

# TODAY LETTER DATED 03.10.2018

## GLOBAL CLINICAL TRIAL

SR. NO.	COMPANY NAME	REFERENCE NO.	STATUS
1	M/S. ROCHE	23884/23885	PA APPROVAL LETTER
2	M/S. ELI LILLY	30907	PA APPROVAL LETTER

## COSMETICS DIVISION

S.NO.	NAME OF APPLICANT	DIARY NO.	TYPE OF LETTER
1.	M/S. NESTLE SKIN HEALTH, MUMBAI	31609	DEFICIENCY LETTER
2.	M/S. NESTLE SKIN HEALTH, MUMBAI	25578	DEFICIENCY LETTER
3.	M/S. NESTLE SKIN HEALTH, MUMBAI	RC/COS-00267	DEFICIENCY LETTER

## SUBSEQUENT NEW DRUG

S. NO.	NAME OF THE FIRM	REFERENCE NO.	COMPUTER NO.	TYPE OF LETTER
1.	M/S AKUMS DRUGS	31347	-	BE NOC
2.	M/S NATCO PHARMA	4479	-	APPROVAL LETTER
3.	M/S MICRO LABS	8528	-	APPROVAL LETTER
4.	M/S RUSAN PHARMA	34624	-	APPROVAL LETTER
5.	M/S SYNOKEM PHARMACEUTICALS	31611	-	BE NOC, DEFICIENCY LETTER
6.	M/S MSN LABORATORIES	7641	-	APPROVAL LETTER
7.	M/S TROIKAA PHARMACEUTICALS	38965	-	APPROVAL LETTER
8.	M/S ALKEM LABORATORIES	-	-	BE NOC
9.	M/S AKUMS DRUGS	28662	10009724	BE NOC, DEFICIENCY LETTER

<b>10.</b>	M/S CADILA HEALTHCARE	5034	-	APPROVAL LETTER (2)
<b>11.</b>	M/S TORRENT PHARMACEUTICALS	31556	1044091	CT NOC
<b>12.</b>	M/S SANDOZ PRIVATE LIMITED	30930	1030565	DEFICIENCY LETTER

### LVP DIVISION

S. NO.	COMPANY NAME	FTS NO. /DIARY NO.	STATUS
01	M/S. AKUMS DRUGS PHARMACEUTICALS, HARIDWAR	1022625, 1022637	APPROVAL
02	M/S. EMCURE PHARMACEUTICALS LTD., PUNE	1029672	APPROVAL
03	M/S. KEYUR PHARMACHEM, (I) PVT. LTD., THANE	1011583	APPROVAL

### FDC DIVISION

S.NO.	NAME OF COMPANY	DIARY NO.	DOCUMENT
<b>1.</b>	M/S. WINDLAS BIOTECH	23792/24829/24943	<b>03 LETTERS</b>
<b>2.</b>	M/S. AJANTA PHARMA	30917/30919/30916/ 30086/30085	<b>05 LETTERS</b>
<b>3.</b>	M/S. J. B. CHEMICALS & PHARMACEUTICALS	965062	<b>LETTER</b>
<b>4.</b>	M/S. SWISS GARNIER LIFE SCIENCES	18429	<b>LETTER</b>
<b>5.</b>	M/S. SKYMAP PHARMACEUTICALS	985993	<b>04 LETTERS</b>
<b>6.</b>	M/S. SMILAX HEALTHCARE	21859/21858/21861/2186 0/21857	<b>05 LETTERS</b>
<b>7.</b>	M/S. LABORATE PHARMACEUTICALS	14745/14731	<b>02 LETTERS</b>
<b>8.</b>	M/S. PURE & CURE HEALTHCARE	14486/26119/24287	<b>03 LETTERS</b>
<b>9.</b>	M/S. MAPRA LABORATORIES	18658	<b>LETTER</b>
<b>10.</b>	M/S. STEDMAN PHARMACEUTICALS	20549	<b>LETTER</b>
<b>11.</b>	M/S. EMCURE PHARMACEUTICALS	18490	<b>LETTER</b>

12.	M/S. ORDAIN HEALTH CARE GLOBAL	19043/19044	<b>02 LETTERS</b>
13.	M/S. D. D. PHARMACEUTICALS	23063	<b>LETTER</b>
14.	M/S. PERCOS INDIA	10121	<b>LETTER</b>
15.	M/S. CRADEL PHARMACEUTICALS	9484	<b>LETTER</b>
16.	M/S. SQUARE PHARMACEUTICALS	13347	<b>LETTER</b>
17.	M/S. HEMA LABORATORIES	22244	<b>LETTER</b>
18.	M/S. OM SAI PHARMA PACK	31200	<b>LETTER</b>
19.	M/S. SANKALP HEALTHCARE & ALLIED PRODUCTS	30001	<b>LETTER</b>
20.	M/S. PHARMA FORCE LAB	24851	<b>LETTER</b>
21.	M/S. UNIBIOTECH FORMULATIONS	25355	<b>LETTER</b>
22.	M/S. MICRO LABS	23903	<b>LETTER</b>
23.	M/S. SUN PHARMA MEDISALES	20670	<b>LETTER</b>
24.	M/S. IPCA LABORATORIES	21782	<b>LETTER</b>
25.	M/S. SYNOKEM PHARMACEUTICALS	18481	<b>LETTER</b>
26.	M/S. ARISTO PHARMACEUTICALS	29366 & 22204	<b>LETTER</b>
27.	M/S. INDU DRUGS	995816	<b>LETTER</b>
28.	M/S. NOVARTIS HEALTHCARE	22384	<b>LETTER</b>
29.	M/S. LUPIN LTD.	29363	<b>LETTER</b>
30.	M/S. IND SWIFT	985992	<b>LETTER</b>
31.	M/S. CIPLA LTD.,	31622 & 9563	<b>APPROVAL LETTER</b>
32.	M/S. SERDIA PHARMACEUTICALS	32260 & 15044	<b>APPROVAL LETTER</b>
33.	M/S. ASTRA ZENECA PHARMA INDIA	7744 & 31965	<b>APPROVAL LETTER</b>
34.	M/S. MEPROMAX LIFESCIENCES	18709	<b>LETTER</b>
35.	M/S. PULSE PHARMACEUTICALS	23724	<b>LETTER</b>

36.	M/S. AEON FORMULATIONS	20326	LETTER
37.	M/S. HETERO LABS	28873	LETTER
38.	M/S. MASCOT HEALTH SERIES	NIL	02 LETTERS
39.	M/S. JUGGAT PHARMA	9353	LETTER

### NEW DRUG

S.NO.	NAME OF APPLICANT	DIARY NO.	TYPE OF LETTER
1.	M/S. SANOFI SYNTHELABO (INDIA) LTD	-	CT NOC LETTER
2.	M/S CADILA HEALTHCARE	-	CT NOC LETTER
3.	M/S PHARMAZZ INDIA PRIVATE LTD	-	CT NOC LETTER
4.	M/S THEMIS MEDICARE LTD	-	TEST LICENSE
5.	M/S GILEAD SCIENCES INDIA PVT LTD	-	TEST LICENSE
6.	M/S COVANCE INDIA PHARMACEUTICALS SERVICES PVT LTD	-	AMENDMENT LETTER
7.	M/S LAMBDA THERAPEUTIC RESEACH LTD	-	LETTER
8.	M/S PFIZER LIMITED	-	PERMISSION ISSUED
9.	M/S RASAYANI BIOLOGICS PVT LTD	-	CLARIFICATION LETTER
10.	M/S ZUVENTUS HEALTHCARE LTD	-	CT NOC LETTER
11.	M/S MSN LABORATORIES PRIVATE LIMITED	-	LETTER
12.	M/S ISSAR PHARMACEUTICALS PVT LTD	-	LETTER
13.	M/S KAPSTONE INDIA PHARMACEUTICAL PRIVATE LIMITED	-	LETTER
14.	M/S HETERO LABS LIMITED	-	CLARIFICATION LETTER
15.	M/S CENTAUR PHARMACEUTICALS PVT LTD	-	QUERY LETTER AND IPC LETTER (3)
16.	M/S LANXESS INDIA PRIVATE LIMITED	-	QUERY LETTER
17.	M/S EMCURE PHARMACEUTICALS	-	LETTER (4)

### MEDICAL DEVICE DIVISION

S.NO.	COMPANY NAME	DIARY NO	STATUS
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1.	M/S. BARD INDIA HEALTHCARE PVT. LTD., ALL PORT OFFICE OF CDSCO	NIL	LETTER
2.	M/S. BARD INDIA HEALTHCARE PVT. LTD., ALL PORT OFFICE OF CDSCO	NIL	LETTER

## BIOLOGICAL DIVISION

S. NO.	NAME OF FIRM	REFERENCE NO.	TYPE OF LETTER
1	M/S BIOCON LTD	31212	APPROVAL LETTER
2	M/S BIOLOGICAL E. LTD	31026	CLARIFICATION LETTER
3	M/S SAMARTH LIFE SCIENCES PVT, LTD	1055106 (FTS NO)	CLARIFICATION LETTER
4	M/S BHARAT BIOTECH INTERNATIONAL LTD	P-949947, 21198, 25506	CLARIFICATION & APPROVAL LETTER
5	M/S BIOCAD INDIA PVT, LTD		AMENDMENT LETTER
6	M/S RELIANCE LIFE SCIENCES PVT, LTD	27974, 31125, 26107	APPROVAL CLARIFICATION LETTER
7	M/S SANOFI PASTEUR INDIA PVT, LTD	21113, 27126	AMENDMENT LETTER
8	M/S BOEHRINGER INGELHEIM INDIA PVT, LTD	24149	AMENDMENT LETTER
9	M/S CADILA HEALTHCARE LTD	27567	APPROVAL LETTER
10	M/S PANACEA BIOTECH LTD	6249	APPROVAL LETTER
11	M/S SHANTHA BIOTECHNICS PVT, LTD	31355	APPROVAL LETTER
12	M/S S.K. LOGISTICS	983390 (FTS NO)	CLARIFICATION LETTER
13	M/S CHIRON BEHRING VACCINES PVT, LTD	26171	ACKNOWLEDGE LETTER
14	M/S STEMPEUTICS RESEARCH PVT, LTD	32204	CLARIFICATION LETTER
15	M/S HEMOPHILIA FEDERATION INDIA	31524, 31525, 31526, 31527, 31528	APPROVAL LETTER
16	M/S DR. REDDY'S LABORATORIES LTD	29367, 2510	APPROVAL & AMENDMENT LETTER
17	M/S GSK ASIA PVT, LTD	23803, 27601	APPROVAL & CONTINUATION LETTER
18	M/S FRONTIER LIFELINE PVT, LTD	1031692	CLARIFICATION LETTER
19	M/S ROCHE PRODUCTS INDIA PVT, LTD	28562	ACKNOWLEDGE & CLARIFICATION LETTER

20	M/S NOVO NORDISK INDIA PVT, LTD	26497	CLARIFICATION LETTER
21	M/S M.J BIOTECH PVT, LTD		CONTINUATION LETTER
22	M/S WOCKHARDT LTD	27327, 20989	APPROVAL LETTER
23	M/S HETERO BIOPHARMA LTD	31500	APPROVAL LETTER
24	M/S INTAS PHARMACEUTICALS LTD	30600	APPROVAL LETTER
25	M/S SUN PHARMACEUTICAL INDUSTRIES LTD	31758	APPROVAL LETTER
26	M/S SERUM INSTITUTE OF INDIA LTD	13798, 30232	ACKNOWLEDGE & AMENDMENT LETTER

### INTERNATIONAL CELL

S. NO	NAME OF FIRM	TYPE
1.	M/S. FOURRTS (INDIA) LABORATORIES PVT LTD, CHENNAI	<b>NOC</b>
2.	M/S. FINEKEM LABORATORIES PVT LTD, AURANGABAD	<b>WC</b>
3.	M/S. HERBAL CREATIONS, NAINITAL	<b>WC</b>
4.	M/S. HETERO LABS LTD, UNIT-IX, VISAKHAPATNAM	<b>WC</b>
5.	M/S. MSN LABORATORIES PVT LTD, UNIT-II, TELANGANA	<b>WC</b>
6.	M/S. MSN LABORATORIES PVT LTD, UNIT-II, TELANGANA	<b>LETTER</b>
7.	M/S. NEULAND LABORATORIES LTD, UNIT-I, TELANGANA	<b>WC</b>
8.	M/S. NEULAND LABORATORIES LTD, UNIT-II, TELANGANA	<b>WC</b>
9.	<b>M/S. QUANTUM DRUGS &amp; CHEMICALS, TAMILNADU</b>	<b>WC</b>