



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



FDA ADVISORY  
No. **2018-195**

08 JUN 2018

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 and 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) Cyproterone acetate + Ethinylestradiol	2mg / 35mcg Tablet	Ridne-35	Hyphens Pharma Philippines Inc.
2) Cyproterone acetate + Ethinylestradiol	2mg / 35mcg Film-Coated Tablet	Ethidol-C	Ambica International Corporation
3) Cyproterone acetate + Ethinylestradiol	2mg / 35mcg Tablet	Estelle-35D	Zuellig Pharma Corporation
4) Cyproterone acetate + Ethinylestradiol	2mg / 35mcg Film-Coated Tablet	Safex	A.T.C. Health Care Int'l Corp.
5) Cyproterone acetate + Ethinylestradiol	2mg / 35mcg Tablet	Diane 35	Bayer Philippines Inc.
6) Cyproterone acetate + Ethinylestradiol	2mg / 35mcg Tablet	Ariane	Innogen Pharmaceuticals, Inc.
7) Cyproterone acetate + Ethinylestradiol	2mg / 35mcg Tablet	Faye	AAA Pharma, Inc.
8) Cyproterone acetate + Estradiol valerate	2mg / 1mg Tablet	Climen 28	Bayer Philippines Inc.
9) Desogestrel	75 mcg Tablet	Andrea	DKT Health, Inc.
10) Desogestrel	75 mcg Film-Coated Tablet	Desirett	Exeltis Philippines Inc.
11) Desogestrel + Ethinylestradiol	150mcg / 30mcg Tablet	Daisy-30	S.M.H.P. Marketing & Consultancy
12) Desogestrel + Ethinylestradiol	150mcg / 30mcg Film-Coated Tablet	Mariona	Exeltis Philippines Inc.



13) Dienogest	2 mg Tablet	Vinca	Chemway Pharma, Inc.
14) Drospirenone + Ethinylestradiol	3mg / 20mcg Tablet	Gvez	Metro Drug, Inc.
15) Drospirenone + Ethinylestradiol	3mg / 30mcg Film-Coated Tablet	Gveza	Metro Drug, Inc.
16) Drospirenone + Ethinylestradiol	3mg / 30mcg Tablet	Erin	DKT Health, Inc.
17) Estradiol + Drospirenone	2mg / 1mg Tablet	Angeliq	Bayer Philippines, Inc.
18) Levonorgestrel	1.5 mg Film-Coated Tablet	Co-Pill	Ambica International Corporation
19) Levonorgestrel	1.5 mg Film-Coated Tablet	Gestrex	Next Chemical Enterprises
20) Levonorgestrel	750 mcg Tablet	Lenor-72	Ambica International Corporation
21) Levonorgestrel	30 mcg Tablet	Safex	Golden Dale Pharma Corp.
22) Levonorgestrel	1.5 mg Tablet	Levonion One	Bonamis Pharmacy Philippines Corporation
23) Levonorgestrel	750 mcg Tablet	Contra 72	Pharmastar Int'l Trading Corporation
24) Levonorgestrel + Ethinylestradiol	20mg/mL Tablet	Aecys	Fresenius Kabi Philippines Inc.
25) Levonorgestrel + Ethinylestradiol	150 mcg / 30 mcg Sugar-Coated Tablet	Zinnia P	S.M.H.P. Marketing & Consultancy
26) Levonorgestrel + Ethinylestradiol	250mcg / 50mcg Film-Coated Tablet	Florina-G	Ambica International Corporation
27) Levonorgestrel + Ethinylestradiol	150mcg / 30mcg Tablet	Besafe	AAA Pharma, Inc.
28) Levonorgestrel + Ethinylestradiol	150mcg / 30mcg Film-Coated Tablet	Meleva	Chemway Pharma, Inc.
29) Levonorgestrel + Ethinylestradiol	150mcg / 30mcg Film-Coated Tablet	Florina	Ambica International Corporation
30) Levonorgestrel + Ethinylestradiol	150mcg / 30mcg Tablet	Conchoice	Sun Pharma Philippines Inc.
31) Levonorgestrel + Ethinylestradiol	250mcg / 50mcg Tablet	Conchoice Plus	Sun Pharma Philippines Inc.
32) Levonorgestrel + Ethinylestradiol + Ferrous fumarate	125mcg / 30mcg; 75mcg Film-Coated Tablet	Safex-Combi	Golden Dale Pharma Corporation
33) Levonorgestrel + Ethinylestradiol + Ferrous fumarate	150mcg / 30mcg / 75mg Film-Coated Tablet	Helena Plus	Eon Pharmatek, Inc.
34) Medroxyprogesterone acetate	150 mg/mL Injection	Famy-Depo	S.M.H.P. Marketing & Consultancy

35) Medroxyprogesterone acetate	50 mg/mL Suspension for Injection (I.M.)	Contracep	Healol Pharma Corporation
36) Medroxyprogesterone acetate	Sterile Aqueous Suspension for Injection	Depo-Provera	Pfizer, Inc.
37) Medroxyprogesterone acetate	104mg / 0.65mL Suspension for Injection	Sayana Press	Pfizer, Inc.
38) Medroxyprogesterone acetate	150 mg/mL Sterile Aqueous Suspension for Injection (I.M.)	Femme-3	Amtol Pharma Imports Inc.
39) Medroxyprogesterone acetate	50 mg/mL (150mg / 3mL) Solution for Injection (I.M.)	Provestin	Phil Pharmawealth, Inc.
40) Medroxyprogesterone acetate	10 mg Tablet	Deporeva	QB International Trade
41) Medroxyprogesterone acetate	10 mg Tablet	Xygyn	Ambica International Corporation
42) Medroxyprogesterone acetate	150 mg/mL	Daisy-30	S.M.H.P. Marketing & Consultancy
43) Lynestrenol	500 mcg Tablet	None	DKT Health, Inc.
44) Norethisterone	5 mg Tablet	None	Ambica International Corporation
45) Norethisterone	5 mg Tablet	Steron	Ambica International Corporation
46) Norethisterone	5 mg Tablet	NCnorm-P	Ambica International Corporation
47) Norethisterone + Ethinylestradiol	400mcg / 35mcg	None	Lloyd Laboratories, Inc.
48) Norgestrel + Ethinylestradiol	500mcg / 50mcg Film-Coated	Florina-N	Ambica International Corporation
49) Intra Uterine Contraceptive Device, Code: TCU 380A	N/A	Eve's	AAA Pharma, Inc.
50) Intrauterine Contraceptive Device	N/A	Pregna	DKT Philippines, Inc.

Documents and scientific evidence can be submitted to the Food and Drug Action Center (FDAC), Civic Drive, Filinvest City, Alabang, Muntinlupa on Mondays to Fridays, 8:00 am to 5:00 pm.



*Charade Puno*  
**NELA CHARADE G. PUNO, RPh**  
 Director-General / Undersecretary