

TODAY LETTER DATED 07-11-2019

LETTER PERTAINING TO MISC/SHELF LIFE (IMPORT & REG.DIV)

| S.NO. | NAME OF APPLICANT | DIARY NO. | TYPE OF LETTER |
|-------|-------------------------|-----------|----------------|
| 1. | DIVINNE SBR | 11886 | LETTER |
| 2. | MYLAN LABORATORIES LTD. | 14604 | LETTER |

MEDICAL DEVICE DIVISION

| S.NO. | COMPANY NAME | DIARY NO | STATUS |
|-------|----------------------------------------------------------------------------------------------------------------------|----------|---------------------|
| 1. | M/S. APOLLO HEALTH AND LIFESTYLE LTD., | 14211 | PRESENTATION LETTER |
| 2. | M/S. VISHAL SURGICAL EQUIPMENT CO. PVT. LTD., | 13241 | PRESENTATION LETTER |
| 3. | M/S. SUN DENTAL AND MEDICAL DEVICES, | 13834 | PRESENTATION LETTER |
| 4. | M/S. LA-MED HEALTHCARE PVT. LTD., THE STATE DRUGS CONTROLLER, PANCHKULA THE DEPUTY DRUGS CONTROLLER, GHAZIABAD | 14567 | LETTER |
| 5. | M/S. HEALTHIUM MEDTECH PVT. LTD., | NIL | LETTER (FSC) |
| 6. | M/S. SAHAJANAND MEDICAL TECHNOLOGIES PVT. LTD., | 14495 | LETTER (FSC) |
| 7. | M/S. RAJIV HYDRAULICS PVT. LTD., | 11271 | LETTER |
| 8. | M/S. BROWNDOVE HEALTHCARE PVT. LTD., | 14440 | LETTER |
| 9. | M/S. CAREGROUP SIGHT SOLUTION LLP, | 7463 | LETTER |
| 10. | M/S. OSSTEM IMPLANT INDIA PVT. LTD., | 13575 | LETTER |
| 11. | M/S. AEGIS LIFESCIENCES PVT. LTD., THE COMMISSIONER, GANDHINAGAR THE DEPUTY DRUGS CONTROLLER, AHMEDABAD | NIL | LETTER (NCC) |
| 12. | M/S. AEGIS LIFESCIENCES PVT. LTD., | NIL | LETTER (MSC) |

DIAGNOSTIC DIVISION

| S. NO. | COMPANY NAME | DIARY NO. | STATUS |
|--------|------------------------------------------|---------------|--------|
| 1. | M/S PREMIER MEDICAL CORPORATION PVT. LTD | 13999 | LETTER |
| 2. | M/S DHR HOLDINGS INDIA PVT. LTD | 10565 | LETTER |
| 3. | M/S BECKMAN COULTER INDIA PVT. LTD | 13990 | LETTER |
| 4. | M/S BIOMERIEUX INDIA PVT. LTD | 14171 | LETTER |
| 5. | M/S PREMIER MEDICAL CORPORATION PVT. LTD | 14000 | LETTER |
| 6. | M/S ROCHE DIAGNOSTIC INDIA PVT. LTD | 13903 | LETTER |
| 7. | M/S ROCHE DIAGNOSTIC INDIA PVT. LTD | 13244 & 14157 | LETTER |

FDC FDC DIVISION

| S.NO. | NAME OF COMPANY | DIARY NO. | DOCUMENT |
|-------|-------------------------------------|--------------|------------------------|
| 1. | M/S. MASCOT HEALTH SERIES | NIL | SEC LETTER |
| 2. | M/S. SUN PHARMA LABORATORIES | 13575 | APPROVAL LETTER |
| 3. | M/S. SYNOKEM PHARMACEUTICALS | 13252 | LETTER |

BE NOC FOR EXPORT

| S. NO. | NAME OF THE COMPANY | REF. NO. | TYPE OF LETTER |
|--------|---------------------|----------|----------------|
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|-----|----------------------------------------------------------|--------------------------|------------------------|
| 7. | M/S. APOTEX RESEARCH PVT. LTD., KARNATAKA-560099 | 14393 | CLARIFICATION LETTER |
| 8. | M/S. DR. REDDY'S LABORATORIES LIMITED, TELANGANA-560090 | 14313 | CLARIFICATION LETTER |
| 9. | M/S. INTAS PHARMACEUTICALS LTD., GUJARAT-380054 | 14448 | AMENDMENT LETTER |
| 10. | M/S. LAMBDA THERAPEUTIC RESEARCH LTD., GUJARAT-382481 | 14288 | ACKNOWLEDGEMENT LETTER |
| 11. | M/S. NOVITIUM LABS PVT. LTD., THIRUPORUR-603103 | P. NO. 1563624 (1569011) | AMENDMENT LETTER |
| 12. | M/S. NOVITIUM LABS PVT. LTD., THIRUPORUR-603103 | P. NO. 1563624 (1569012) | AMENDMENT LETTER |
| 13. | M/S. VEEDA CLINICAL RESEARCH PVT. LTD., AHMEDABAD-380015 | 14326 | AMENDMENT LETTER |
| 14. | M/S. VEEDA CLINICAL RESEARCH PVT. LTD., AHMEDABAD-380015 | 14327 | CLARIFICATION LETTER |

NEW DRUG

| S.NO. | NAME OF APPLICANT | DIARY NO. | TYPE OF LETTER |
|-------|-------------------------------|-----------|----------------|
| 1. | M/S. MSN LABORATORIES PVT LTD | - | IPC NOC |
| 2. | M/S. ZYDUS PHARMA | - | CT, BE NOC |

BIOLOGICAL DIVISION

| S. NO. | NAME OF FIRM | REFERENCE NO. | TYPE OF LETTER |
|--------|--------------------------------|---------------|-----------------|
| 1 | M/S BIOCON BIOLOGICS INDIA LTD | 14351, 10814 | APPROVAL LETTER |
| 2 | M/S PANACEA BIOTECH LTD | 12010 | CDL LETTER |
| 3 | M/S GSK ASIA PVT, LTD | 13123, 11923 | CDL LETTER |

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| 4 | M/S SERUM INSTITUTE OF INDIA LTD | 11522 | CDL & CLARIFICATION LETTER |
| 5 | M/S INTAS PHARMACEUTICALS LTD | 10097 | CLARIFICATION LETTER |
| 6 | M/S LAMBDA CLINICAL SERVICES LTD | 13077 | CLARIFICATION LETTER |
| 7 | M/S MJ BIOPHARM PVT, LTD | 13360 | APPROVAL LETTER |
| 8 | M/S PREMIUM SERUMS & VACCINES PVT, LTD | 131164 | CLARIFICATION LETTER |
| 9 | M/S CADILA HEALTHCARE LTD | 13531 | CLARIFICATION LETTER |

BE NOC FOR EXPORT

| S. NO. | NAME OF THE COMPANY | REF. NO. | TYPE OF LETTER |
|--------|----------------------------------------------------------|----------|------------------------|
| 1. | M/S. AUROBINDO PHARMA LIMITED, TELANGANA-500038 | 14469 | ACKNOWLEDGEMENT LETTER |
| 2. | M/S. JUBILANT GENERICS LTD., NOIDA, UTTAR PRADESH-201301 | 14457 | CLARIFICATION LETTER |
| 3. | M/S. SUN PHARMACEUTICAL INDUSTRIES LTD., GUJARAT-390012 | 14386 | AMENDMENT LETTER |
| 4. | M/S. SUN PHARMACEUTICAL INDUSTRIES LTD., GUJARAT-390012 | 14388 | AMENDMENT LETTER |
| 5. | M/S. VEEDA CLINICAL RESEARCH PVT. LTD., AHMEDABAD-380015 | 14401 | AMENDMENT LETTER |
| 6. | M/S. VEEDA CLINICAL RESEARCH PVT. LTD., AHMEDABAD-380015 | 14279 | ACKNOWLEDGEMENT LETTER |

SUBSEQUENT NEW DRUG

| S. NO. | NAME OF THE FIRM | REFERENCE NO. | COMPUTER NO. | TYPE OF LETTER |
|--------|--------------------------------|---------------|--------------|-------------------|
| 1. | M/S STEDMAN PHARMACEUTICALS | 18265 | - | LETTER |
| 2. | M/S GENNOVA BIOPHARMACEUTICALS | - | - | DEFICIENCY LETTER |

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| 3. | M/S PURE CURE HEALTHCARE | - | - | BE NOC |
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BE NOC FOR EXPORT

| S. NO. | NAME OF THE COMPANY | REF. NO. | TYPE OF LETTER |
|--------|------------------------------------------------------------------------------------|----------------|------------------------|
| 7. | M/S. ACCUTEST RESEARCH LABORATORIES (I) PVT. LTD., NAVI MUMBAI-400709, MAHARASHTRA | 14434 | CLARIFICATION LETTER |
| 8. | M/S. ACCUTEST RESEARCH LABORATORIES (I) PVT. LTD., NAVI MUMBAI-400709, MAHARASHTRA | 14529 | CLARIFICATION LETTER |
| 9. | M/S. GLENMARK PHARMACEUTICALS LT., MAHARASHRA-400026 | 14485 | AMENDMENT LETTER |
| 10. | M/S. LAMBDA THERAPEUTIC RESEARCH LTD., GUJARAT-382481 | 14446 | ACKNOWLEDGEMENT LETTER |
| 11. | M/S. LAMBDA THERAPEUTIC RESEARCH LTD., GUJARAT-382481 | 14448 | AMENDMENT LETTER |
| 12. | M/S. NOVITIUM LABS PVT. LTD., THIRUPORUR-603103 | P. NO. 1563624 | CLARIFICATION LETTER |
| 13. | M/S. PANEXCELL CLINICAL LAB PVT. LTD., MAHARASHTRA-14076 | 14442 | AMENDMENT LETTER |
| 14. | M/S. QPS BIOSERVE INDIA PVT. LTD., TELANGANA-500037 | 14427 | ACKNOWLEDGEMENT LETTER |
| 15. | M/S. RAPTIM RESEARCH LTD., MAHARASHTRA-400701 | 14431 | ACKNOWLEDGEMENT LETTER |
| 16. | M/S. UMEDICA LABORATORIES PVT. LTD., NAVI MUMBAI-400705 | 14251 (14686) | AMENDMENT LETTER |