

# TODAY LETTER DATED 23.07.2019

## VETERINARY CELL

| S. NO. | NAME OF FIRM                               | REFERENCE NO.                               | STATUS                               |
|--------|--|---|--------------------------------------|
| 1      | M/S UNI-CHEMIE,<br>INTERNATIONAL           | NIL   | CLARIFICATION LETTER                 |
| 2      | M/S ZOETIS INDIA LIMITED                   | 6708, 2502, 5825,<br>6707, 8195, 6416, 8405 | CLARIFICATION AND<br>APPROVAL LETTER |
| 3      | M/S INTERVET INDIA PVT.<br>LTD             | 8431  | APPROVAL LETTER                      |
| 4      | M/S BOEHRINGER<br>INGELHEIM INDIA PVT. LTD | 4171, 7804                                  | APPROVAL LETTER                      |
| 5      | M/S CEVA POLCHEM PVT. LTD                  | 7685  | APPROVAL LETTER                      |

## SUBSEQUENT NEW DRUG

| S. NO. | NAME OF THE FIRM                             | REFERENCE NO. | COMPUTER<br>NO. | TYPE OF LETTER                    |
|--------|--|---------------|-----------------|-----------------------------------|
| 1.     | M/S. SUN PHARMA<br>LABORATORIES LIMITED.,    | -             | -               | DEFICIENCY, IPC NOC<br>LETTER (3) |
| 2.     | M/S BDR<br>PHARMACEUTICALS IND<br>PVT. LTD., | -             | -               | IPC NOC LETTER                    |
| 3.     | M/S CADILA<br>PHARMACEUTICALS<br>LIMITED.,   | -             | -               | DEFICIENCY LETTER                 |
| 4.     | M/S AGIO<br>PHARMACEUTICALS<br>LIMITED.,     | 6084          | 1341956         | DEFICIENCY LETTER                 |
| 5.     | M/S HETERO LABS<br>LIMITED.,                 | -             | -               | DEFICIENCY LETTER                 |
| 6.     | M/S NOVARTIS<br>HEALTHCARE PRIVATE<br>LTD.,  | -             | -               | DEFICIENCY LETTER                 |

## MEDICAL DEVICE DIVISION

| S.NO. | COMPANY NAME   | DIARY NO | STATUS              |
|-------|--|----------|---------------------|
| 1.    | M/S. ORTHO CARE  | 8070     | QUERY LETTER        |
| 2.    | M/S. LIFELINE MEDICAL DEVICES PVT. LTD.,<br>THE DEPUTY DRUGS CONTROLLER, MUMBAI  | NIL      | QUERY LETTER        |
| 3.    | M/S. PETERS SURGICALS INDIA PVT. LTD.,   | 7682     | QUERY LETTER        |
| 4.    | M/S. AVANTOR PERFORMANCE MATERIALS<br>INDIA LTD.,  | 4192     | QUERY LETTER        |
| 5.    | M/S. BARD INDIA HEALTHCARE PVT. LTD.,  | 6562     | PRESENTATION LETTER |
| 6.    | M/S. COOK INDIA PVT. LTD.,   | 7339     | PRESENTATION LETTER |
| 7.    | M/S. COOK INDIA PVT. LTD.,   | 7338     | PRESENTATION LETTER |
| 8.    | M/S. TRISTEL INDIA PVT. LTD.,  | 6981     | PRESENTATION LETTER |
| 9.    | M/S. BOSTON SCIENTIFIC INDIA PVT. LTD.,<br>THE STATE DRUGS CONTROLLER, PANCHKULA<br>THE DEPUTY DRUGS CONTROLLER, GHAZIABAD | 8815     | LETTER (MSC)        |
| 10.   | M/S. BOSTON SCIENTIFIC INDIA PVT. LTD.,<br>THE STATE DRUGS CONTROLLER, PANCHKULA<br>THE DEPUTY DRUGS CONTROLLER, GHAZIABAD | 8815     | LETTER (NC)         |
| 11.   | M/S. RECUES BIOSCIENCES PVT. LTD.,   | 3034     | LETTER              |
| 12.   | M/S. BECKTON DICKINSON INDIA PVT. LTD.,  | 6941     | LETTER              |
| 13.   | M/S. ST. JUDE MEDICAL INDIA PVT. LTD.,   | 8251     | LETTER              |
| 14.   | M/S. DATT MEDIPRODUCTS PVT. LTD.,  | 6008     | LETTER              |
| 15.   | M/S. DOLPHIN LIFE SCIENCES INDIA LLP   | 8735     | LETTER (FSC)        |
| 16.   | M/S. DOLPHIN LIFE SCIENCES INDIA LLP<br>THE COMMISSIONER, GANDHINAGAR<br>THE DEPUTY DRUGS CONTROLLER,<br>AHMEDABAD         | 8735     | LETTER (NC)         |
| 17.   | M/S. EDWARDS LIFE SCIENCES (INDIA) PVT.<br>LTD.,   | 1298     | LETTER              |
| 18.   | M/S. TELEFLEX MEDICAL PVT. LTD.,   | 4701     | LETTER              |
| 19.   | M/S. CONSULTUS-INDIA   | 4091     | LETTER              |

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| 20. | M/S. MEDIASHA TECHNOLOGIES PVT. LTD.,  | NIL  | LETTER       |
| 21. | M/S. BOSTON SCIENTIFIC INDIA PVT. LTD.,  | 7507 | LETTER       |
| 22. | M/S. INDIA MEDTRONIC PVT. LTD.,  | 6898 | LETTER       |
| 23. | M/S. INDELOX GLOBAL DISTRIBUTION PVT. LTD.,  | 6868 | LETTER       |
| 24. | M/S. MERIL LIFE SCIENCES PVT. LTD.,  | 8708 | LETTER (FSC) |
| 25. | M/S. MERIL LIFE SCIENCES PVT. LTD.,  | 8708 | LETTER (FSC) |
| 26. | M/S. MERIL LIFE SCIENCES PVT. LTD.,  | 8708 | LETTER (FSC) |
| 27. | M/S. ABBOTT HEALTHCARE PVT. LTD.,  | 6522 | LETTER       |
| 28. | M/S. SURETEX PROPHYLACTICS (INDIA) PVT. LTD.,  | 8638 | LETTER (FSC) |
| 29. | M/S. AEGIS LIFESCIENCES,   | NIL  | LETTER (MSC) |
| 30. | M/S. AEGIS LIFESCIENCES,   | NIL  | LETTER (NCC) |
| 31. | M/S. MACO PHARMA INDIA TRANSFUSION PVT. LTD.,<br>THE STATE DRUGS CONTROLLER, BANGALORE<br>THE DEPUTY DRUGS CONTROLLER, BANGALORE | NIL  | LETTER       |
| 32. | M/S. ADVANCE LIFE SCIENCES PVT. LTD.,  | 8623 | LETTER (MSC) |
| 33. | M/S. COSMOS PURIFICATION SYSTEMS PVT. LTD.,  | NIL  | LETTER       |
| 34. | M/S. PENTA LATEX LLP   | 7752 | LETTER (FSC) |
| 35. | M/S. BAXTER (INDIA) PVT. LTD.,   | 3665 | LETTER       |
| 36. | M/S. BECTON DICKINSON INDIA PVT. LTD.,   | 1760 | LETTER       |
| 37. | M/S. NARAYANA HRUDAYALAYA LTD.,  | 7699 | QUERY LETTER |

### DIAGNOSTIC DIVISION

| S.NO. | COMPANY NAME                              | DIARY NO | STATUS       |
|-------|---|----------|--------------|
| 1.    | M/S. BIORAD LABORATORIES INDIA PVT. LTD., | 8898     | QUERY LETTER |

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| 2. | M/S.HIMEDIA LABORATORIES PVT. LTD.,  | NIL  | LETTER |
| 3. | M/S. ROCHE DIAGNOSTICS INDIA PVT. LTD.,<br>ALL PORT OFFICE OF THROUGH E-MAIL | 8413 | LETTER |
| 4. | M/S. FUJIRBIO INDIA PVT. LTD.,   | 7746 | LETTER |
| 5. | M/S. J. MITRA & CO. PVT. LTD.,<br>THE DRUGS CONTROLLER, KARKARDOOMA          | 8189 | LETTER |
| 6. | M/S. UNIPHARMA PRODUCTS PVT. LTD.,   | 8569 | LETTER |

### GLOBAL CLINICAL TRIAL

| SR. NO. | COMPANY NAME        | REFERENCE NO. | STATUS             |
|---------|---------------------|---------------|--------------------|
| 1       | M/S. MAYA CLINICALS | 8501          | TL APPROVAL LETTER |

### INTERNATIONAL CELL

| S. NO | NAME OF FIRM                                    | TYPE |
|-------|---|------|
| 1     | M/S. ALEMBIC PHARMACEUTICALS PVT LTD<br>GUJARAT | WC   |
| 2     | M/S. ALEMBIC PHARMACEUTICALS PVT LTD<br>GUJARAT | WC   |
| 3     | M/S. AURO PEPTIDE PVT LTD<br>TELANGANA          | WC   |
| 4     | M/S. AUROBINDO PHARMA PVT LTD<br>HYDERABAD      | WC   |
| 5     | M/S. ARTEMIS BIOTECH<br>HYDERABAD               | WC   |
| 6     | M/S. BIOCON LTD<br>BANGALORE                    | WC   |
| 7     | M/S. BEC CHEMICALS PVT LTD<br>RAIGAD            | WC   |
| 8     | M/S. BDR LIFE SCIENCES PVT LTD<br>VADODARA      | WC   |
| 9     | M/S. DISHMAN CARBOGEN AMICS LTD<br>AHMEDABAD    | WC   |

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| 10 | M/S. DISHMAN CARBOGEN AMICS LTD<br>AHMEDABAD       | WC               |
| 11 | M/S. HARMAN FINOCHEM LTD<br>SHENDRA                | WC               |
| 12 | M/S. HARMAN FINOCHEM LTD<br>AURANGABAD             | WC               |
| 13 | M/S. INDIANA OPHTHALMICS<br>GUJARAT                | NOC              |
| 14 | M/S. MANGLAM DRUGS AND ORGANICS LTD<br>VALSAD      | WC               |
| 15 | M/S. MEGAFINE PHARMA (P) LTD<br>NASHIK             | WC/ QUERY LETTER |
| 16 | M/S. MEDIGRAPH PHARMACEUTICAL PVT LTD<br>RAIGAD    | WC               |
| 17 | M/S. ORCHID PHARMA LTD<br>TAMILNADU                | WC               |
| 18 | M/S. PIRAMAL ENTERPRISES LTD<br>TELANGANA          | WC               |
| 19 | M/S. RELIANCE LIFE SCIENCES PVT LTD<br>NAVI MUMBAI | WC               |
| 20 | M/S. R L FINE CHEM PVT LTD<br>BANGALORE            | WC/ QUERY LETTER |
| 21 | M/S. RA CHEM PHARMA LTD<br>HYDERABAD               | WC/ QUERY LETTER |
| 22 | M/S. SUN PHARMA INDUSTRIES LTD<br>PUNJAB           | WC               |
| 23 | M/S. SARACA LABORATORIES LTD<br>A.P                | WC               |
| 24 | M/S. SAI LIFE SCIENCES LTD<br>KARNATAKA            | WC               |
| 25 | M/S. SMS PHARMACEUTICALS PVT LTD<br>A.P            | WC               |
| 26 | M/S. SMS PHARMACEUTICALS PVT LTD<br>HYDERABAD      | WC               |
| 27 | M/S. SWATI SPENTOSE PVT LTD<br>GUJARAT             | WC               |
| 28 | M/S. SYNTHOKEM LABS PVT LTD<br>HYDERABAD           | WC               |
| 29 | M/S. UNICHEM LABORATORIES LTD<br>DHAR              | WC               |

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| 30 | M/S. UNIMARK REMEDIES LTD<br>VALSAD | WC               |
| 31 | M/S. WOCKHARDT LTD<br>GUJARAT       | WC/ QUERY LETTER |

### BIOLOGICAL DIVISION

| S. NO. | NAME OF FIRM                                | REFERENCE NO. | TYPE OF LETTER                    |
|--------|---|---------------|-----------------------------------|
| 1      | M/S BHARAT BIOTECH<br>INTERNATIONAL LTD     | 6652          | APPROVAL LETTER                   |
| 2      | M/S PFIZER LTD                              | 2076          | APPROVAL LETTER                   |
| 3      | M/S SERUM INSTITUTE OF<br>INDIA PVT, LTD    | 8716          | APPROVAL LETTER                   |
| 4      | M/S SHIRE BIOTECH INDIA<br>PVT, LTD         | 5591          | CONTINUATION LETTER               |
| 5      | M/S ELI LILLY AND COMPANY<br>INDIA PVT, LTD | 4616          | CONTINUATION LETTER               |
| 6      | M/S GSK PHARMACEUTICALS<br>PVT, LTD         | 4477, 8769    | APPROVAL & AMENDMENT<br>LETTER    |
| 7      | M/S HUMAN BIOLOGICALS<br>INSTITUTE          |               | OM LETTER                         |
| 8      | M/S LUPIN LTD                               | 7062, 6831    | CONTINUATION &<br>APPROVAL LETTER |
| 9      | M/S MYLAN LABORATORIES<br>LTD               | 7925          | APPROVAL LETTER                   |
| 10     | M/S HETERO BIOPHARMA<br>LTD                 | 8115          | APPROVAL LETTER                   |