


F. No. 19(78)/2014/DP/NPPA/Div.II
भारत सरकार
Government of India
रसायन एवं उर्वरक मंत्रालय
Ministry of Chemical and Fertilizers
औषध विभाग
Department of Pharmaceuticals
राष्ट्रीय औषध मूल्य निर्धारण प्राधिकरण
National Pharmaceutical Pricing Authority

5th/3rd Floor,
YMCA cultural Centre Building
1, Jai Singh Road, N. Delhi- 11001
Dated: 20.9.2017

OFFICE MEMORANDUM

Subject: Form - I application of new drug on account of incomplete documents/information under Para 2(u) of DPCO, 2013.

I am directed to refer to the letter/letters sent to applicant company/ies as shown in the annexure and OM of even no dated 19.07.2017 on the above subject uploading a list of companies on NPPA website whose Form I applications were pending on account of incomplete documents/information. On review of Form - I applications of new drug reveals that in 39 cases applicant company/companies who had applied on or before 19.07.2017 (out of the above application) failed to complete their documents/information till date. The status of these cases was put up for consideration in the 49th Authority meeting held on 19.09.2017 and the Authority decided that these cases be rejected. In view of the above, the cases listed in the Annexure I may be treated as rejected. In case the company/ies still wish to seek price approval for the said new drug, the company/ies will be required to apply afresh with all necessary informations.


(APS Sawhney)
Director (Pricing)

Copy to: All Apex Pharma Organizations / Associations i.e. OPPI, IDMA, AISSPMA, PICCI, CII, IPA and FOPE.

List of Form -I applications received on or before 19.07.2017 pending for want of complete documents/information.

Sl. No.	F.No.	Name of the Company/ Formulation	Date of receipt of application	Letter/Reminder issued to companies for submission of complete documents	Remark
1.	235	M/s Meridian Enterprises Pvt. Ltd. Clotrimazole + Clindamycin Passaries Each suppositories contains: Clotrimazole 200mg Clindamycin Phosphate eq. to Clindamycin 100mg Suppository base	19.12.2016 May, 2016	L- 28.12.2016 - 17.01.2017 - 16.02.2017 - 11.04.2017 - 24.05.2017	PENDING FOR COMPLETE DOCUMENTS
2.	540	M/s Synokem Pharmaceuticals Ltd. and marketed by M/s Obsurge Biotech Ltd., Norethisterone Acetate 10mg tablet Each film coated tablet contains: Norethisterone Acetate 10mg	29.11.2016 April, 2016	L - 14.02.2017 - 11.04.2017	PENDING FOR COMPLETE DOCUMENTS
3.	708	Marketed by M/s Fourrts (India) Laboratories Pvt. Ltd. & Manufacturer by M/s Pure & Cure Healthcare Pvt Ltd. . Rejunuron D3 tablet Each film coated tablet contains: Methylcobalamin 15000mcg, Alpha Lipoic Acid USP 100mg Vitamin D3 IP 1000 IU, Pyridozine Hydrochloride IP 3mg, Folic Acid IP 1.5mg	04.5.2016 October, 2015	L - 15.02.2017 18.04.2017 13.06.2017	PENDING FOR COMPLETE DOCUMENTS
4.	838	Manufacturer M/s Inventia Healthcare Pvt Ltd. And Marketer FDC Limited Each uncoated bi-layer tablet contains: Metformin Hydrochloride IP 500mg (in sustained release form) Voglibose IP 0.2 mg Glimepiride IP 1 mg Excipients q.s. Colours: Lake of Brilliant Blue and Lake of Erythrosine.	24.10.2016 March, 2016	L - 10.02.2017 - 17.04.2017 - 22.8.2017	PENDING FOR COMPLETE DOCUMENTS
5.	839	Manufacturer M/s Inventia Healthcare Pvt Ltd. And Marketer FDC Limited Each uncoated bi-layer tablet contains: Metformin Hydrochloride IP 500mg (in sustained release form) Voglibose IP 0.2 mg Glimepiride IP 2 mg Excipients q.s. Colours: Lake of Brilliant Blue and Lake of Erythrosine.	24.10.2016 March, 2016	L - 10.02.2017 - 17.04.2017 - 22.8.2017	PENDING FOR COMPLETE DOCUMENTS
6.	847	Manufacturer And Marketer by M/s Dales Remedies Private Ltd. Sinus CM Exoectorant 60ml & 100ml Each 5 ml contains: Terbutaline Sulphate IP 1.25mg, Ambroxol Hydrochloride IP 15mg, Guaiphenesin IP 50mg, Menthol IP 2.5mg	07.11.2016 April, 2016	L - 17.04.2017 - 18.5.2017	PENDING FOR COMPLETE DOCUMENTS
7.	853	Manufacturer by M/s Sunways Rohto Pharmaceutical Private Limited & Marketer by M/s Sunways (India) Private Limited Each ml contains: Chloramphenicol IP 1% w/v, Dexamethasone Sodium Phosphate IP 0.1% w/v, Polymyxin B' Sulphate BP 5000IU, Phenyl Mercuric Nitrate IP 0.005% w/v	10.11.2016 April, 2016	L - 17.11.2016 - 14.02.2017 - 11.4.2017 - 12.6.2017	PENDING FOR COMPLETE DOCUMENTS
8.	854	Manufacturer by M/s Sunways Rohto Pharmaceutical Private Limited & Marketer by M/s Sunways (India) Private Limited Each gram contains: Chloramphenicol IP 10mg, Dexamethasone Sodium Phosphate IP 1mg, Polymyxin B' Sulphate BP 5000IU,	10.11.2016 April, 2016	L - 17.11.2016 - 14.02.2017 - 11.4.2017 - 12.6.2017	PENDING FOR COMPLETE DOCUMENTS
9.	882	Manufactured by M/s Pure and Care Healthcare Pvt. Ltd. and marketed by M/s Wallace Pharmaceuticals Pvt. Ltd. OPARA XTRA Tablet Each Uncoted Tablet contains: Tramadol Hydrochloride IP 37.5mg,	20.12.2016 May, 2016	L - 10.02.2017 - 19.4.2017	PENDING FOR COMPLETE DOCUMENTS

		Acetaminophen (Paracetamol) IP 325mg			
10.	887	Manufacturer by M/s Pure and Care Healthcare Pvt. Ltd. & marketer By M/s Indoco Remedies Limited Glychek M+ tablet Each uncoated tablet contains: Metformin Hydrochloride IP 500mg (ER) Gliclazide IP 40mg (MR)	21.12.2016 May, 2016	L – 26.12.2016 - 16.02.2017 - 18.4.2017	PENDING FOR COMPLETE DOCUMENTS
11.	894	Manufacturer By M/s ACME Generics LLP and marketer by M/s Glenmark pharmaceutical Ltd Each Prolonged Release Film Coated tablet contains: Diclofenac Sodium IP 100mg	26.12.2016 May, 2016	L – 13.02.2017 - 19.4.2017 - 08.5.2017	PENDING FOR COMPLETE DOCUMENTS
12.	901	Manufactured and marketed by M/s Skymap Pharmaceuticals Pvt. Ltd. Cefimap-AZ tablet Each film coated tablet contains: Cefexime Trihydrate IP eq. to Anhydrous Cefexime 200mg, Azithromycin Dihydrate IP eq. to Anhydrous Azithromycin 250mg	10.01.2017 June, 2016	L – 17.01.2017 - 13.02.2017 - 18.4.2017	PENDING FOR COMPLETE DOCUMENTS
13.	902	Manufactured by M/s Skymap Pharmaceuticals Pvt. Ltd. and marketed by M/s Medicare Pvt. Ltd. Fexiwell-AZ tablet Each film coated tablet contains: Cefexime Trihydrate IP eq. to Anhydrous Cefexime 200mg, Azithromycin Dihydrate IP eq. to Anhydrous Azithromycin 250mg	10.01.2017 June, 2016	L – 17.01.2017 - 13.02.2017 - 18.4.2017	PENDING FOR COMPLETE DOCUMENTS
14.	903	Manufactured by M/s Albert David Limited Ferrous Ascorbate 100mg, Folic Acid 1.5mg tablet	16.01.2017 June, 2016	L – 13.02.2017 - 19.04.2017	PENDING FOR COMPLETE DOCUMENTS
15.	904	Manufactured by M/s Synokem Pharmaceuticals Pvt. Ltd. and marketed by M/s Cadila Pharmaceuticals Ltd. contains: Drospirenone 3mg, Ethinylestradiol 0.03mg	16.01.2017 June, 2016	L – 20.07.2017	PENDING FOR COMPLETE DOCUMENTS
16.	913	Manufactured by M/s Glenmark Pharmaceuticals Pvt. Ltd. and marketed by M/s Ordain Health Care Global Pvt. Ltd. Teneligliptin and Metformin HCL tablet Each film coated tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg Metformin HCL 500mg	06.02.2017 July, 2016	L – 14.02.2017 - 18.04.2017	PENDING FOR COMPLETE DOCUMENTS
17.	919	Manufactured by M/s Unicare India Ltd. and marketed by M/s Obsurge Biotech Ltd., Each tablet contains: Hydroxychloroquine Sulphate 400mg	15.02.2017 July, 2016	L – 23.02.2017 - 18.04.2017	PENDING FOR COMPLETE DOCUMENTS
18.	920	Manufactured M/s Akums Drugs and Pharmaceuticals Ltd. and Marketer M/s Wallace Pharmaceuticals Pvt. Ltd. Walaphage Trio 1 Tablets Each uncoated Bi- Layered tablet contains: Glimepiride IP 1mg, Voglibose 0.2% Metformin HCL IP 500mg (As sustained release form)	27.02.2017 July, 2016	L – 16.03.2017 - 18.04.2017 - 13.06.2017	PENDING FOR COMPLETE DOCUMENTS
19.	921	Manufactured M/s Akums Drugs and Pharmaceuticals Ltd. and Marketer M/s Wallace Pharmaceuticals Pvt. Ltd. Walaphage Trio 1 Tablets Each uncoated Bi- Layered tablet contains: Glimepiride IP 1mg, Voglibose 0.2% Metformin HCL IP 500mg (As sustained release form)	27.02.2017 July, 2016	L – 16.03.2017 - 18.04.2017 - 13.06.2017	PENDING FOR COMPLETE DOCUMENTS
20.	925	Manufactured and Marketer M/s Intas Pharmaceuticals Pvt. Ltd. Each film coated Extended release tablet contains: Metoprolol Succinate IP 71.25mg eq. to Metoprolol Tartrate 75mg (ER)	07.03.2017 August, 2016	L – 16.03.2017 - 09.05.2017	PENDING FOR COMPLETE DOCUMENTS WPA
21.	927	Manufactured and Marketer M/s Infutech Healthcare Limited Each 100ml contains: Sodium Chloride IP 0.45g, Water for injection	09.03.2017 August, 2016	CP is to be fixed. Data awaited. L – 16.03.2017	PENDING FOR COMPLETE DOCUMENTS
22.	928	Manufactured and Marketer M/s Pharma Force Lab contains:	09.03.2017 August, 2016	L – 16.03.2017 - 18.04.2017	PENDING FOR COMPLETE

		Clobetasol Propionate IP 0.05%w/w, Clotrimazole IP 1.00%w/w, Neomycin Sulphate IP 0.50% w/w			DOCUMENTS
23.	931	Manufacturer M/s Immacule Lifesciences Pvt. Ltd. and marketer M/s Cadila Healthcare Ltd. Clarithromycin 500mg injection Each vial contains: Clarithromycin Lactobionic acid 500mg	30.03.2017 August, 2016	L - 11.05.2017	PENDING FOR COMPLETE DOCUMENTS
24.	938	Manufacturer M/s Staywell Formulation Pvt. Ltd. and marketer M/s Profic Organic Ltd. Glimepiride & Metformin tablet Each uncoated bilayered tablet contains: Glimepiride 1mg Metformin Hydrochloride 500mg (as sustained release form)	31.03.2017 August, 2016	L - 18.04.2017 - 23.05.2017 - 13.06.2017	PENDING FOR COMPLETE DOCUMENTS
25.	945	Manufacturer and marketer By M/s Zydus Cadila Healthcare Ltd. Each uncoated tablet contains: Methotrexate IP 20mg	19.4.2017 September, 2016	L - 24.05.2017	PENDING FOR COMPLETE DOCUMENTS WPA
26.	960	Manufacturer And Marketer by M/s Burnet Pharmaceuticals Pvt. Ltd. Clonet Tablet Each uncoated tablet contains: Aceclofenac IP 100mg, Paracetamol IP 325mg,	24.5.2017 October, 2016	L -01.06.2017 - 23.06.2017 - 28..08.2017	PENDING FOR COMPLETE DOCUMENTS
27.	961	Manufacturer And Marketer by M/s Burnet Pharmaceuticals Pvt. Ltd. Clonet Tablet Each capsule contains: Pantaprazole IP (as enteric coated granuales) 20mg, Domperidone IP 10mg	24.5.2017 October, 2016	L -01.06.2017 - 23.06.2017 - 28..08.2017	PENDING FOR COMPLETE DOCUMENTS
28.	983	Manufacturer by M/s Gnosis Pharmaceuticals Pvt. Ltd. and marketed by M/s Neomac Pharmaceuticals Pvt. Ltd. Each film coated tablet contains: Escitalopram Oxalate IP eq. to Escitalopram 5mg, Clonazepam IP 0.25mg	12.6.2017 November, 2016	L - 15.09.2017	PENDING FOR COMPLETE DOCUMENTS
29.	986	Manufacturer by M/s Pure and Cure Healthcare Pvt. Ltd. and marketer M/s East India Pharmaceutical Works Ltd. PYRIGESIC - A Each Film coated tablet contains: Aceclofenac IP 100mg Paracetamol IP 325mg	23.6.2017 November, 2016	L - 20.07.2017	PENDING FOR COMPLETE DOCUMENTS
30.	987	Manufacturer by M/s Pure and Cure Healthcare Pvt. Ltd. and marketer M/s East India Pharmaceutical Works Ltd. PYRIGESIC - T Each Film coated tablet contains: Aceclofenac IP 325mg Tramadol HCL 37.5mg	23.6.2017 November, 2016	L - 20.07.2017	PENDING FOR COMPLETE DOCUMENTS
31.	990	Manufactured by M/s Uttaranchal Biotech Limited and marketed by M/s Neon Laboratories Ltd. LOXHEAL Cream contains: Nifedipine IP 0.3 % Lidocaine BP 1.5 % Imidurea IP 0.2% in a cream base	29.6.2017 November, 2016	L - 20.07.2017	PENDING FOR COMPLETE DOCUMENTS
32.	991	Manufacturer By Ms Tirupati Medicare Ltd. and Marketer by M/s IPCA laboratories Limited. Pacimol MF 125 Suspension Each 5ml contains: Mefenamic Acid IP 50mg Paracetamol IP 125mg Flavoured Syrup base	30.6.2017 November, 2016	L - 20.07.2017	PENDING FOR COMPLETE DOCUMENTS
33.	994	Manufacturer by M/s Ravenbhel Healthcare (P) Ltd. and marketer by M/s IPCA Laboratories Limited Each film coated tablet contains: Etoricoxib IP 60mg, Paracetamol IP 325mg	05.7.2017 December, 2016	L - 19.07.2017	PENDING FOR COMPLETE DOCUMENTS
34.	995	Manufacturer by M/s Synokem Pharmaceuticals Ltd. and marketer by M/s Bharat Serums and Vaccines Limited Each uncoated tablet contains: Misoprostol IP 600mcg (As 1% Misoprostol Dispersion)	10.7.2017 December, 2016	L - 19.07.2017	PENDING FOR COMPLETE DOCUMENTS

35.	1004	Manufacturer by M/s Sunglow Pharmaceuticals Pvt. Ltd. and marketer by M/s Ajanta Pharma Limited Each uncoated bilayer tablet Contains: Metformin Hydrochloride IP 500mg SR, Glimepride IP 1mg	14.7.2017 December, 2016	L - 19.07.2017	PENDING FOR COMPLETE DOCUMENTS
36.	1005	Manufacturer by M/s Sunglow Pharmaceuticals Pvt. Ltd. and marketer by M/s Ajanta Pharma Limited Each uncoated bilayer tablet Contains: Metformin Hydrochloride IP 500mg SR, Glimepride IP 2mg	14.7.2017 December, 2016	L - 19.07.2017	PENDING FOR COMPLETE DOCUMENTS
37.	1006	Manufacturer and marketer by M/s IPCA Laboratories Limited Each film coated tablet Contains: Paracetamol IP 650mg, Caffeine Anhydrous IP 50mg	14.7.2017 December, 2016	L - 19.07.2017	PENDING FOR COMPLETE DOCUMENTS
38.	1009	Manufacturer by M/s Ordain Healthcare Global Pvt. Ltd. and marketer by M/s Ajanta Pharma Ltd. Each film coated bilayered tablet contains: Clinidipine 20mg, Metoprolol Succinate (23.75mg) IP 25mg eq. to Metoprolol Tartrate (As Extended Release)	17.7.2017 December, 2016	L - 19.07.2017	PENDING FOR COMPLETE DOCUMENTS
39.	1010	Manufacturer by M/s Ordain Healthcare Global Pvt. Ltd. and marketer by M/s Ajanta Pharma Ltd. Each film coated bilayered tablet contains: Clinidipine 20mg, Metoprolol Succinate (23.75mg) IP 50mg eq. to Metoprolol Tartrate (As Extended Release)	17.7.2017 December, 2016	L - 19.07.2017	PENDING FOR COMPLETE DOCUMENTS