practice for Finished Pharmaceuticals); and

(v) 21 C.F.R. Part 600, Subpart B (Establishment Standards) and Subpart C (Establishment Inspection).

ANNEX 2

List of Products Covered by this Agreement

1. To the extent described in paragraphs 3 and 4, the provisions of this Agreement apply to finished pharmaceuticals for human or animal use, intermediates (for Switzerland as defined in Swiss law) and in-process materials (for the United States as defined under U.S. law), certain biological products for human use, and active pharmaceutical ingredients.

2. The list of products covered by the Agreement is provided in paragraph 4. The laws and regulations listed in Annex 1 of each Party provide the definition of each product listed in paragraph 4 applicable in each Party.

3. Notwithstanding any other provision of this Agreement, human blood, human plasma, human tissues, cells, organs, and veterinary immunologicals are excluded from the scope of this Agreement.

4. The following products are covered by this Agreement:

(a) marketed finished pharmaceuticals for human use in various pharmaceutical dosage forms such as tablets, capsules, ointments, and injectables, including:

(i) medical gases;

(ii) radiopharmaceuticals or radioactive biological products;

(iii) herbal (botanical) products*; and

(iv) homeopathic products;

(b) the following marketed biological products:

(i) plasma derived pharmaceuticals;

(ii) therapeutic biotechnology-derived biological products;

(iii) allergenic products; and

(iv) vaccines for human use***;

(c) in process materials (for the United States) and intermediates (for Switzerland);

(d) active pharmaceutical ingredients or bulk drug substances;

(e) investigational products (clinical trial material)**; and

(f) veterinary products:

(i) veterinary pharmaceuticals, including prescription and non-prescription drugs, with the exclusion of veterinary immunologicals; and

(ii) pre-mixes for the preparation of veterinary medicated feeds (for Switzerland) and Type A medicated articles for the preparation of veterinary medicated feeds (for the United States).

* These are included to the extent that they are regulated as drugs by FDA and medicinal products by Switzerland.

** Swissmedic conducts inspections of investigational medicinal products. FDA does not routinely conduct GMP inspections for investigational medicinal products. Inspection information on these products will be provided to the extent that they are available and resources allow.

*** These products are only included within the product coverage of this Agreement to the extent the Joint Committee of the Authority decides to include them and the Joint Committee of the Parties amends this annex pursuant to Article 12.

ANNEX 3

Criteria and Procedure for Assessments Under this Agreement

I. Criteria for Assessments under this Agreement:

Each Party will apply the following criteria to determine whether to recognize an Authority:

(i) The Authority has the legal and regulatory authority to conduct inspections against a standard for GMP;

(ii) The Authority manages conflict of interest in an ethical manner;

(iii) The Authority has the ability to evaluate risks and mitigate them;

(iv) The Authority maintains appropriate oversight of manufacturing facilities within its jurisdiction;

(v) The Authority has and uses sufficient resources;

(vi) The Authority employs trained and qualified inspectors with the skills and knowledge to identify manufacturing practices that may lead to patient harm; and

(vii) The Authority has the tools necessary to take action to protect the public from harm due to poor quality drugs or medicinal products.

II. Procedures for Assessment under this Agreement

A. Assessment of Swissmedic by FDA

1. To receive a capability assessment for an authority, Swissmedic shall submit capability assessment packages containing the following materials before FDA will initiate an assessment:

(i) a finalized Pharmaceutical Inspection Convention/Scheme (PIC/S) audit report of an audit or assessment reports provided by a non-Party with which Switzerland has an agreement. Such information should include any associated corrective measures and all documents cited by the auditors in the report for the indicators as identified by FDA in the audit checklist as essential

for the assessment and for any indicators that required the authority to propose a corrective and preventative action;

(ii) a completed conflicts of interest questionnaire established by FDA signed by a principal of Swissmedic;

(iii) a total of four inspection reports including the report from the inspections observed by FDA;

(iv) standard operating procedures or a description of how the authority finalizes inspection reports, including inspection reports of foreign facilities;

(v) standard operating procedures related to training and inspector qualification, including training files and ongoing competency evaluations for all inspectors who conducted the inspections in the reports provided to FDA (pursuant to subparagraph (iii)); and

(vi) its most recent inventory of manufacturing facilities within its territory and under the authority's jurisdiction, including type of manufacturing facility of products falling within the product coverage of this Agreement, and upon request, completion of a table provided by FDA detailing types of manufacturing facilities.

2. FDA observed inspections representative of the different regions, if applicable.

3. During a capability assessment, FDA may require additional or alternative information or further clarification from Swissmedic.

4. FDA may waive the requirement to submit certain information listed under II.A of this Annex. The decision to waive any assessment materials will be made by FDA on a case-by-case basis.

B. Assessment of FDA by Swissmedic

1. To receive an equivalency assessment for an authority, FDA shall submit equivalency assessment packages containing the following materials before Swissmedic will initiate an assessment:

(i) a finalized Pharmaceutical Inspection Convention/Scheme (PIC/S) audit report of an audit or assessment reports provided by a non-Party with which the United States has an agreement. Such information should include any associated corrective measures and all documents cited by the auditors in the report for the indicators as identified by Swissmedic in the audit checklist as essential for the assessment and for any indicators that required the authority to propose a corrective and preventative action;

(ii) a completed conflicts of interest questionnaire established by Swissmedic signed by a principal of FDA;

(iii) a total of four inspection reports including the report from the inspections observed by Swissmedic;

(iv) standard operating procedures or a description of how the authority finalizes inspection reports, including inspection reports of foreign facilities;

(v) standard operating procedures related to training and inspector qualification, including training files and ongoing competency evaluations for all inspectors who conducted the inspections in the reports provided to Swissmedic (pursuant to subparagraph (iii)); and

(vi) its most recent inventory of manufacturing facilities within its territory and under the authority's jurisdiction, including type of manufacturing facility of products falling within the product coverage of this Agreement, and upon request, completion of a table provided by Swissmedic detailing types of manufacturing facilities.

2. Swissmedic observed inspections representative of the type of inspections, if applicable.

During an equivalency assessment, Swissmedic may require additional or alternative information or further clarification from FDA.

4. Swissmedic may waive the requirement to submit certain information listed under II.B of this Annex. The decision to waive any assessment materials will be made by Swissmedic on a case-by-case basis.

C. Reassessment of an Authority

An Authority may reassess the other Authority to maintain ongoing status of each Authority's capability or in the event an Authority issues a suspension or negative determination of an Authority. In the event of a suspension or negative determination, the scope of the reassessment shall relate to the reasons for the suspension or negative determination.

III. Maintaining Recognition

To maintain recognition, the recognized Authority must continue to meet the criteria set out in section I of this Annex. In case a recognized Authority has not been subject to a PIC/S reassessment for a period of six years, the recognizing Authority shall have the right to audit the recognized Authority.