ANNEX A

DEFINITION OF TERMS

The following terms or words and phrases shall mean or be understood as follows:

A. Advance Therapy Medicinal Product (ATMP) for human use – refers to any cell or gene therapy product or tissue engineered product that has been substantially manipulated and/or performs a different function in the recipient than in the donor. Although typically produced from substantially manipulated or genetically modified somatic cells or tissues, ATMPs may also include nucleic acids, and viral and non-viral vectors, as well as recombinant bacterial cells and recombinant oncolytic viruses.

B. Authorized Person - refers to the owner, President, Chief Executive Officers (CEO), manager, or its equivalent officer representing the establishment in an authorized or official capacity as signatories to required documents for purposes of filing of covered applications before the FDA.

C. Contract Research Organization (CRO) – refers to a person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions (ICH GCP 1.20).

D. Contracting – refers to the formal and documented evidence of activities, including such other activities included in this AO, undertaken by the contract acceptor (referred to as Contract Manufacturer including Packer and Repacker) to its contract giver (referred to as its Client) with regard to the manufacturing/packing/repacking of the client.

E. Custom-Made Medical Device – refers to any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient. For the purpose of clarity, mass produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user shall not be considered to be custom-made medical devices.

F. Declaration and Undertaking – refers to a binding agreement of the applicant-establishment with the FDA in providing accurate information, affirming primary responsibility over the products and facilities, and complying with all the rules and regulations set forth during and after the application process, among others. Declaration of false, other forms of misrepresentation, or withholding of data or information are grounds for disapproval of the application, or suspension or revocation of the issued authorization and may subject the person involved to criminal prosecution.

G. Distributor-Exporter - refers to any establishment that exports raw materials, active ingredients, and finished products for distribution to other establishments outside the country.

H. Distributor-Importer – refers to any establishment that imports raw materials, active ingredients and/or finished products for wholesale distribution to other local FDA-licensed establishments.

I. Distributor-Wholesaler - refers to any establishment that procures raw materials, active ingredients and/or finished products from local FDA-licensed establishments for local distribution on a wholesale basis.

J. Good Practice (GxP) – refers to officially acceptable practices and standards in the conduct of health product activities such as but not limited to good manufacturing Practices (GMP), good laboratory practices (GLP), good clinical practices (GCP), and good distribution and storage practices (GDSP).

K. Health-related device – refers to any device not used in health care but has been determined by the FDA to adversely affect the health of the people.

L. Initial Application - refers to the type of LTO application submitted to the FDA prior to engaging in the business or operation involving the manufacture, importation, exportation, retail, distribution, transfer, and where applicable the use, testing, promotion, advertisement, and/or sponsorship of health products.

M. Institutional Pharmacy – refers to drug establishment which is non-government entity/organization procuring drugs to be dispensed whether at a cost or as part of employee's benefits and/or its dependents.

N. License to Operate – refers to an authorization issued by the FDA granting an application to operate or establish an establishment prior to engaging in the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and where applicable the use, testing, promotion, advertisement, and/or sponsorship of health products.

O. Major Variation - covers changes in the operations of the establishment that may affect significantly and/or directly the aspects of safety and quality and when applicable, efficacy of the products.

P. Manufacturer - refers to any establishment engaged in any and all operations involved in the production of health products including preparation, processing, compounding, formulating, filling, packing, repacking, altering, ornamenting, finishing, and labeling with the end in view of its storage, sale, or distribution: Provided, that the term shall not apply to the compounding and filling of prescriptions in drugstores and hospital pharmacies. A trader shall be categorized as a manufacturer.

Q. Minor Variation - covers changes in administrative matters and/or changes in the operations of the establishments but with minimal impact on the safety, quality, and when applicable, efficacy of the products.

R. Micro Small Medium Enterprises (MSMEs) - the defined under Republic Act No. 9501 entitled "Magna Carta for Micro, Small and Medium Enterprises (MSMEs)", refers to any business activity or enterprise engaged in industry, agribusiness and/or services, whether single proprietorship, cooperative, partnership or corporation whose total assets, inclusive of those arising from loans but exclusive of the land on which the particular business entity's office, plant and equipment are situated, must have value falling under the following categories: a.) Micro, not more than P3,000,000, b.) Small, P3,000,001 but not more than P15,000,000, and c.) Medium, P15,000,001 but not more than P100,000,000. More than P100,000,000 is considered a large enterprise.

S. Packer – refers to any establishment that packages bulk products into its immediate container with the end view of storage, distribution, or sale of the product.

T. Pre-licensing Inspection – refers to an inspection performed prior to the approval of a license (initial application) or significant change (major variation) to facility(ies), warehouses, and/or offices of an establishment to ensure compliance to the provisions of this Order and to the other related FDA-implemented and existing regulations and standards.

U. Qualified Person (QP) - refers to an organic or full-time employee of the establishment who possesses technical competence related to the establishment's activities and health products by virtue of his profession, training, or experience. A qualified person has the responsibility to comply with the technical requirements of the FDA, discuss or clarify matters with the FDA when submitting technical requirements, or engage FDA officials when conducting inspections or Post-Marketing Surveillance (PMS) activities. The qualified person may also be the duly Authorized Person of the establishment.

V. Refurbisher – refers to an establishment engaged in the rebuilt of certain medical device (in whole or any part thereof), whether or not using parts from one or more used certain medical devices of the same kind, so as to create a medical device that can be used for the purpose originally intended by the product owner of the original medical device.

W. Renewal Application - refers to the type of LTO application submitted to the FDA before the expiration of the validity of the current LTO for business operation continuity involving manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and where applicable, the use, testing, promotion, advertisement, and/or sponsorship of health products.

X. Repacker - refers to any establishment that repacks a finished product into smaller quantities in a separate container and/or secondary packaging, including but not limited to relabeling, stickering, and bundling for promo packs with the end view of storage, distribution, or sale of the product.

Y. Request for Reconsideration – refers to the process where an applicant formally requests and seeks a review or re-evaluation of a decision disapproving an application for initial licensing, renewal, or variation.

Z. Retailer – refers to any establishment which sells or offers to sell any health product directly to the general public.

AA. Risk Categorization on Establishment is a classification system used to assess and categorize health product manufacturers based on the complexity of the site, the processes involved in production, and the types of health products manufactured. The classification can be low, medium, or high risk or their equivalence.

In case of more than one product line in a manufacturer with a different identified risk category, the highest risk shall prevail.

BB. Risk Management Plan - refers to a set of health product vigilance activities and interventions designed to identify, characterize, prevent, or minimize risks relating to health products, and the assessment of the effectiveness of those interventions. The risk management plan is a requirement for the issuance of the appropriate authorization.

CC. Routine Inspection - refers to the general process of physical or remote inspection of the factories, facility(ies), warehouses, and/or offices of an establishment in which health products are manufactured, processed, packed, or held, for introduction into domestic commerce or are held after such introduction, which is conducted by the FDA at any time during the validity of the issued LTO. A routine inspection is also referred to as a post-licensing inspection.

DD. Site Master File - refers to specific information about the quality assurance, production, and/or quality control of manufacturing operations carried out at the named site and any closely integrated operations at adjacent and nearby buildings. If only part of an operation is carried out on the site, a Site Master File needs only to describe those operations, e.g., analysis, packaging, for documentation.

EE. Sponsor - refers to an individual, company, institution, organization, or entity that takes responsibility for the initiation, management, and/or financing of a clinical trial.

FF. Trader - refers to an establishment that is a registered owner of a health product, procures the raw materials and packing components, provides the production, monographs, quality control standards, and procedures, but subcontracts the manufacture of such a product to a licensed Manufacturer. In addition, a trader may also engage in the distribution and/or marketing of its products.