

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION





1 6 AUG 2019

TO:

THE GENERAL PUBLIC

SUBJECT: Certification of Contraceptive Products in Compliance to the Implementing Rules and Regulations of the Republic Act No. 10354, Also Known as the Responsible Parenthood

Reproductive Health Act of 2012

In compliance with Republic Act No. 10354, also known as "The Responsible Parenthood and Reproductive Health Act of 2012" and its IRR, the Food and Drug Administration (FDA) hereby invites all concerned to submit their petitions and any corresponding evidence on the mechanism of action of the following contraceptive products within ten (10) calendar days from the posting of this Advisory:

	Generic Name	Dosage Strength and Form	Brand Name	Marketing Authorization Holder (MAH)
1)	Chlormadinone acetate + Ethinylestradiol	2 mg + 30 mcg Film- Coated Tablet	Belara	PharmAsia-Cuvest, Inc.
2)	Levonorgestrel + Ethinylestradiol	150 mcg/30 mcg Tablet	None	Endure Medical, Inc.
3)	Lynestrenol	500 mcg Tablet	Lyndel	Endure Medical, Inc.
4)	Medroxyprogesterone acetate	50 mg/mL Suspension for Injection (IM)	Trust 1Ml Injectable	DKT Health Inc.
5)	Medroxyprogesterone acetate	50 mg/mL Suspension for Injection (IM)	Trust 3Ml Injectable	DKT Health Inc.
6)	Medroxyprogesterone acetate + Estradiol Cypionate	25 mg/0.5 mL + 5 mg/0.5 mL Suspension for Injection (IM)	Trust One- Month Injectable	DKT Health Inc.
7)	Levonorgestrel	75 mg Subdermal Implant	Jadelle	Bayer Philippines, Inc.
8)	Norethisterone	5 mg Tablet	Primolut N	Bayer Philippines, Inc.
9)	Drospirenone + Ethinylestradiol	3 mg + 20 mcg Film- Coated Tablet	Dronis	Sun Pharma Philippines, Inc.
10)	Drospirenone + Ethinylestradiol	3 mg + 30 mcg Film- Coated Tablet	Drospill	Sun Pharma Philippines, Inc.
11)	Cyproterone acetate + Ethinylestradiol	2 mg + 35 mcg Film- Coated Tablet	Suncet 35	Sun Pharma Philippines, Inc.



12) Levonorgestrel + Ethinylestradiol	150 mcg + 30 mcg Tablet	Solenn	Lloyd Laboratories, Inc.
13) Drospirenone +	30 mcg + 300 mcg	Zahra	Atlantic
Ethinylestradiol	Tablet		Pharmaceuticals, Inc.

Documents and scientific evidence can be submitted to the Food and Drug Action Center (FDAC), 3rd Floor Starmall, Alabang, Muntinlupa on Mondays to Fridays, 8:00 am to 5:00 pm.

20190806170214

ROLANDO ENRIQUE D. DOMINGO, MD, DPBO

Undersecretary of Health
Officer-in-Charge, Director General