ANNEX A

POLICY EVIDENCE REFERENCES

1. Administrative Order No. 7 s.1986	Amending A.O. No. 133 s. 1985 Re: Guidelines on the evaluation and registration of Fixed Dose Combination
2. Administrative Order No. 67 s.1989	Revised Rules and Regulations on Registration of Pharmaceutical Products
3. Administrative Order No. 96 s. 1990	Guidelines on the Registration of Fixed-Dose Combination Drug Products
4. BFAD Circular 12 s.1991	Clarification of New Registration when there is a Change of Manufacturer
5. Administrative Order No. 117 s.1992	Providing for the Classification of Household Remedies
6. Bureau Circular No. 17 s.1992	Registration of Household Remedies
7. Republic Act No. 7719	National Blood Services Act of 1994
8. Administrative Order No. 9 s.1995	Rules and Regulations Implementing RA 7719 otherwise known as “the National Blood Service Act of 1994”
9. BFAD Circular 05 s.1997	Revised Checklist of Requirements and the 1997 Guidelines for the Registration of Pharmaceutical Products
10. Administrative Order No. 23-C s.2000	Policies and Guidelines on Over-The-Counter (OTC) Drug Products
11. Bureau Circular No. 11 s.2001	Over-the-Counter (OTC) Drugs Reclassified as Household Remedies
12. Bureau Circular No. 13-A s.2001	Amendment to Bureau Circular No. 11 s., 2001 "Over-the-Counter (OTC) Drugs reclassified as Household Remedies”
13. Bureau Circular No. 14 s.2001	Amendment to Bureau Circular No. 13-A s., 2001 "Over-the-Counter (OTC) Drugs Reclassified as Household Remedies"
14. Bureau Circular No. 17 s.2001	(No subject) Answers to queries on classification
15. Bureau Circular No. 3 s.2002	Reclassification of Sambong 250mg Tablet from Over-the-Counter (OTC) to Household Remedy
16. Bureau Circular No. 02 s.2003	Classification of Paracetamol Syrup/Suspension 120 mg/5 mL and 125 mg/5 mL
17. Administrative Order No. 142 s.2004	Bureau of Food and Drugs (BFAD)'s issuance of Certificate of Product Registration for Foreign Assisted Projects Procurement and Laboratory Testing of Pharmaceutical and Biological products Procured by and/or delivered to the Department of Health

18. Administrative Order No. 2005-0002	Rules and Regulations for the Establishment of the Philippine National Blood Services Amending Pertinent Provisions of the Admin. Order No. 9, s. 1995 (Rules and Regulations Implementing RA 7719 Otherwise Known as the National Blood Services Act of 1994)
19. Administrative Order No. 2005-0007	Amending Administrative Order No. 142, s. 2004 by providing exemption from the requirement of Certificate of Product Registration for all goods procured through UNICEF, UNDP, WHO, and GDF
20. Administrative Order No. 2005-0030	Guidelines and Procedure for the Automatic Renewal of the Certificate of Product Registration issued by the Bureau of Food and Drugs
21. Administrative Order No. 2005-0031	Guidelines and Procedure for the Issuance of the Principal Certificate of Product Registration and the Listing of Identical Drug Products based on the Identity of Manufacturer and Pharmaceutical Formulation
22. Administrative Order No. 2006-0021	Supplemental Guidelines to Administrative Order (AO) 67 s. 1987, Revised Rules and Regulations on Registration of Pharmaceutical Products and Bureau Circular 05 s. 1997 in evaluating New Drug Applications
23. Administrative Order No. 2012-0011	Further Amendment of Administrative Order No. 142 s. 2004
24. FDA Circular No. 2013-004	Post Market Surveillance (PMS) of Authorized Drug Products
25. Administrative Order No. 2013-0012	Rules and Regulations Governing the Accreditation of Health Facilities Engaging in Human Stem Cell and Cell-Based or Cellular Therapies in the Philippines
26. Administrative Order No. 2014-0016	Adoption of the World Health Organization "Guidelines on Evaluation of Similar Biotherapeutic Products (SBPs)" for the Registration of Biosimilar Products
27. Administrative Order No. 2014-0034	Rules and Regulations on the Licensing of Establishments Engaged in the Manufacture, Conduct of Clinical Trial, Distributions, Importation, Exportation, and Retailing of Drug Products, and Issuance of Other Related Authorizations
28. FDA Circular No. 2014-008	Application Process and Requirements for Post-approval Changes of Pharmaceutical Products
29. FDA Circular No. 2014-015	Manufacture, Sale, and Distribution of Traditional and Alternative Medicines
30. FDA Advisory No. 2014-016	Review of Guidelines for Over-the-Counter Drugs
31. FDA Circular No. 2014-028	Guidelines on the Implementation of New Rules and Regulations on the Licensing of Retail Outlet for Non-Prescription Drugs

	(RONPDs) following Administrative Order No. 2014-0034, dated 13 October 2014
32. Administrative Order No. 2016-0004	Revised Guidelines in the Facilitation and Management of Foreign Donations involving Health and Health-Related Products
33. Administrative Order No. 2016-0008	Revised Rules and Regulations Governing the Generic Labeling Requirements of Drug Products for Human Use
34. FDA Circular No. 2018-012	Rescinding FDA Circ No. 2013-004 and Instituting Post-marketing Surveillance (PMS) Requirements for New Drugs Under Monitored Release
35. FDA Circular No. 2018-014	Validity of Certificated of Product Registration (CPRs) in the Pilot Project on Review of Over-the-Counter Medicines Applications (ROTCA) Medicines
36. Administrative Order No. 2020-0001	Guidelines in the Importation, Facilitation, and Management of Foreign Donations involving Health and Health-Related Products
37. Administrative Order No. 2020-0010	Regulations on the Conduct of Clinical Trials for Investigational Products
38. Administrative Order No. 2020-0028	Amendment to Administrative Order No. 4 s. 1992 entitled "Policy Requirements for Availing Compassionate Special Permit (CSP) for Restricted Use of Unregistered Drug and Device Product/Preparation"
39. FDA Circular No. 2020-003	Guidelines for Pharmaceutical Industry on Pharmacovigilance
40. FDA Circular No. 2020-006	Guidance for Application and Transactions at the Food and Drug Administration in Light of the Community Quarantine Declaration
41. FDA Circular No. 2020-006-A	Amendment to FDA Circ No. 2020-006 Issued on 17 March 2020
42. FDA Circular No. 2020-026	Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the Food and Drug Administration (FDA)
43. FDA Circular No. 2020-029	Guidance on Applications for the Conduct of COVID-19 Clinical Trials
44. FDA Circular No. 2020-029-A	Amendment to FDA Circ No. 2020-029
45. FDA Circular No. 2020-036	Guidelines on the Issuance of Emergency Use Authorization for Drugs and Vaccines for COVID-19
46. FDA Circular No. 2021-006	Interim Guidelines on the Issuance of Certificate of Accreditation and Inspection of Bioequivalence (BE) Testing
47. FDA Circular No. 2021-008	Updated Guidelines for the Registration of Drug Products under Emergency Use (DEU) for COVID-19

48. FDA Circular No. 2021-020	Revised Post-Marketing Surveillance Requirements for New Drugs under Monitored Release
49. Republic Act No. 1517	An Act Regulating the Collection, Processing And Sale Of Human Blood, And The Establishment And Operation Of Blood Banks And Blood Processing Laboratories