

## OFFICE OF THE MISSION DIRECTOR NATIONAL HEALTH MISSION, ASSAM Saikia Commercial Complex, Christian Basti, Srinagar Road, Guwahati-5

No. NHM/PROC/QLTY/2681/2015-16/ Pt-1/ 14127

Dated:- 21 1 081 18

To,

M/S Zee Laboratories 47, Industrial Area, Paonta Sahib, H.P. 173205.

Sub: Product Debarment Notice & Disqualify to participate in tender for next 5 years.

Ref No: 1. Letter from Jt. Drug Controller (HQ) vide No. HSD/65/2005/Pt/2498, Dated. 3/8/18.

- 2. Show cause letter from MD, NHM vide NHM/PROC/QLTY/2681/2015-16/14213, Dated.07/12/16
- 3. Final show cause letter from MD, NHM vide NHM/PROC/QLTY/2681/2015-16/Pt-1/179-P, Date.9/8/18
- 4. Old reply letter from Zee Lab vide letter no. ZL/ D/R/2018/019 Dated. 21/4/2018.

This is to inform you that vide letter no. referred at serial pt. 3 above and also in view of Sir, the letter received from the Jt. Drug Controller (HQ), i/c Assam (referred at pt.1 above) it was already informed to you that Amoxycillin Oral suspension IP 125 mg/ 5 ml manufactured & supplied by your company having batch no 717-108, 717-56, 713-43 (Mfg. Date:-Sep-16 and Exp. Date:-Aug-18), batch no. 717-43 (Mfg. Date:-Apr-17 and Exp. Date:-Sep-18) and 716-154 (Mfg. Date:-Sep-16 and Exp. Date:-Aug-18) were declared as Not of Standard Quality as per report of RDTL, Guwahati, Assam.

You have not replied to the notice issued to you referred at pt. 3. In the month of April you have submitted one reply against the show cause issued to you referred at pt.2 was not found suitable and you have claimed that stock has been replaced from your end of Amoxicillin-Oral suspension through our authorized distributor but there was no approval has been taken from MD, NHM or ED, NHM and there was no such scope in the tender clause and no documentary evidence was submitted from your end regarding replacement. Hence, it is found very clear that your reply is not satisfactory to support your claim and you have failed to furnish justified replies within prescribed time frame.

Hence in the interest of public service, you are hereby disqualified to participate in any tender of NHM / Govt. of Assam/ AMSCL Assam for a period of 5 years as per the tender clause from the date of issue of this letter and also your product "Amoxycillin Oral suspension IP 125 mg/ 5 ml" is here by debarred for a period of 5 years in the state of Assam.

Please be noted that you need to withdraw all the unconsumed batches of "Amoxycillin Oral suspension IP 125 mg/ 5 ml by next 30 days of time from the district drug store as well as medical college drug store or subsequent penal action as per tender clause will also be incorporated against your firm. Your Sincerely

Mission Director, NHM, Assam

Memo No. NHM/PROC/QLTY/2681/2015-16/Pt-1/ 14128 - 35 Dated:- 21 Los/ 18
Copy forwarded for information to: -

- 1. Principal Secretary, Health and FW Deptt. GoA for kind information.
- 2. Commissioner Drugs safety & Food Administration for information.
- 3. Managing Director, Assam Medical Service Corporation Ltd.
- 4. Executive Director, NHM, Assam for information and needful.
- 5. Drug Controller of Assam for information for information and necessary action.
- 6. Jt. Drug Controller (HQ), i/c Assa for further legal action accordingly.
- DPM/DDSM- NHM, Assam-All Districts/ M.O I/C. CMS- All Medical Colleges. He/She
  is informed to stop all kind of distribution and administration of the all batches of
  "Amoxycillin Oral suspension IP 125 mg/5 ml mfg. by Zee Laboratories.
- 8. P.S to the Hon'ble Minister, Health and FW Deptt. GoA for kind information of the Hon'ble Minister.

Mission Director, NHM, Assam