

F. No. 04-01/2013-DC (Misc. 13-PSC)
Directorate General of Health Services
Office of Drugs Controller General (India)
(FDC Division)

Dated: 14th October 2016

NOTICE

**Subject : Examination of safety and efficacy of FDCs licensed for manufacture for sale
in the country without due approval from DCG(I)**

This has reference to this Directorate letter of even no. Dated 15.1.2013 on the subject cited above. In this regard, various applications filed by the manufacturers have been examined in consultation with Expert Committee constituted for the purpose. Based on such examination, decisions on the applications for issuance of NOCs for continued manufacturing and marketing/ show cause notices/ letters for conducting Phase IV trial have been taken. Accordingly, these letters have been prepared and are ready for despatch. Details of the applicants with number of such letters against each of these applicants are given below.

The concerned applicants can directly collect these letters from 'CRU' section. In case, these letters are not collected within stipulated time, same will be despatched through Speed / Registered post.

FDC DIVISION 13.10.2016

S.NO.	NAME OF COMPANY	DOCUMENT
1.	M/s. Allianz Biosciences Pvt. Ltd.,	10 Letters
2.	Akums Drugs & Pharmaceuticals Pvt. Ltd.,	52 Letters
3.	M/s. Accent Pharma	05 Letters
4.	M/s. Aeon Formulations,	19 Letters
5.	M/s. Axa Parenterals Ltd.,	07 Letters
6.	M/s. Anglo-French Drugs & Industries Ltd.,	02 Letters
7.	M/s. Arius Formulations Pvt. Ltd.,	03 Letters
8.	M/s. Acron Pharmaceuticals	03 Letters
9.	M/s. Alchemist Ltd.,	05 Letters
10.	M/s. Ajanta Pharma	08 Letters
11.	M/s. Argion Cosmed India (P) Ltd.,	01 Letter
12.	M/s. Avalanche Pharmaceuticals	01 Letter

13.	M/s. Anphar Organics Pvt. Ltd.,	01 Letter
14.	M/s. Affy Pharma Pvt. Ltd.,	01 Letter
15.	M/s. Ahlcon Parenterals (I) Pvt. Ltd.,	02 Letters
16.	M/s. AtoZ Lifesciences	01 Letter
17.	M/s. Acme Lifesciences	07 Letters
18.	M/s. Acme Formulations	02 Letter
19.	M/s. AASSK Pharmaceuticals	05 Letters
20.	M/s. Alkem Laboratories	04 Letters
21.	M/s. Abbott Healthcare	05 Letters
22.	M/s. Alembic Pharmaceuticals	09 Letters
23.	M/s. Aurochem Laboratories (I) Pvt. Ltd.,	08 Letters
24.	M/s. Arvind Remedies Ltd.,	02 Letters
25.	M/s. Agio Pharmaceutical Ltd.,	04 Letters
26.	M/s. Admac Formulations Ltd.,	03 Letters
27.	M/s. Aayushi Pharmaceuticals Pvt. Ltd.,	01 Letter
28.	M/s. Aurio Pharm Laboratories	02 Letters
29.	M/s. Advanced Vital Enzymes	01 Letter
30.	M/s. Adcock Ingram Healthcare	01 Letter
31.	M/s. Appasamy Ocular Devices Pvt. Ltd.,	01 Letter
32.	M/s. Able Pharma Ltd.,	01 Letter
33.	M/s. Abro Pharmaceuticals Ltd.,	02 Letters
34.	M/s. Abaris Healthcare Pvt. Ltd.,	01 Letter
35.	M/s. Bethal Pharmaceuticals	03 Letters
36.	M/s. Bonn Schetering Biosciences	09 Letters
37.	M/s. BRD Medilabs	09 Letters
38.	M/s. Biogenetic Drugs Pvt. Ltd.,	06 Letters
39.	M/s. Bidhan Pharmaceuticals	03 Letters
40.	M/s. Biomaarks Drugs India Pvt. Ltd.,	05 Letters
41.	M/s. Befam Pharmaceuticals Pvt. Ltd.,	01 Letter
42.	M/s. Bionext Pharma Pvt. Ltd.,	01 Letter
43.	M/s. BACTEC Pharmaceuticals	01 Letter
44.	M/s. Bal Pharma Ltd.,	01 Letter

45.	M/s. Brassica Pharma Pvt. Ltd.,	01 Letter
46.	M/s. BDH Industries Ltd.,	01 Letter
47.	M/s. BHC Lab Pvt. Ltd.,	02 Letters
48.	M/s. Burnet Pharmaceuticals Pvt. Ltd.,	02 Letters
49.	M/s. Centaur Pharmaceuticals Pvt. Ltd.,	09 Letters
50.	M/s. Cachet Pharmaceuticals Pvt. Ltd.,	11 Letters
51.	M/s. Creative Health Care Pvt. Ltd.,	10 Letters
52.	M/s. Cris Pharma (I) Ltd.,	04 Letter
53.	M/s. Cipla Ltd.,	02 Letters
54.	M/s. Cosmo Life Sciences	03 Letters
55.	M/s. Curetech Skincare	02 Letters
56.	M/s. Cradel Pharmaceuticals Pvt. Ltd.,	03 Letters
57.	M/s. CU-V-Kar Genetics	02 Letters
58.	M/s. Cian Healthcare Ltd.,	01 Letter
59.	M/s. Central Drugs and Pharmaceuticals	06 Letters
60.	M/s. Crescent Therapeutics Ltd.,	01 Letter
61.	M/s. Caplet India Pvt. Ltd.,	02 Letters
62.	M/s. Cotec Healthcare Pvt. Ltd.,	01 Letter
63.	M/s. Corona Remedies Pvt. Ltd.,	01 Letter
64.	M/s. Cheryl Laboratories Pvt. Ltd.,	01 Letter
65.	M/s. Chinubhai Pharma Pvt. Ltd.,	01 Letter
66.	M/s. Consern Pharma (I) Pvt. Ltd.,	01 Letter
67.	M/s. Daeiou Pharmaceuticals (P) Ltd.,	05 Letters
68.	M/s. D.M. Pharma	05 Letters
69.	M/s. Diamond Drugs Pvt. Ltd.,	03 Letters
70.	M/s. Darwin Formulations Pvt. Ltd.,	02 Letters
71.	M/s. Dynamic Organics Life Sciences Pvt. Ltd.,	05 Letters
72.	M/s. Dusap Pharmaceuticals	01 Letter
73.	M/s. Dagon Pharmaceuticals Pvt. Ltd.,	04 Letters
74.	M/s. D.R. Johns Pvt. Ltd.,	03 Letters
75.	M/s. Deepin Pharmaceuticals Pvt. Ltd.,	02 Letters

76.	M/s. Dabur India Ltd.,	01 Letter
77.	Dr. Miltons Laboratories Pvt. Ltd.,	03 Letters
78.	M/s. Dallas Formulations Ltd.,	01 Letter
79.	M/s. Dr. Sains Laboratories	01 Letter
80.	M/s. Encube Ethicals Pvt. Ltd.,	06 Letters
81.	M/s. East African (I) Overseas	03 Letters
82.	M/s. Elder Pharmaceuticals Ltd.,	02 Letters
83.	M/s. Elder Healthcare Ltd.,	01 Letter
84.	M/s. Eskag Pharma Pvt. Ltd.,	03 Letters
85.	M/s. Eucare Pharmaceuticals Pvt. Ltd.,	02 Letters
86.	M/s. Emcee Pharmaceuticals (P) Ltd.,	04 Letters
87.	M/s. East India Pharmaceuticals Works Ltd.,	04 Letters
88.	M/s. Embiotic Laboratories (P) Ltd.,	03 Letters
89.	M/s. East West Pharma	12 Letters
90.	M/s. Elan Pharma (I) Pvt. Ltd.,	01 Letter
91.	M/s. Everest Formulations	03 Letters
92.	M/s. Eisen Pharmaceuticals ltd.,	01 Letter
93.	M/s. Esteem Lab Pvt. Ltd.,	02 Letters
94.	M/s. Emcure Pharmaceuticals Ltd.,	01 Letter
95.	M/s. Fourrts (India) Laboratories Pvt. Ltd.,	01 Letter
96.	M/s. Franco-Indian Remedies Pvt. Ltd.,	01 Letter
97.	M/s. Goodman Pharmaceuticals	09 Letters
98.	M/s. GKM New Pharma	11 Letters
99.	M/s. Geno Pharmaceuticals Ltd.,	05 Letters
100.	M/s. Galpha Laboratories Ltd.,	03 Letters
101.	M/s. Glenmark Pharmaceuticals Ltd.,	03 Letters
102.	M/s. Gurufcure,	02 Letters
103.	M/s. Gopaldas Vishram Co Ltd.,	01 Letter
104.	M/s. GlaxoSmithKline Pharmaceuticals Ltd.,	01 Letter
105.	M/s. Glenwell Pharma	01 Letter
106.	M/s. Garima healthcare Pvt. Ltd.,	01 Letter
107.	M/s. Hiral Labs Ltd.,	01 Letter

108.	M/s. Huntra Labs	02 Letters
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109.	M/s. Herb Edge Healthcare Pvt. Ltd.,	02 Letters
110.	M/s. Healkraft Pharma (I) Pvt. Ltd.,	01 Letter
111.	M/s. Healers Lab	02 Letters
112.	M/s. Helios Pharmaceuticals	01 Letter
113.	M/s. Hema Laboratories Pvt. Ltd.,	13 Letters
114.	M/s. HeSa Pharmaceuticals	03 Letters
115.	M/s. Harson laboratories	01 Letter
116.	M/s. Hygeia Pharmaceuticals Mfg. (P) Ltd.,	01 Letter
117.	M/s. Indi Pharma Pvt. Ltd.,	01 Letter
118.	M/s. Indoco Remedies Ltd.,	01 Letter
119.	M/s. Indchemie Health Specialities Pvt. Ltd.,	02 Letters
120.	M/s. IPCA Laboratories Ltd.,	06 Letters
121.	M/s. Inga Laboratories Pvt. Ltd.,	03 Letters
122.	M/s. Japshi Chem Pharmaceuticals	05 Letters
123.	M/s. J.R. Pharmaceuticals	02 Letters
124.	M/s. Jubilant Pharmaceuticals Pvt. Ltd.,	01 Letter
125.	M/s. J's Laboratories (P) ltd.,	02Letters
126.	M/s. Juggat Pharma	01 Letter
127.	M/s. Khandelwal Laboratories Pvt. Ltd.,	04 Letters
128.	M/s. Kaizen Pharmaceuticals	07 Letters
129.	M/s. Krebs Healthcare (P) Ltd.,	03 Letters
130.	M/s. Knox Life Sciences	04 Letters
131.	M/s Kaptab Pharmaceuticals	01 Letter
132.	M/s. Karnataka Antibiotics & Pharmaceuticals Ltd.,	01 Letter
133.	M/s. Kamron Laboratories Ltd.,	02 Letters
134.	M/s. Karlin Pharmaceuticals and Exports Pvt. Ltd.,	02 Letters
135.	M/s. Klar Sehen Pvt. Ltd.,	01 Letter
136.	M/s. Logos Pharma	1 Letter
137.	M/s. Lark Laboratories India Ltd.,	01 Letter
138.	M/s. Livin Formulations	04 Letters

139.	M/s. Life Line Pharma	03 Letters
140.	M/s. Lyra Laboratories Pvt. Ltd.,	05 Letters

141.	M/s. Laborate Pharmaceuticals India Ltd.,	02 Letters
142.	M/s. Leben Laboratories Pvt. Ltd.,	01 Letter
143.	M/s. Lincoln Pharmaceuticals Ltd.,	01 Letter
144.	M/s. Lustre Derma Care	01 Letter
145.	M/s. Laboratories Griffon Pvt. Ltd.,	04 Letters
146.	M/s. Lessac Research Laboratories Pvt. Ltd.,	01 Letter
147.	M/s. Lok-Beta Pharmaceuticals India Pvt. Ltd.,	01 Letter
148.	M/s. Libra Drug (India)	01 Letter
149.	M/s. MC Riyavin Bio-Research	01 Letter
150.	M/s. Mercury Laboratories Ltd.,	03 Letters
151.	M/s. Maneesh Pharmaceuticals Ltd.,	03 Letters
152.	M/s. Mascot Health Series Pvt. Ltd.,	09 Letters
153.	M/s. Meyer Organics Pvt. Ltd.,	10 Letters
154.	M/s. Med Manor Organics Pvt. Ltd.,	08 Letters
155.	M/s. MDC Pharmaceuticals (P) Ltd.,	08 Letters
156.	M/s. Marien Pharmatech Pvt. Ltd.,	02 Letters
157.	M/s. Madras Pharmaceuticals	05 Letters
158.	M/s. Moraceae Pharmaceuticals Pvt. Ltd.,	06 Letters
159.	M/s. Micro Labs Ltd.,	05 Letters
160.	M/s. Medibest Pharma Pvt. Ltd.,	03 Letters
161.	M/s. Morepen Laboratories Ltd.,	02 Letters
162.	M/s. Mepromax Lifesciences Pvt. Ltd.,	03 Letters
163.	M/s. Mistair Health & Hygiene Pvt. Ltd.,	01 Letter
164.	M/s. Mediforce Health Care Pvt. Ltd.,	02 Letters
165.	M/s. Maxtar Biogenics	02 Letters
166.	M/s. Millennium Herbal Care Ltd.,	01 Letter
167.	M/s. Midas Care Pharmaceuticals Pvt. Ltd.,	02 Letters
168.	M/s. Medipol Pharmaceuticals	01 Letter
169.	M/s. Medeor Pharma Pvt. Ltd.,	01 Letter

170.	M/s. Mendine Pharmaceuticals Pvt. Ltd.,	03 Letters
171.	M/s. Marien Pharmatech Pvt. Ltd.,	01 Letter
172.	M/s. Marc Laboratories Ltd.,	01 Letter

173.	M/s. Mamta Pharmaceuticals	01 Letter
174.	M/s. Macleods Pharmaceuticals Ltd.,	01 Letter
175.	M/s. Mediguard Remedies	01 Letter
176.	M/s. Noel Pharma India Pvt. Ltd.,	09 Letters
177.	M/s. National Pharmaceuticals	03 Letters
178.	M/s. Naxpar Pharma Pvt. Ltd.,	05 Letters
179.	M/s. NANZ Med Science Pharma (P) Ltd.,	01 Letter
180.	M/s. Next Wave India	01 Letter
181.	M/s. NTK Pharma	01 Letter
182.	M/s. ONEX Life Science Pvt. Ltd.,	01 Letter
183.	M/s. Orbit Life Sciences Pvt. Ltd.,	07 Letters
184.	M/s. Ontop Pharmaceuticals Pvt. Ltd.,	01 Letter
185.	M/s. Psychotropics India Pvt. Ltd.,	07 Letters
186.	M/s. Pro Laboratories Pvt. Ltd.,	07 Letters
187.	M/s. Pro-Laboratories Pvt. Ltd.,	04 Letters
188.	M/s. Pharma Synth Formulations Ltd.,	07 Letters
189.	M/s. Promed Laboratories Pvt. Ltd.,	03 Letters
190.	M/s. Panacea Biotech Ltd.,	03 Letters
191.	M/s. Pristine Lifesciences	04 Letters
192.	M/s. Pulse Pharmaceuticals Ltd.,	01 Letter
193.	M/s. PURO-Pharma Laboratories	01 Letter
194.	M/s. Pegasus Farmaco India Pvt. Ltd.,	01 Letter
195.	M/s. Piramal Enterprises Ltd.,	01 Letter
196.	M/s. Pharmafabicon,	01 Letter
197.	M/s. Pilco Healthcare Pvt. Ltd.,	01 Letter
198.	M/s. Parker Robinson Pvt. Ltd.,	02 Letters
199.	M/s. Preet International Pvt. Ltd.,	02 Letters
200.	M/s. Prakruti Products Pvt. Ltd.,	01 Letter
201.	M/s. P & B Laboratories Ltd.,	01 Letter

202.	M/s. Parnax Lab Ltd.,	01 Letter
203.	M/s. Pfizer Ltd.,	01 Letter
204.	M/s. Surien Pharmaceuticals (P) Ltd.,	01 Letter

205.	M/s. Sarvotham Care Ltd.,	01 Letter
206.	M/s. Symbiotic Drugs & Diabetic Care Pvt. Ltd.,	01 Letter
207.	M/s. Stedman Pharmaceuticals Pvt. Ltd.,	06 Letters
208.	M/s. Shreya Life Sciences Pvt. Ltd.,	02 Letters
209.	M/s. Skan Research Labs Pvt. Ltd.,	05 Letters
210.	M/s. Savi Pharma	02 Letters
211.	M/s. Saichem Parenterals Pvt. Ltd.,	01 Letter
212.	M/s. Santo Formulations	01 Letter
213.	M/s. Sankalp Healthcare & Allied Products Pvt. Ltd.,	01 Letter
214.	M/s. SKN Organics Pvt. Ltd.,	01 Letter
215.	M/s. Softgel Healthcare Pvt. Ltd.,	01 Letter
216.	M/s. Selvok Pharmaceuticals Co.,	01 Letter
217.	M/s. Sterile Gene Life Sciences (P) Ltd.,	01 Letter
218.	M/s. Suraksha Pharma Pvt. Ltd.,	02 Letters
219.	M/s. Sunways (India) Pvt. Ltd.,	02 Letters
220.	M/s. Sunglow Pharmaceuticals Pvt. Ltd.,	02 Letter
221.	M/s. Strassenburg Pharmaceuticals Ltd.,	03 Letters
222.	M/s. Swastik Pharmaceuticals	02 Letters
223.	M/s. Salute Bestochem	03 Letters
224.	M/s. Shiva Biogenetic Pharmaceuticals Pvt. Ltd.,	06 Letters
225.	M/s. Scott-Edil Pharmacia Ltd.,	03 Letters
226.	M/s. Sain Medicaments Pvt. Ltd.,	04 Letters
227.	M/s. Sayora Pharma Pvt. Ltd.,	03 Letters
228.	M/s. Syncom Healthcare Ltd.,	09 Letters
229.	M/s. Sun Pharma Drugs Pvt. Ltd.,	03 Letters
230.	M/s. Sun Pharmaceuticals Industries Ltd.,	02 Letters
231.	M/s. SAF Fermion Ltd.,	05 Letters
232.	M/s. SAAR Biotech	09 Letters
233.	M/s. Synokem Pharmaceuticals Ltd.,	07 Letters

234.	M/s. Swiss Garnier Life Sciences	10 Letters
235.	M/s. Suncare Formulations Pvt. Ltd.,	05 Letters
236.	M/s. Sunrise International Labs Ltd.,	01 Letter
237.	M/s. Safetab Life Sciences	10 Letters
238.	M/s. Smilax Health Care Pvt. Ltd.,	04 Letters
239.	M/s. Sanzyme Ltd.,	01 letter
240.	M/s. Serin Formulations Pvt. Ltd.,	01 Letter
241.	M/s. Restech Pharma	07 Letters
242.	M/s. Resilient Cosmeceuticals Pvt. Ltd.,	03 Letters
243.	M/s. Ravian Life Sciences Pvt. Ltd.,	05 Letter
244.	M/s. RPG Life Sciences	02 Letters
245.	M/s. Res Sancta,	08 Letters
246.	M/s. Rivpra Formulation Pvt. Ltd.,	05 Letters
247.	M/s. Ricker Pharmaceuticals Pvt. Ltd.,	04 Letters
248.	M/s. Ravenbhel Healthcare Pvt. Ltd.,	05 Letters
249.	M/s. Reltsen Health Care	05 Letters
250.	M/s. Retort Laboratories	01 Letter
251.	M/s. Tanned Pharmaceuticals	04 Letters
252.	M/s. Tychos Therapeutics Pvt. Ltd.,	06 Letters
253.	M/s. Themis Medicare Ltd.,	02 Letters
254.	M/s. The Pharmaceuticals and Chemicals Travancore Pvt. Ltd.,	16 Letters
255.	M/s. Tirupati Medicare Ltd.,	07 Letters
256.	M/s. The Madras Pharmaceuticals	02 Letters
257.	M/s. Tristar Formulations Pvt. Ltd.,	03 Letters
258.	M/s. Tablet (India) Ltd.,	15 Letters
259.	M/s. Unichem Laboratories Ltd.,	01 Letter
260.	M/s. Unibiotech Formulations	06 Letters
261.	M/s. Unix Biotech	10 Letters
262.	M/s. Unique Biotech Ltd.,	04 Letters
263.	M/s. Unimarck Pharma (India) Ltd.,	03 Letters
264.	M/s. Unijules Life Sciences Ltd.,	03 Letters
265.	M/s. UCB India Pvt. Ltd.,	01 Letter
266.	M/s. Universal Twin Labs	03 Letters

267.	M/s. Unicare (India) Pvt. Ltd.,	02 Letters
268.	M/s. Universal Pharmaceuticals Ltd.,	02 Letters
269.	M/s. Vance & Health Pharmaceuticals Pvt. Ltd.,	05 Letters
270.	M/s. Vivimed Labs Ltd.,	05 Letters
271.	M/s. Valence healthcare	04 Letters
272.	M/s. V.G.I. Pharma Pvt. Ltd.,	01 Letter
273.	M/s. Visa Drugs & Pharmaceuticals	01 Letter
274.	M/s. Vapi Care Pharma	01 Letter
275.	M/s. Wallace Pharmaceuticals Ltd.,	05 Letters
276.	M/s. Windlas Biotech Ltd.,	11 Letters
277.	M/s. Wockhardt Ltd.,	03 Letters
278.	M/s. Win Medicare Pvt. Ltd.,	02 Letter
279.	M/s. Yash Pharma Laboratories Pvt. Ltd.,	01 Letter
280.	M/s. Yash Pharma Laboratories	05 Letters
281.	M/s. Yash Medicare Pvt. Ltd.,	02 Letters
282.	M/s. Zuventus Healthcare Ltd.,	04 Letters
283.	M/s. Zim Laboratories	02 Letters