



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA CIRCULAR

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No. **2018-014**

SUBJECT: Validity of Certificates of Product Registration (CPRs) in the Pilot Project on Review of Over-the-Counter Medicines Application (ROTCA) Medicines

Pursuant to the strategies and directives of the Center for Drug Regulation and Research (CDRR) to streamline the registration process, Pilot Project ROTCA is hereby promulgated.

Pilot Project ROTCA is a prospective, short duration, medium-resource project to obtain information on the feasibility of streamlined measures. The objectives of the pilot project are the following:

- Identification of gaps in the proposed tier system
- Reduction of the number of registration backlogs
- Hastening the availability of Over-the-Counter (OTC) drug products to the public. Under the OTCs are Household Remedies (HR, Schedule 6, refer to Annex B) and Pharmacist-Only Medicines (POMs, Schedule 5, refer to Annex A).

An estimated reduction on the processing timelines of 75% for HR and 30% for POMs are expected on proposed tier system.

To operationalize the project, participating applications, as nominated by their respective associations are hereby authorized to submit only the following requirements as part of their registration dossier:

Table 1. List of Requirements for the Tier 1 and Tier 2 Systems	
Tier 1 Notification Applications (Applicable for Schedule 6 or HR)	Tier 2 Compliance to Monograph Applications (Applicable for Schedule 5 or POMs)
<ol style="list-style-type: none">1. Two (2) original hard copies of notarized notification form2. Notification form in .doc or .docx format3. Portable Document Format (PDF) copy of the signed integrated application form4. Integrated Application Form (IAF) in .xls or .xlsx format5. Facsimile of labeling materials	<ol style="list-style-type: none">1. IAF in .xls or .xlsx format2. Unit dose and batch formulation3. Finished product specifications4. Container closure system5. Stability data6. Facsimile of labeling materials



Likewise, participating applications are hereby authorized to undergo the proposed process as described below:

Table 2. Step by Step Procedure for Tier 1 and Tier 2 Systems Application	
Tier 1 Notification Applications	Tier 2 Compliance to Monograph Applications
<ol style="list-style-type: none"> 1. Using the same process of application for FDAC submission: <ol style="list-style-type: none"> a. The applicant shall send an email to fdac@fda.gov.ph and add "ROTCA<space>" at the beginning of the standard subject used for scheduling. b. A Document Tracking Log (DTL) will be issued through email along with the schedule to appear. 2. Payment 3. Submission to ROTCA Officers of the requirements for Tier 1 application. 4. Processing of Tier 1 applications is within fifteen (15) Calendar Days (CD). 5. Issuance and release of assessed notification form, including Certificate of Product Registration (CPR) or Letter of Disapproval (LOD) at FDAC. 	<ol style="list-style-type: none"> 1. Using the same process of application for FDAC submission: <ol style="list-style-type: none"> a. The applicant shall send an email to fdac@fda.gov.ph and add "ROTCA<space>" at the beginning of the subject of the standard subject used for scheduling. b. A DTL will be issued through email along with the schedule to appear. 2. Payment 3. Submission of dossier requirements to designated ROTCA officers using the prescribed electronic format (e.g. .pdf file) 4. Processing of Tier 2 applications is within thirty (30) CD. 5. Issuance and release of CPR with commitment letter (if applicable) or LOD at FDAC.


If application is approved, a Certificate of Product Registration (CPR) shall be issued and shall be valid for use similar to existing CPRs issued following the existing requirements.

Existing fees and charges as well as the payment procedure of an OTC drug application shall still apply.

This Order takes effect immediately.



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 Director General



Annex A

Schedule 5: Pharmacy-only OTC Medicines

Aspirin Oral
Aspirin + Sodium Bicarbonate Oral
Brompheniramine Maleate + Phenylephrine Hydrochloride Tablet
Bromhexine (for veterinary use) Oral
Bromhexine Hydrochloride + Guaifenesin Oral
Calamine + Diphenhydramine Hydrochloride Topical
Carbocisteine Oral
Chlorphenamine Maleate Oral
Chlorphenamine Maleate + Phenylephrine Hydrochloride Oral
Chlorphenamine Maleate + Phenylpropanolamine Hydrochloride Oral
Chlorphesodiummine Maleate + Phenylephrine Hydrochloride Oral
Chlorphesodiummine Maleate + Phenylpropanolamine Hydrochloride Oral
Cetirizine Oral
Clemastine Oral
Clemastine + Phenylpropanolamine Hydrochloride Oral
Dextromethorphan Hydrobromide + Bromphenamine Maleate + Phenylephrine Hydrochloride Oral
Dextromethorphan Hydrobromide + Chlorphenamine Maleate Oral
Dextromethorphan Hydrobromide + Chlorphenamine Maleate + Phenylpropanolamine Hydrochloride + Sodium Citrate Oral



Dextromethorphan Hydrobromide + Chlorphenamine Maleate + Phenylpropanolamine Hydrochloride Oral
Dextromethorphan Hydrobromide + Guaifenesin Oral
Dextromethorphan Hydrobromide + Guaifenesin + Chlorphenamine Maleate + Phenylpropanolamine Hydrochloride Oral
Dextromethorphan Hydrobromide + Guaifenesin + Phenylephrine Hydrochloride Oral
Dextromethorphan Hydrobromide + Guaifenesin + Phenylpropanolamine Hydrochloride Oral
Dextromethorphan Hydrobromide + Guaifenesin + Sodium Citrate Oral
Dextromethorphan Hydrobromide + Guaifenesin + Sodium Citrate + Chlorphenamine Maleate Oral
Dextromethorphan Hydrobromide + Phenylephrine Hydrochloride Oral
Dextromethorphan Hydrobromide + Sodium Citrate + Chlorphenamine Maleate + Phenylpropanolamine Hydrochloride Oral
Dextromethorphan Hydrobromide + Sodium Citrate + Chlorphenamine Maleate + Phenylpropanolamine Hydrochloride Oral
Diphenhydramine Hydrochloride Oral
Diphenhydramine Hydrochloride + Phenylpropanolamine Hydrochloride Oral
Guaifenesin Oral
Guaifenesin + Chlorphenamine Maleate + Phenylephrine Hydrochloride Oral
Guaifenesin + Chlorphenamine Maleate + Phenylpropanolamine Hydrochloride Oral
Guaifenesin + Fluid of Ipecac Oral
Guaifenesin + Oxeladin Citrate + Chlorphenamine Maleate + Phenylpropanolamine Hydrochloride Oral
Guaifenesin + Phenylpropanolamine Hydrochloride Oral
Guaifenesin + Sodium Citrate Oral
Guaifenesin + Sodium Citrate + Ammonium Chloride Oral
Guaifenesin + Sodium Citrate + Ammonium Chloride + Chlorphenamine Maleate Oral

Guaifenesin + Sodium Citrate + Chlorphenamine Maleate + Phenylpropanolamine Hydrochloride Oral
Guaifenesin + Diphenhydramine Hydrochloride + Phenylephrine Hydrochloride Oral
Guaifenesin + Sodium Citrate + Ammonium Chloride + Phenylpropanolamine Hydrochloride Oral
Guaifenesin + Sodium Citrate + Diphenhydramine Hydrochloride + Phenylpropanolamine Hydrochloride Oral
Hyoscine-N-Butylbromide Oral
Ibuprofen Oral
Ibuprofen + Caffeine Oral
Ibuprofen + Paracetamol Oral
Loperamide Oral
Loratadine Hydrochloride Oral
Loratadine Hydrochloride + Phenylephrine Hydrochloride Oral
Mefenamic Acid 250mg only Oral
Mefenamic Acid (for veterinary use) Oral
Minoxidil Topical
Naproxen Sodium 275mg Oral
Orlistat 60mg Oral
Oxymetazoline Hydrochloride Nasal Spray
Paracetamol Oral
Paracetamol (for veterinary use) Oral
Paracetamol + Caffeine Oral
Paracetamol + Caffeine + Chlorphenamine Maleate + Phenylephrine Hydrochloride Oral
Paracetamol + Chlorphenamine Maleate + Phenylephrine Hydrochloride Oral
Paracetamol + Chlorphenamine Maleate + Phenylpropanolamine Hydrochloride Oral

Paracetamol + Chlorphenesodiummine Maleate + Phenylephrine Hydrochloride Oral
Paracetamol + Chlorphenesodiummine Maleate + Phenylpropanolamine Hydrochloride Oral
Paracetamol + Dextromethorphan Hydrobromide + Phenylephrine Hydrochloride Oral
Paracetamol + Dextromethorphan Hydrobromide + Chlorphenamine Maleate + Phenylpropanolamine Hydrochloride Oral
Paracetamol + Dextromethorphan Hydrobromide + Guaifenesin + Chlorphenamine Maleate + Phenylpropanolamine Hydrochloride Oral
Paracetamol + Hyoscine-N-Butylbromide Oral
Paracetamol + Phenylephrine Hydrochloride Oral
Paracetamol + Phenylpropanolamine Hydrochloride Oral
Paracetamol + Propyphenazone + Caffeine Oral
Paracetamol + Dextromethorphan Hydrobromide + Phenylephrine Hydrochloride Oral
Phenylephrine Hydrochloride Oral
Phenylpropanolamine Hydrochloride Oral
Sodium Picosulfate Oral
Bisacodyl Oral
Aluminum Hydroxide + Magnesium Hydroxide Oral
Aluminum Hydroxide + Magnesium Hydroxide + Simethicone Oral

Annex B

Schedule 6: Household Remedy Products

Ammonium Carbonate + Aromatic Spirit of Ammonia Topical
Amylmetacresol + Dichlorobenzyl Alcohol Oral
Amylmetacresol + Dichlorobenzyl Alcohol + Ascorbic Acid (Vitamin C) (and its derivatives and/or salts) Oral
Arnica Tincture Topical
Aromatic Spirit of Ammonia Topical
Ascorbic Acid (Vitamin C) (and its derivatives and/or salts) Oral
Ascorbic Acid (Vitamin C) (and its derivatives and/or salts) for veterinary use Oral
Ascorbic Acid (Vitamin C) (and its derivatives and/or salts) + Tocopherol (Vitamin E) (and its derivatives and/or salts) Oral
Ascorbic Acid (Vitamin C) (and its derivatives and/or salts) + Tocopherol (Vitamin E) (and its derivatives and/or salts) for veterinary use Oral
Ascorbic Acid (Vitamin C) (and its derivatives and/or salts) + Zinc Oral
Benzoic Acid + Salicylic Acid Topical
Benzoic Acid + Salicylic Acid (for veterinary use) Topical
Benzoic Acid + Salicylic Acid + Resorcinol Topical
Benzoic Acid + Salicylic Acid + Resorcinol + Thymol Topical
Benzoic Acid + Salicylic Acid + Resorcinol + Iodine Topical
Benzoic Acid + Salicylic Acid + Sulfur + Cetyl Alcohol + Menthol Topical
Benzoic Acid + Salicylic Acid + Sulfur + Zinc Oxide Topical
Benzoyl Peroxide Topical
Benzoyl Peroxide + Sulfur Topical
Bergamot Oil + Lemon Oil + Orange Oil + Pine Oil + Rosemary Oil + Wintergreen Oil Topical
Biotin Oral

Biotin (for veterinary use) Oral
Calamine Topical
Calamine + Zinc Oxide Topical
Calcium (and its derivatives and/or salts) Oral
Calcium (and its derivatives and/or salts) for veterinary use Oral
Camphor Topical
Camphor + Methyl Salicylate + Vanillylamide Nonylate Topical
Camphor + Chlorobutanol + Clove Oil + Creosote + Phenol Liquid + Ethyl Alcohol Topical
Camphor + Menthol Topical
Camphor + Menthol + Cajuput Oil + Clove Oil Topical
Camphor + Menthol + Cinnamon Oil + Clove Oil + Eucalyptus Oil + Turpentine Oil + Wintergreen Oil Topical
Camphor + Menthol + Clove Oil + Peppermint Oil Topical
Camphor + Menthol + Eucalyptus Oil Topical
Camphor + Menthol + Eucalyptus Oil + Borneol + Peppermint Oil Topical
Camphor + Menthol + Eucalyptus Oil + Capsicum Topical
Camphor + Menthol + Eucalyptus Oil + Peppermint Oil Topical
Camphor + Menthol + Methyl Salicylate Topical
Camphor + Menthol + Methyl Salicylate + Borneol + Thymol + Zinc Oxide Topical
Camphor + Menthol + Methyl Salicylate + Clove Oil + Peppermint Oil Topical
Camphor + Menthol + Methyl Salicylate + Eucalyptus Oil Topical
Camphor + Menthol + Methyl Salicylate + Eucalyptus Oil + Herbal Extract + Mineral Oil Topical
Camphor + Menthol + Methyl Salicylate + Eucalyptus Oil + Peppermint Oil Topical
Camphor + Menthol + Methyl Salicylate + Eucalyptus Oil + Turpentine Oil Topical
Camphor + Menthol + Methyl Salicylate + Peppermint oil Topical

Camphor + Menthol + Peppermint Oil Topical
Camphor + Methyl Salicylate Topical
Castor Oil Oral
Castor Oil (for veterinary use) Oral
Benzalkonium Chloride + Cetrimide Topical
Benzalkonium Chloride + Cetrimide (for veterinary use) Topical
Chamomile Oil Topical
Chamomile Oil + Mineral Oil Topical
Chlorhexidine Topical
Chlorhexidine + Isopropyl Alcohol Topical
Cholecalciferol (Vitamin D) (and its derivatives and/or salts) Oral
Cholecalciferol (Vitamin D) (and its derivatives and/or salts) for veterinary use Oral
Clove Oil + Creasote Topical
Cod Liver Oil Oral
Cod Liver Oil (for veterinary use) Oral
Cyanocobalamin (Vitamin B12) (and its derivatives and/or salts) Oral
Cyanocobalamin (Vitamin B12) (and its derivatives and/or salts) for veterinary use Oral
70 % Ethyl Alcohol Topical
70 % Ethyl Alcohol (for veterinary use) Topical
Ethyl Alcohol + Chlorhexidine Gluconate Topical
Ethyl Alcohol + Propyl Alcohol Topical
Ethyl Alcohol + Propyl Alcohol (for veterinary use) Topical
Eucalyptus Oil Topical
Eucalyptus Oil (for veterinary use) Topical

Folic Acid (Vitamin B9) (and its derivatives and/or salts) Oral
Folic Acid (Vitamin B9) (and its derivatives and/or salts) for veterinary use Oral
Gentian Violet Topical
Gentian Violet (for veterinary use) Topical
Glycerin Rectal preparation
Glycerin (for veterinary use) Rectal preparation
Glycerin + Hypromellose + Polyethylene Glycol Rectal preparation
Glycol Salicylate + Menthol + Tocopherol (Vitamin E) (and its derivatives and/or salts) + Camphor Topical
Hexetidine Oral
Hexetidine (for veterinary use) Oral
Hydrogen Peroxide Topical
Hydrogen Peroxide (for veterinary use) Topical
2% Hydroquinone Topical
Iodine + Salicylic Acid Topical
Iodine + Salicylic Acid (for veterinary use) Topical
Iodine + Benzoic Acid + Salicylic Acid + Resorcinol Topical
Iodine + Benzoic Acid + Salicylic Acid + Resorcinol (for veterinary use) Topical
Iron (and its derivatives and/or salts) Oral
Iron (and its derivatives and/or salts) for veterinary use Oral
70% Isopropyl Alcohol Topical
70% Isopropyl Alcohol (for veterinary use) Topical
Isopropyl Alcohol + Benzalkonium Chloride Topical
Isopropyl Alcohol + Benzalkonium Chloride (for veterinary use) Topical
Lactic Acid Topical

Lactic Acid (for veterinary use) Topical
Lactic Acid + Lactoserum Topical
Lactic Acid + Salicylic Acid Topical
Menthol Topical
Menthol + Bergamot Oil + Lavender Oil + Lemon Oil + Orange Oil + Pine Oil + Rosemary Oil + Terpineol + Terpinyl Acetate + Wintergreen Oil Topical
Menthol + Chamomile Oil Topical
Menthol + Eucalyptus Oil Topical
Menthol + Methyl Salicylate Topical
Menthol + Methyl Salicylate + Capsicum Oil Topical
Menthol + Methyl Salicylate + Citronella Oil Topical
Menthol + Methyl Salicylate + Eucalyptus Oil Topical
Menthol + Methyl Salicylate + Eugenol Topical
Menthol + Methyl Salicylate + Tocopherol (Vitamin E) (and its derivatives and/or salts) + Camphor Topical
Menthol + Methyl Salicylate + Zinc Oxide + Angelicae Sinensis + Radix Angelicae Dahuricae Radix Topical
Menthol + Peppermint Oil Topical
Menthol + Resorcinol + Salicylic Acid + Sulfur + Zinc Oxide Topical
Methyl Salicylate Topical
Mineral Oil Topical
Mineral Oil (for veterinary use) Topical
Mucopolysaccharide Polysulfate Rectal Preparation
Nicotinic Acid (and its derivatives and/or salts) Oral
Nicotinic Acid (and its derivatives and/or salts) for veterinary use Oral
Oral Rehydration Salts Oral

Oral Rehydration Salts (for veterinary use) Oral
Pantothenic Acid (Vitamin B5) (and its derivatives and/or salts) Oral
Pantothenic Acid (Vitamin B5) (and its derivatives and/or salts) for veterinary use Oral
Peppermint Oil Topical
Petrolatum Topical
Polyethylene Glycol Oral
Povidone Iodine Topical
Povidone Iodine (for veterinary use) Topical
Pyridoxine (Vitamin B6) (and its derivatives and/or salts) Oral
Pyridoxine (Vitamin B6) (and its derivatives and/or salts) for veterinary use Oral
Resorcinol + Salicylic Acid + Sulfur + Zinc Oxide Topical
Retinol (Vitamin A) (and its derivatives and/or salts) Oral
Retinol (Vitamin A) (and its derivatives and/or salts) for veterinary use Oral
Riboflavin (Vitamin B2) Oral
Riboflavin (Vitamin B2) for veterinary use Oral
Salicylic Acid Topical
Salicylic Acid (for veterinary use) Topical
Salicylic Acid + Benzalkonium Chloride Topical
Salicylic Acid + Benzalkonium Chloride (for veterinary use) Topical
Salicylic Acid + Sulfur + Camphor + Menthol + Eucalyptus Oil Topical
Resorcinol + Salicylic Acid Topical
Salicylic Acid + Resorcinol + Phenol + Glycerin + Benzoin Tincture Topical
Salicylic Acid + Sulfur Topical
Salicylic Acid + Sulfur (for veterinary use) Topical

Salicylic Acid + Sulfur + Camphor + Menthol + Eucalyptus Oil Topical
Salicylic Acid + Zinc Oxide Topical
Selenium (and its derivatives and/or salts) Oral
Selenium (and its derivatives and/or salts) for veterinary use Topical
Sodium Bicarbonate Oral
Sulfur Topical
Sulfur (for veterinary use) Topical
Sulfur + Zinc Oxide Topical
Sulfur + Zinc Oxide (for veterinary use) Topical
Tetrahydrozoline Hydrochloride Topical
Thiamine (Vitamin B1) (and its derivatives and/or salts) Oral
Thiamine (Vitamin B1) (and its derivatives and/or salts) for veterinary use Oral
Thiamine (Vitamin B1) (and its derivatives and/or salts) + Iron (and its derivatives and/or salts) Oral
Thiamine (Vitamin B1) (and its derivatives and/or salts) + Iron (and its derivatives and/or salts) for veterinary use Oral
Tocopherol (Vitamin E) (and its derivatives and/or salts) Oral
Tocopherol (Vitamin E) (and its derivatives and/or salts) for veterinary use Oral
Zinc Oxide Topical
Zinc Oxide (for veterinary use) Topical