

TODAY LETTER DATED 09.11.2020

INTERNATIONAL CELL

| S. NO | NAME OF FIRM | TYPE |
|-------|---|--------|
| 1 | M/S APICORE PHARMACEUTICALS PVT LTD VADODARA | WC |
| 2 | M/S SARV BIOLABS PVT LTD SIRMOUR | WC |
| 3 | M/S LAMBDA THERAPEUTICS RESEARCH LTD NAVI MUMBAI | LETTER |
| 4 | M/S CLIANTHA RESEARCH LTD AHMEDABAD | LETTER |

DIAGNOSTIC DIVISION

| S. NO. | COMPANY NAME | DIARY NO. | STATUS |
|--------|---------------------------------------|-----------|--------|
| 1. | M/S ROCHE DIAGNOSTICS INDIA PVT. LTD. | 8278 | LETTER |

MEDICAL DEVICE DIVISION

| S.NO. | COMPANY NAME | DIARY NO | STATUS |
|-------|---|----------|--------|
| 1. | M/S. POLY MEDICURE LTD., THE STATE DRUGS CONTROLLER, PANCHKULA THE DEPUTY DRUGS CONTROLLER, GHAZIABAD | 8139 | LETTER |
| 2. | M/S. POLY MEDICURE LTD., THE STATE DRUGS CONTROLLER, PANCHKULA THE DEPUTY DRUGS CONTROLLER, GHAZIABAD | 8140 | LETTER |
| 3. | M/S. POLY MEDICURE LTD., THE STATE DRUGS CONTROLLER, PANCHKULA THE DEPUTY DRUGS CONTROLLER, GHAZIABAD | 8138 | LETTER |
| 4. | M/S. POLY MEDICURE LTD., THE STATE DRUGS CONTROLLER, PANCHKULA THE DEPUTY DRUGS CONTROLLER, GHAZIABAD | 8132 | LETTER |
| 5. | M/S. POLY MEDICURE LTD., THE STATE DRUGS CONTROLLER, PANCHKULA THE DEPUTY DRUGS CONTROLLER, GHAZIABAD | 8135 | LETTER |
| 6. | M/S. POLY MEDICURE LTD., THE STATE DRUGS CONTROLLER, PANCHKULA THE DEPUTY DRUGS CONTROLLER, GHAZIABAD | 8136 | LETTER |

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| 7. | M/S. POLY MEDICURE LTD., THE STATE DRUGS CONTROLLER, PANCHKULA THE DEPUTY DRUGS CONTROLLER, GHAZIABAD | 8213 | LETTER |
| 8. | M/S. VENTURA ADHESIVE COATINGS PVT. LTD., THE DEPUTY DRUGS CONTROLLER, BANGALORE THE DRUGS CONTROLLER, BANGALORE | NIL | LETTER |
| 9. | MS. BIORAD MEDISYS PVT. LTD., | 8161 | LETTER |
| 10. | MS. BIORAD MEDISYS PVT. LTD., | 8161 | LETTER |
| 11. | M/S. SURETEX PROPHYLACTICS (INDIA) PVT. LTD., | 8046 | LETTER |

BIOLOGICAL DIVISION

| S. NO. | NAME OF FIRM | REFERENCE NO. | TYPE OF LETTER |
|--------|--|-------------------|--|
| 1 | M/S PFIZER LTD | 7653, 6146 | CLARIFICATION LETTER |
| 2 | M/S BRISTOL MYERS SQUIBB INDIA PVT, LTD | 7661 | CLARIFICATION LETTER |
| 3 | M/S PLASMAGEN BIOSCIENCES PVT, LTD | 8086 | CLARIFICATION LETTER |
| 4 | M/S REGENIX BIOSCIENCES LTD | | APPROVAL LETTER |
| 5 | M/S NOVO NORDISK INDIA PVT, LTD | 7254 | ACKNOWLEDGE LETTER |
| 6 | M/S SANOFI INDIA LTD | 4799 | ACKNOWLEDGE LETTER |
| 7 | M/S GSK PHARMACEUTICALS LTD | 7832 | ACKNOWLEDGE & APPROVAL LETTER |
| 8 | M/S GSK ASIA PVT, LTD | 6362 | APPROVAL LETTER |
| 9 | M/S ZUVENTUS HEALTHCARE LTD | 5523 | CONTINUATION LETTER |
| 10 | M/S MJ BIPHARM PVT, LTD | 13947 | APPROVAL LETTER |
| 11 | M/S CADILA PHARMACEUTICALS LTD | 13947 | APPROVAL LETTER |
| 12 | M/S BHARAT BIOTECH INTERNATIONAL LTD | 327 | APPROVAL LETTER |
| 13 | M/S JOHNSON & JOHNSON PVT, LTD | 5240 , 7214 | ACKNOWLEDGE & APPROVAL LETTER |
| 14 | M/S SHIRE BIOTECH INDIA PVT, LTD | 8209, 5053 , 5484 | ACKNOWLEDGE & APPROVAL LETTER |
| 15 | M/S DR. REDDY'S LABORATORIES LTD | 8500, 6739, 7335 | CONTINUATION, CLARIFICATION & ACKNOWLEDGE LETTER |
| 16 | M/S ROCHE PRODUCTS INDIA PVT, LTD | 4756, 5578, 5577 | CLARIFICATION LETTER |
| 17 | M/S BIOLOGICAL E. LTD | | OM LETTER |

NEW DRUG

| S.NO. | NAME OF APPLICANT | DIARY NO. | TYPE OF LETTER |
|-------|---------------------------------------|-----------|----------------|
| 1. | M/S. BDR PHARMA | - | QUERY LETTER |
| 2. | M/S BDR PHARMACEUTICALS INTERNATIONAL | - | CT-17 LETTER |

FDC DIVISION

| S.NO. | NAME OF COMPANY | DIARY NO. | DOCUMENT |
|-------|-----------------------------------|------------|--|
| 1. | M/S. ABBOTT HEALTHCARE | NIL | CT-23 (APPROVAL LETTER) |
| 2. | M/S. MASCOT HEALTHCARE | NIL | LETTER |
| 3. | M/S. THEO PHARMA | 13100 | LETTER |
| 4. | M/S. AGIO PHARMACEUTICALS | NIL | AMENDMENT LETTER |
| 5. | M/S. MSN LABORATORIES | NIL | LETTER |
| 6. | M/S. SYNOKEM PHARMACEUTICALS | NIL | CT NOC & APPROVAL LETTER (CT-23) |
| 7. | M/S. OTSUKA PHARMACEUTICALS INDIA | NIL | CT-06 (CT NOC) & TEST LICENSE (CT-17) |
| 8. | M/S. HETERO HEALTHCARE | NIL | CT-07 (BE NOC) |
| 9. | M/S. LUPIN LTD. | NIL | IPC NOC |
| 10. | M/S. NEON LABORATORIES | NIL | LETTER |