

| DOCUMENT TITLE: REGULATORY DIRECTIVE ON DISCONTINUATION OF REGISTRATION OF SOME FIXED-DOSE COMBINATION (FDC) DRUGS | | |
|---|------------------------|-------------------------|
| DOC. REF. NO.: | EFFECTIVE DATE: | REVIEW DUE DATE: |
| NAFDAC-RDD-030-00 | 01-07-2024 | 30-06-2029 |



NATIONAL AGENCY FOR FOOD & DRUG ADMINISTRATION AND CONTROL (NAFDAC)

Regulatory Directive on Discontinuation of Registration of some Fixed-Dose Combination (FDC) Drugs

1.0 Purpose:

This regulatory directive aims to discontinue the registration of some Fixed-Dose Combination (FDC) drugs due to the risks associated with product safety. The therapeutic justifications for these FDCs have not been established and irrational therapy with accompanying Adverse Drug Reactions (ADR) have been well documented. These FDCs are banned in several countries including India (which is a major source of these medicines) because they were found to pose risks to human health.

2.0 Scope:

This Regulatory Directive applies to locally and imported pharmaceutical Fixed-Dose Combinations (FDCs) in which new, renewal and variation applications are not received anymore.

3.0 Directive Details:

The control or discontinuation is imperative because of the increased risk of liver and kidney damage caused by these Fixed-Dose Combinations. **In view of the foregoing, the Agency will no longer accept applications for new, renewal and variations for the attached list of the locally & imported versions of these medicines.**

| S/NO | FIXED DOSE COMBINATIONS |
|------|---|
| 1 | Diclofenac, Paracetamol |
| 2 | Aceclofenac, Paracetamol, Chlorzoxazone |
| 3 | Diclofenac, Paracetamol, Chlorzoxazone |
| 4 | Ibuprofen, Paracetamol, Caffeine |
| 5 | Aceclofenac, Paracetamol |
| 6 | Aceclofenac, Paracetamol, Serratiopeptidase |
| 7 | Aceclofenac, Serratiopeptidase |
| 8 | Ibuprofen, Paracetamol |
| 9 | Aceclofenac (SR) + Paracetamol |
| 10 | Aceclofenac + Paracetamol + Famotidine |

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| 11 | Aceclofenac + Paracetamol + Rabeprazole |
| 12 | Aceclofenac + Zinc Carnosine |
| 13 | Acetaminophen + Guaifenesin + Dextromethorphan + Chlorpheniramine |
| 14 | Acetaminophen + Loratadine + Ambroxol + Phenylephrine |
| 15 | Acriflavine + Thymol + Cetrimide |
| 16 | Acrivastine + Paracetamol + Caffeine + Phenylephrine |
| 17 | Albuterol + Bromhexine + Theophylline |
| 18 | Albuterol + Etofylline + Bromhexine + Menthol |
| 19 | Algic Acid + Sodium Bicarbonate + Dried Aluminium Hydroxide + Magnesium Hydroxide |
| 20 | Allantoin + Dimethieone + Urea + Propylene + Glycerin + Liquid Paraffin |
| 21 | Ambroxol + Levocetirizine + Phenylephrine + Guaiphenesin + Menthol |
| 22 | Ambroxol + Guaifenesin + Phenylephrine + Chlorpheniramine |
| 23 | Ambroxol + Salbutamol + Choline Theophyllinate + Menthol |
| 24 | Ambroxol + Salbutamol + Theophylline |
| 25 | Ambroxol + Terbutaline + Dextromethorphan |
| 26 | Ambroxol+ Guaiphenesin + Ammonium Chloride + Phenylephrine + Chlorpheniramine Maleate + Menthol |
| 27 | Ammonium Chloride + Dextromethorphan + Cetirizine + Menthol |
| 28 | Ammonium Chloride + Sodium Citrate + Chlorpheniramine Maleate + Menthol |
| 29 | Ammonium Citrate + Vitamin B 12 + Folic Acid + Zinc Sulphate |
| 30 | Amoxicillin + Cefixime + Potassium Clavulanic Acid |
| 31 | Amoxicillin + Dicloxacillin |
| 32 | Amoxicillin 250 mg + Potassium Clavulanate Diluted 62.5 |
| 33 | Amoxycillin + Dicloxacillin + Serratiopeptidase |
| 34 | Amoxycillin + Tinidazole |
| 35 | Ascorbic Acid + Manadione Sodium Bisulphate + Rutin + Dibasic Calcium Phosphate + Adrenochrome mono Se |
| 36 | Atorvastatin + Vitamin D3 + Folic Acid + Vitamin B12 + Pyridoxine |
| 37 | Azithromycin + Acebrophylline |
| 38 | Azithromycin + Ambroxol |
| 39 | Azithromycin + Cefixime |
| 40 | Azithromycin + Cefpodoxime |
| 41 | Azithromycin + Levofloxacin |
| 42 | Azithromycin + Ofloxacin |
| 43 | Becloemthasone + Clotrimazole + Chloramphenicol + Gentamycin + Lignocaine Ear drops |
| 44 | Beclometasone + Clotrimazole + Neomycin + Iodochlorhydroxyquinone |
| 45 | Beclometasone + Clotrimazole + Gentamicin + Iodochlorhydroxyquinoline |
| 46 | Beclometasone Dipropionate + Neomycin + Tolnaftate + Iodochlorhydroxyquinoline +Chlorocresol |
| 47 | Benfotiamine + Metformin |
| 48 | Benzoxonium Chloride + Lidocaine |
| 49 | Betahistine + Ginkgo Biloba Extract + Vinpocetine + Piracetam |
| 50 | Betamethasone + Fusidic Acid + Gentamycin + Tolnaftate + Iodochlorhydroxyquinoline (ICHQ) |
| 51 | Betamethasone + Gentamicin + Tolnaftate + Iodochlorhydroxyquinoline |
| 52 | Betamethasone + Gentamycin + Zinc Sulphate + Clotrimoazole + Chlorocresol |
| 53 | Betamethasone + Neomycin + Tolnaftate + Iodochlorhydroxyquinoline + Cholorocresol |
| 54 | Borax + Boric Acid + Naphazoline + Menthol + Camphor + Methyl Hydroxy Benzoate |

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| 55 | Bromhexine + Phenylephrine + Chlorpheniramine + Paracetamol |
| 56 | Bromhexine + Cetirizine + Phenylephrine IP+Guaifenesin + Menthol |
| 57 | Bromhexine + Dextromethorphan |
| 58 | Bromhexine + Dextromethorphan + Phenylephrine + Menthol |
| 59 | Bromhexine + Phenylephrine + Chloreheniramine Maleate |
| 60 | Caffeine + Paracetamol + Chlorpheniramine |
| 61 | Caffeine + Paracetamol + Phenylephrine + Cetirizine |
| 62 | Calcium Gluconate + Chlorpheniramine + Vitamin C |
| 63 | Calcium Gluconate + Levocetirizine |
| 64 | Cefixime + Levofloxacin |
| 65 | Cefixime + Linezolid |
| 66 | Cefpodoxime Proxetil + Levofloxacin |
| 67 | Cefuroxime + Linezolid |
| 68 | Cephalexin + Neomycin + Prednisolone |
| 69 | Cetirizine + Phenylephrine + Paracetamol + Caffeine + Nimesulide |
| 70 | Cetirizine + Acetaminophen + Dextromethorphan + Phenylephrine + Zinc Gluconate |
| 71 | Cetirizine + Ambroxol + Guaiphenesin + Ammonium Chloride + Phenylephrine + Menthol |
| 72 | Cetirizine + Dextromethorphan + Ambroxol |
| 73 | Cetirizine + Dextromethorphan + Bromhexine + Guaifenesin |
| 74 | Cetirizine + Dextromethorphan + Phenylephrine + Tulsi |
| 75 | Cetirizine + Dextromethorphan + Phenylephrine + Zinc Gluconate + Paracetamol + Menthol |
| 76 | Cetirizine + Dextromethorphan + Zinc Gluconate + Menthol |
| 77 | Cetirizine + Diethyl Carbamazine |
| 78 | Cetirizine + Phenylephrine + Dextromethorphan + Menthol |
| 79 | Cetirizine + Phenylephrine + Paracetamol + Ambroxol + Caffeine |
| 80 | Cetirizine + Phenylephrine + Paracetamol + Zinc Gluconate |
| 81 | Cetirizine + Nimesulide + Phenylephrine |
| 82 | Chlopheniramine Maleate + Dextromethorphan + Guaiphensin + Phenylephrine |
| 83 | Chloramphenicol + Beclomethasone + Clotrimazole + Lignocaine |
| 84 | Chloramphenicol + Lignocaine + Betamethasone + Clotrimazole + Ofloxacin + Antipyrine |
| 85 | Chlorphaniramine + Ammonium Chloride + Sodium Chloride |
| 86 | Chlorpheniramine + Ammonium Chloride + Chloroform + Menthol |
| 87 | Chlorpheniramine + Ammonium Chloride + Noscapine + Sodium Citrate |
| 88 | Chlorpheniramine + Codeine + Sodium Citrate + Menthol Syrup |
| 89 | Chlorpheniramine + Dextromethorphan + Phenylephrine + Paracetamol |
| 90 | Chlorpheniramine + Paracetamol + Pseudoephedrine + Caffeine |
| 91 | Chlorpheniramine + Phenylephrine + Caffeine |
| 92 | Chlorpheniramine + Phenylephrine + Dextromethorphan + Menthol |
| 93 | Chlorpheniramine + Phenylephrine + Paracetamol + Zink Gluconate |
| 94 | Chlorpheniramine + Terpin + Antimony Potassium Tartrate + Ammonium Chloride + Sodium Citrate + Menthol |
| 95 | Chlorpheniramine + Vasaka + Tolubalsm + Ammonium Chloride + Sodium Citrate + Menthol |
| 96 | Chlorpheniramine + Vitamin C |
| 97 | Chlorpheniramine Maleate + Ammonium Chloride + Sodium Citrate |
| 98 | Chlorpheniramine+Ammonium Chloride + Menthol |
| 99 | Chlorpromazine + Trihexyphenidyl |
| 100 | Chromium Polynicotinate + Metformin |
| 101 | Cilnidipine + Metoprolol Succinate + Metoprolol Tartrate |

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| 102 | Ciprofloxacin + Fluocinolone + Clotrimazole + Neomycin + Chlorocresol |
| 103 | Ciprofloxacin + Fluticasone + Clotrimazole + Neomycin |
| 104 | Ciprofloxacin + Phenazopyridine |
| 105 | Clidinium + Paracetamol + Dicyclomine + Activated Dimethicone |
| 106 | Clindamycin + Clotrimazole + Lactic Acid Bacillus |
| 107 | Clindamycin + Telmisartan |
| 108 | Clobetasol + Gentamicin + Tolnaftate + Iodochlorhydroxyquinone + Ketoconazole |
| 109 | Clobetasol + Neomycin + Miconazole + Clotrimazole |
| 110 | Clobetasol + Neomycin + Miconazole + Zinc Sulphate |
| 111 | Clobetasol + Ofloxacin + Ketoconazole + Zinc Sulphate |
| 112 | Clobetasol + Ofloxacin + Miconazole + Zinc Sulphate |
| 113 | Clobetasol Propionate + Ofloxacin + Ornidazole + Terbinafine |
| 114 | Clobetasole + Gentamicin + Miconazole + Zinc Sulphate |
| 115 | Clomifene Citrate + Ubidecarenone + Zinc + Folic Acid + Methylcobalamin + Pyridoxine + Lycopene + Selenium + Levocarnitine Tartrate + L-Arginine |
| 116 | Clotrimazole + Beclomethasone + Lignocaine + Ofloxacin + Acetic Acid + Sodium Methyl Paraben + Propyl Paraben |
| 117 | Clotrimazole + Beclomethasone + Ofloxacin + Lignocaine |
| 118 | Clotrimazole + Ofloxacin + Lignocaine + Glycerine and Propylene Glycol |
| 119 | Codeine + Chlorpheniramine + Alcohol Syrup |
| 120 | Codeine + Levocetirizine + Menthol |
| 121 | Combikit of 3 tablets of Serratiopeptidase (enteric coated 20000 units) + Diclofenac Potassium & 2 tablets of D |
| 122 | Combikit of Azithromycin, Secnidazole and Fluconazole |
| 123 | Combikit of Fluconazole Tablet, Azithromycin Tablet and Ornidazole Tablets |
| 124 | Cyproheptadine + Thiamine |
| 125 | Dextromethorphan + Chlorpheniramine + Ammonium Chloride + Menthol |
| 126 | Dextromethorphan + Chlorpheniramine + Ammonium + Sodium Citrate + Menthol |
| 127 | Dextromethorphan + Phenylephrine + Guaiphenesin |
| 128 | Dextromethorphan + Chlorpheniramine + Bromhexine |
| 129 | Dextromethorphan + Ambroxol + Ammonium Chloride + Chlorpheniramine + Menthol |
| 130 | Dextromethorphan + Ambroxol + Guaifenesin + Phenylephrine + Chlorpheniramine |
| 131 | Dextromethorphan + Bromhexine + Guaiphenesin |
| 132 | Dextromethorphan + Bromhexine + Guaiphenesin + Menthol |
| 133 | Dextromethorphan + Cetirizine |
| 134 | Dextromethorphan + Cetirizine + Guaifenesin + Ammonium Chloride |
| 135 | Dextromethorphan + Chlorpheniramine + Chlorpheniramine Maleate |
| 136 | Dextromethorphan + Chlorpheniramine + Guaiphenesin |
| 137 | Dextromethorphan + Levocetirizine + Phenylephrine + Zinc |
| 138 | Dextromethorphan + Paracetamol + Cetirizine + Phenylephrine |
| 139 | Dextromethorphan + Phenylephrine + Ammonium Chloride + Menthol |
| 140 | Dextromethorphan + Phenylephrine + Bromhexine + Guaifenesin + Chlorpheniramine |

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| 141 | Dextromethorphan + Phenylephrine + Cetirizine + Paracetamol + Caffeine |
| 142 | Dextromethorphan + Phenylephrine + Cetirizine + Zinc + Menthol |
| 143 | Dextromethorphan + Phenylephrine + Guaifenesin + Certirizine + Acetaminophen |
| 144 | Dextromethorphan + Phenylephrine + Guaifenesin + Triprolidine |
| 145 | Dextromethorphan + Phenylephrine + Tripolidine + Menthol |
| 146 | Dextromethorphan + Phenylephrine + Zinc Gluconate + Menthol |
| 147 | Dextromethorphan + Tripolidine + Phenylephrine |
| 148 | Dextromethorphan + Tripolidine + Phenylephrine |
| 149 | Dextromethorphan + Bromhexine + Chlorpheniramine Maleate + Guaiphenesin |
| 150 | Dextromethorphan + Promethazine |
| 151 | Diclofenac + paracetamol + chlorpheniramine maleate + magnesium Trisilicate |
| 152 | Diclofenac + Paracetamol + Chlorzoxazone + Famotidine |
| 153 | Diclofenac + paracetamol + magnesium Trisilicate |
| 154 | Diclofenac + Paracetamol injection |
| 155 | Diclofenac + Tramadol + Chlorzoxazone |
| 156 | Diclofenac + Tramadol + Paracetamol |
| 157 | Diclofenac + Zinc Carnosine |
| 158 | Dicyclomine + Paracetamol + Domperidone |
| 159 | Diethyl Carbamazine + Chlorpheniramine + Guaifenesin |
| 160 | Diethylcarbamazine Citrate + Cetirizine + Guaiphenesin |
| 161 | Diethylcarbamazine + Cetirizine + Ambroxol |
| 162 | Diphenhydramine + Guaifenesin + Bromhexine + Ammonium Chloride + Menthol |
| 163 | Diphenhydramine + Guaiphenesin + Ammonium Chloride + Bromhexine |
| 164 | Diphenhydramine + Terpine + Ammonium Chloride + Sodium Chloride + Menthol |
| 165 | Diphenoxylate + Atropine + Furazolidonee |
| 166 | Disodium Hydrogen Citrate + Paracetamol |
| 167 | Doxycycline + Serratiopeptidase |
| 168 | Doxylamine + Pyridoxine + Mefenamic Acid + Paracetamol |
| 169 | Dried Alumnum Hydroxie Gel + Propantheline + Diazepam |
| 170 | Drotaverine + Clidinium + Chlordiazepoxide |
| 171 | Enrofloxacin + Bromhexin |
| 172 | Ergotamine Tartrate + Belladona Dry Extarct+Caffeine + Paracetamol |
| 173 | Ethylmorphine + Noscapine + Chlorpheniramine |
| 174 | Famotidine + Oxytacaine + Magaldrate |
| 175 | Flunarizine + Paracetamole + Domperidone |
| 176 | Flupentixol + Escitalopram |

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| 177 | Furazolidone + Metronidazole + Loperamide |
| 178 | Gabapentin + Mecobalamin + Pyridoxine + Thiamine |
| 179 | Gentamicin Sulphate + Clotrimazole + Betamethasone + Lignocaine |
| 180 | Gentamycin + Dexamethasone + Chloramphenicol + Tobramycin + Ofloxacin |
| 181 | Glibenclamide + Metformin (SR)+ Pioglitazone |
| 182 | Gliclazide 40mg + Metformin 400mg |
| 183 | Gliclazide 80 mg + Metformin 325 mg |
| 184 | Glimepiride + Pioglitazone + Metformin |
| 185 | Glimepiride 1mg/2mg/3mg + Pioglitazone 15mg/15mg/15mg + Metformin 1000mg/1000mg/1000mg |
| 186 | Glimepiride 1mg/2mg+ Pioglitazone 15mg/15mg + Metformin 850mg/850mg |
| 187 | Glipizide 2.5mg + Metformin 400 mg |
| 188 | Glucosamine + Methyl Sulfonyl Methane + Vitamin D3 + Manganese + Boron + Copper + Zinc |
| 189 | Guaifenesin + Bromhexine + Chlorpheniramine + Paracetamol |
| 190 | Guaifenesin + Bromhexine + Chlorpheniramine + Phenylephrine + Paracetamol + Serratiopeptidase(as enteric coated granules) 10000 SP Units |
| 191 | Guaifenesin + Dextromethorphan |
| 192 | Guaifenesin + Diphenhydramine + Bromhexine + Phenylephrine |
| 193 | Heparin + Diclofenac |
| 194 | Imipramine + Chlordiazepoxide + Trifluoperazine + Trihexyphenidyl |
| 195 | Ketoconazole + Tea Tree oil + Allantion + Zinc Oxide + Aloe Vera + Jojoba oil + Lavander oil + Soa noodels |
| 196 | Ketotifen + Cetirizine |
| 197 | Ketotifen + Levocetirizine |
| 198 | Ketotifen + Theophylline |
| 199 | L-5-Methyltetrahydrofolate Calcium + Escitalopram |
| 200 | L-Arginine + Sildenafil |
| 201 | Levocetirizine + Ambroxol + Phenylephrine + Guaiphenesin |
| 202 | Levocetirizine + Ambroxol + Phenylephrine + Paracetamol |
| 203 | Levocetirizine + Dextromethorphan + Zinc |
| 204 | Levocetirizine + Montelukast + Acebrophylline |
| 205 | Levocetirizine + Paracetamol + Phenylephirine + Caffeine |
| 206 | Levocetirizine + Phenylephrine + Ambroxol + Guaiphenesin + Paracetamol |
| 207 | Levocetirizine + Ranitidine |
| 208 | Levofloxacin + Bromhexine |
| 209 | Levofloxacin + Ornidazole + Alpha Tocopherol Acetate |
| 210 | Levothyroxine + Phyridoxine + Nicotinamide |
| 211 | Lignocaine + Clotrimazole + Ofloxacin + Beclomethasone |

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| 212 | Lornoxicam + Paracetamol + serratiopeptidase |
| 213 | Lornoxicam + paracetamol + Tramadol |

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| 214 | Lornoxicam + paracetamol + trypsin |
| 215 | Magaldrate + Famotidine + Simethicone |
| 216 | Magaldrate + Papain + Fungul Diastase + Simethicone |
| 217 | Magaldrate + Ranitidine + Pancreatin + Domperidone |
| 218 | Mebeverine & Inner HPMC capsule (Streptococcus Faecalis + Clostridium butyricum + Bacillusmesentericus + Lactic Acid Bacillus) |
| 219 | Menthol + Anesthetic Ether |
| 220 | Metformin (SR) 500mg + Pioglitazone 5mg |
| 221 | Metformin (Sustained Release) 500mg + Pioglitazone 15 mg + Glimepiride 3mg |
| 222 | Metformin + Atorvastatin |
| 223 | Metformin + Bromocriptine |
| 224 | Metformin + Gliclazide + Chromium Polynicotinate |
| 225 | Metformin + Gliclazide + Pioglitazone + Chromium Polynicotinate |
| 226 | Metformin + Glimepiride + Methylcobalamin |
| 227 | Metformin 1000/1000/500/500mg + Pioglitazone 7.5/7.5/7.5/7.5mg + Glimepiride 1/2/1/2mg |
| 228 | Metformin 500mg/500mg+Gliclazide SR 30mg/60mg + Pioglitazone 7.5mg/7.5mg |
| 229 | Metformin 850mg + Pioglitazone 7.5 mg + Glimepiride 1mg |
| 230 | Metformin 850mg + Pioglitazone 7.5 mg + Glimepiride 2mg |
| 231 | Metformin ER + Gliclazide MR + Voglibose |
| 232 | Metronidazole + Norfloxacin |
| 233 | Metronidazole + Tetracycline |
| 234 | N-Acetyl Cysteine + Ambroxol + Phenylephrine + Levocetirizine |
| 235 | Naphazoline + Carboxy Methyl Cellulose + Menthol + Camphor + Phenylephrine |
| 236 | Naphazoline + Chlorpheniramine + Zinc Sulphate + Boric Acid + Sodium Chloride + Chlorobutol |
| 237 | Naproxen + Paracetamol |
| 238 | Neomycin + Doxycycline |
| 239 | Nimesulide + Certirizine + Phenylephrine |
| 240 | Nimesulide + Cetirizine + Caffeine |
| 241 | Nimesulide + Diclofenac |
| 242 | Nimesulide + Dicyclomine |
| 243 | Nimesulide + Loratadine + Phenylephrine + Ambroxol |
| 244 | Nimesulide + Paracetamol + Cetirizine + Phenylephrine |
| 245 | Nimesulide + Paracetamol + Levocetirizine + Phenylephrine + Caffeine |
| 246 | Nimesulide + paracetamol Injection |
| 247 | Nimesulide + Paracetamol Suspension |

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| 248 | Nimesulide + Phenylephrine + Caffeine + Levocetirizine |
| 249 | Nimesulide + Pitofenone + Fenpiverinium + Benzyl Alcohol |
| 250 | Nimesulide + Serratiopeptidase |
| 251 | Nimesulide + Tizanidine |
| 252 | Nimorazole + Ofloxacin |
| 253 | Norfloxacin+ Metronidazole + Zinc Acetate |

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| 254 | Oflaxacin + Ornidazole Suspension |
| 255 | Ofloxacin + Clotrimazole + Betamethasone + Lignocaine |
| 256 | Ofloxacin + Metronidazole + Zinc Acetate |
| 257 | Ofloxacin + Nitazoxanide |
| 258 | Ofloxacin + Ornidazole + Zinc Bisglycinate |
| 259 | Olmesartan + Hydrochlorothiazide + Chlorthalidone |
| 260 | Omeprazole + Paracetmaol + Diclofenac |
| 261 | Oxetacaine + Magaldrate + Famotidine |
| 262 | Pantoprazole (as Enteric Coated Tablet) + Zinc Carnosine (as Film Coated Tablets) |
| 263 | Paracetamol + Ambroxol + Phenylephrine + Chlorpheniramine |
| 264 | Paracetamol + Caffeine + Codeine |
| 265 | Paracetamol + Caffine + Phenylephrine + Chlorpheniramine |
| 266 | Paracetamol + Cetrizine + Caffeine |
| 267 | Paracetamol + Chlorpheniramine + Ambroxol + Guaifenesin + Phenylephrine |
| 268 | Paracetamol + Codeine + Chlorpheniramine |
| 269 | Paracetamol + Dextromethorphan + Bromhexine + Phenylephrine + Diphenhydramine |
| 270 | Paracetamol + Dextromethorphan + Chlorpheniramine |
| 271 | Paracetamol + Diclofenac + famotidine |
| 272 | Paracetamol + Disodium Hydrogen Citrate + Caffeine |
| 273 | Paracetamol + DL Methionine |
| 274 | Paracetamol + domperidone + Caffeine |
| 275 | Paracetamol + Levocetirizine + Phenylephirine + Zink Gluconate |
| 276 | Paracetamol + Levocetirizine + Pseudoephedrine |
| 277 | Paracetamol + Loratadine + Dextromethophan + Pseudoephedrine + Caffeine |
| 278 | Paracetamol + Loratadine + Phenylephrine + Dextromethorphan + Caffeine |
| 279 | Paracetamol + mefenamic Acid + ranitidine + Dicyclomine |
| 280 | Paracetamol + Pheniramine |
| 281 | Paracetamol + Phenylephrine + Chlorpheneramine + Dextromethorphan + caffeine |
| 282 | Paracetamol + Phenylephrine + Chlorpheniramine + Zinc Gluconate |
| 283 | Paracetamol + Phenylephrine + Desloratadine + Zinc Gluconate + Ambroxol |
| 284 | Paracetamol + Phenylephrine + Levocetirizine + Caffeine |
| 285 | Paracetamol + Phenylephrine + Triprolidine |
| 286 | Paracetamol + Phenylephrine + Triprolidine + Caffeine |
| 287 | Paracetamol + Prochloperazine |
| 288 | Paracetamol + Prochlorperazine Maleate |
| 289 | Paracetamol + Promethazine |
| 290 | Paracetamol + Propyphenazone + Caffeine |
| 291 | Paracetamol + Pseudoephedrine + Cetrizine |
| 292 | Paracetamol + Pseudoephedrine + Dextromethorphan + Cetirizine |
| 293 | Paracetamol + Tapentadol |
| 294 | Paracetamol+Phenylephrine+Levocetirizine+Sodium Citrate |
| 295 | Paracetamol+Pseudoephedrine+Certirizine+Caffeine |
| 296 | Permethrin + Cetrimide + Menthol |
| 297 | phenylbutazone + sodium salicylate |
| 298 | Phenylephrine + Chlorpheniramine + Paracetamol + Bromhexine + Caffeine |

**DOCUMENT TITLE: REGULATORY DIRECTIVE ON DISCONTINUATION OF
REGISTRATION OF SOME FIXED-DOSE COMBINATION (FDC) DRUGS**

| DOC. REF. NO.: | EFFECTIVE DATE: | REVIEW DUE DATE: |
|-------------------|-----------------|------------------|
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|-----|--|
| 299 | Pholcodine + Phenylephrine + Promethazine |
| 300 | Pioglitazone 15mg + Metformin 850 mg |
| 301 | Pioglitazone 30 mg + Metformin 500 mg |
| 302 | Pioglitazone 7.5/7.5mg + Metformin 500/1000mg |
| 303 | Pseudoephedrine + Bromhexine |
| 304 | Pseudoephedrine + Cetirizine |
| 305 | Pseudoephedrine + Dextromethorphan + Cetirizine |
| 306 | Rabeprazole + Diclofenac + Paracetamol |
| 307 | Rabeprazole + Zinc + Domperidone |
| 308 | Rabeprazole + Zinc Carnosine |
| 309 | Ranitidine + Domperidone + Simethicone |
| 310 | Ranitidine + Magaldrate |
| 311 | Ranitidine + Magaldrate + Simethicone |
| 312 | Roxithromycin + Serratiopeptidase |
| 313 | Salbutamol + Aminophylline + Guaiphensin |
| 314 | Salbutamol + Bromhexine + Guaiphenesin + Menthol |
| 315 | Salbutamol + Certirizine + Ambroxol |
| 316 | Salbutamol + Choline Theophyllinate + Ambroxol |
| 317 | Salbutamol + Choline Theophyllinate + Carbocisteine |
| 318 | Salbutamol + Theophylline + Bromhexine |
| 319 | Salbutamol+Hydroxyethyltheophylline (Etofylline) + Bromhexine |
| 320 | Sildenafil + Estradiol Valerate |
| 321 | Tamsulosin + Diclofenac |
| 322 | Telmisartan + Metformin |
| 323 | Terbutaline + Ambroxol + Guaiphenesin + Zinc + Menthol |
| 324 | Terbutaline + Bromhexine + Etofylline |
| 325 | Terbutaline + Bromhexine + Guaiphenesin + Dextromethorphan |
| 326 | Terbutaline + Etofylline + Ambroxol |
| 327 | Terbutaline + N-Acetyl L-Cysteine + Guaifenesin |
| 328 | Terpinhydrate + Dextromethorphan + Menthol |
| 329 | Thyroid + Thiamine + Riboflavin + Phyridoxine + Calcium Pantothenate + Tocopheryl Acetate + Nicotinamide |
| 330 | Thyroxine + Pyridoxine + Folic Acid |
| 331 | Tranexamic Acid + Proanthocyanidin |
| 332 | Ursodeoxycholic Acid + Silymarin |
| 333 | Voglibose + Pioglitazone + Metformin |
| 334 | Voglibose+ Metformin + Chromium Picolinate |
| 335 | Zinc Carnosine + Magnesium Hydroxide + Dried Aluminium Hydroxide + Simethicone |
| 336 | Zinc Carnosine + Oxetacaine |
| 337 | Zinc Carnosine + Sucralfate |
| 338 | Artesunate + Arteether + Artemether |

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Approved By:

Director-General (NAFDAC)

Prof. (Mrs.) Mojisola Christianah Adeyeye

Signature:  **Date:** 30/6/24