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25 JAN 2012
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REGISTERED POST
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Government of Rajasthan

Rajasthan Health Systems Development Project
RHSDP Block, Swasthya Bhawan, Tilak Marg,
C-Scheme Jaipur-302005

F.2 (448) RHSDP/ EPMC/2010/ *4442*

Date: *24.1.12*

M/s. Denis Chem Lab Limited,
401, Abhishree, Opp. Om Tower, Satellite Road,
Ahmedabad-380015

mys
Dennis Chem Lab Ltd.

Sub: Black listing/ Debarring for supply of Drugs in Govt. / RHSDP in the state of Rajasthan.

Black Listed

RHSDP had invited tenders for supply of I.V. Fluid Dextrose 5% w/v, Dextrose+ Normal Saline Solution & Ringers Lactate Solution vide IFB No. F.2 (35) / RHSDP/ EPMC/ 2009/ 7224 dated 5.12.2009 (NCB A) for which M/s. Denis Chem Lab Limited, 401, Abhishree, Opp. Om Tower, Satellite Road, Ahmedabad Gujrat, factory at M/s. Denis Chem Lab Limited, Block No. 457, Village, Chhatral, Ta: Kalol (N.G.) Distt. Gandhinagar, Gujarat, participated in tender and submitted its bid for supply of above said three drugs. The bid was examined and rates submitted by you were found the lowest and therefore notification of award was issued for Dextrose 5% w/v vide IFB no. F.2 (448) / RHSDP/ EPMC/ 2010/ 1541 dated 8.4.2010, Dextrose+ Normal Saline Solution vide IFB no. F.2 (449) / RHSDP/ EPMC/ 2010/ 1542 dated 8.4.2010 and for Ringers Lactate Solution vide IFB no. F.2 (450) / RHSDP/ EPMC/ 2010/ 1540 dated 8.4.2010 in your favour.

Some complaints regarding the quality of drugs and presence of fungal growth in I.V. Fluids, were received and therefore samples of following batches of the drugs manufactured by you were drawn by the Drug Control Officers of the Department at various Government Health Facilities under RHSDP. The samples were tested by the Govt. Analyst Rajasthan, Jaipur and following samples have been declared as "Not of standard quality" under the provisions of Drugs & Cosmetic act 1940 and rules made thereunder:-

Sr. no	Name of Drug	Batch no.	Date Exp.	Reason for declaring as "Not of standard quality"	Govt. Analyst test report no./ date
1	Dextrose Injection I.P. 5% w/v (5D 500 ml)	RJA020	06/13	Fails in "sterility test "	840/2011-2012/DTL/2011 dated 02/Sept./ 2011
2	Compound Sodium Lactate Injection I.P. (RL 500 ml.)	RJC 006	06/13	Fails in "sterility test "	891/2011-2012/DTL/2011 dated 29/Sept./ 2011
3	Compound Sodium Lactate Injection I.P. (RL 500 ml.)	RJC 003	06/13	Fails in "sterility test "	893/2011-2012/DTL/2011 dated 29/Sept./ 2011
4	Sodium Chloride & Dextrose Injection I.P. 0.9& 5% w/v (DNS 500 ml.)	RJB008	06/13	Fails in "sterility test "	864/2011-2012/DTL/2011 dated 19/Sept./ 2011
5	Dextrose Injection I.P. 5% w/v (5D 500ml.)	1005P538	04/13	Fails in "sterility test "	841/2011-2012/DTL/2011 dated 02/Sept./ 2011
6	Compound Sodium Lactate Injection I.P. (RL 500 ml.)	RJC012	06/13	Fails in "sterility test "	1089/2011-2012/DTL/2011 dated 16/Nov./ 2011
7	Sodium Chloride & Dextrose Injection I.P. 0.9& 5% w/v (DNS 500 ml.)	1007P715	06/13	Fails in "sterility test "	1160/2011-2012/DTP/ 2011 dated 09/Dec. /2011
8	Sodium Chloride & Dextrose Injection I.P. 0.9& 5% w/v (DNS 500 ml.)	1006P678	05/13	Fails in "sterility test "	1159/2011-2012/DTL/2011 dated 09/ Dec. / 2011
9	Sodium Chloride & Dextrose Injection I.P. 0.9& 5% w/v (DNS 500 ml.)	RJB 050	06/13	Fails in "sterility test "	1164/2011-2012/DTL/ 2011 dated 09/Dec./ 2011
10	Sodium Chloride &	RJB 046	06/13	Fails in "sterility test "	1165/2011-

	Dextrose Injection I.P. 0.9& 5% w/v (DNS 500 ml.)				2012/DTL/ 2011 dated 09/Dec. /2011
11	Sodium Chloride & Dextrose Injection I.P. 0.9& 5% w/v (DNS 500 ml.)	RJB 032	06/13	Fails in "sterility test "	1219/2011-2012/ DTL/ 2011 dated 14/ Dec. / 2011
12	Sodium Chloride & Dextrose Injection I.P. 0.9& 5% w/v (DNS 500 ml.)	RJB 054	06/13	Fails in "sterility test "	1314/2011-2012/ DTL/ 2011 dated 30/Dec. / 2011
13	Sodium Chloride & Dextrose Injection I.P. 0.9& 5% w/v (DNS 500 ml.)	RJB 001	06/13	Fails in "sterility test "	1368/2011-2012/ DTL/ 2012/ dated 13/ Jan. / 2012
14	Dextrose Injection I.P. 5% w/v (5D 500 ml)	1004-P44-8	03/13	Fails in "sterility test "	1367/2011-2012/ DTL./ 2012 dated 13/ Jan. / 2012
15	Dextrose Injection I.P. 5% w/v (5D 500 ml)	RJA 058	06/13	Fails in "sterility test "	1365/2011-2012/ DTL/ 2012 dated 13/Jan. / 2012

That after receiving so many adverse reports about the poor quality of your products i.e. failing in sterility test, which is a major offence you were asked to explain and show cause letter vide no. F.2 () / RHSDP/ EPMC/ 2011/ 4163 dated 30.12.2011 and no. F.2 () / RHSDP/ EPMC/ 2011/ 4218 dated 5.1.2012, as to why the company should not be black listed/ banned for supplying poor quality drugs in Government/ RHSDP supply.

In your letter dated 9.1.2012 in which you have stated that, storage conditions may not be proper or the stacking of cartoons/boxes may be more than 7-8 layers, due to which there can be micro puncture in the bottles resulting in fungal growth. Said reply have been examined and found unsatisfactory as all the boxes were properly stored in the District warehouses/ drug stores and no case of stacking of corrugated boxes in more than

7-8 layers have been reported. You have also stated that you have also stated that, you have challenged the test reports of Govt. Analyst Rajasthan, Jaipur with regard to above batches of drugs, but you have failed to produce any test report declaring the above batches as of standard quality by the Appellant Laboratory i.e. Director, Central Drug Laboratory, Kolkata and therefore the report of Govt. Analyst Rajasthan is conclusive evidence till it is contradicted by a report from Director C.D.L. Kolkata.

Fifteen batches of I.V. Fluids supplied by you in Government / RHSDP supply have failed in sterility test, administration of such I.V. fluids to a patient may result in serious consequences to the patient. Therefore considering all the facts and circumstances of the case and after examining the reply in toto, it is concluded that the reply is not found satisfactory and you should not be permitted to continue the supplies in Government / RHSDP any more, therefore you i.e. M/s. Denis Chem Lab Limited, Block No. 457, Village, Chhatral, Ta: Kalol (N.G.) Distt. Gandhinagar, Gujarat, Adm. office M/s. Denis Chem Lab Limited, 401, Abhishree, Opp. Om Tower, Satellite Road, Ahmedabad Gujarat is Blacklisted/Debarred for supply of drugs in Govt./RHSDP in the state of Rajasthan till further orders.

Project Director
RHSDP

Copy to:-

1. PS to Honorable Health Minister
2. PS to Principal Secretary (ME)
3. PS to Principal Health Secretary
4. MD, RMSC
5. Director PH, DM & HS
6. Director RCH, DM & HS
7. Director AIDS, DM & HS
8. Drugs Controller Of Rajasthan
9. SSPO, DM & HS
10. I/C Server room to put on Deptt. Website
11. Guard File

Project Director
RHSDP

राजस्थान सरकार

औषधि नियंत्रण संगठन, स्वास्थ्य भवन, तिलक मार्ग, जयपुर राज

क्रमांक-डीसी/डी-2/जनरल टैस्ट प्रभावली/2012/106

दिनांक 30.04.2012

प्रतिलिपि निम्न को सूचनार्थ एवं आवश्यक कार्यवाही हेतु प्रेषित है।

1- समस्त सहायक औषधि नियंत्रक, राजस्थान/जयपुर कोष/नियंत्रण/उपनिवेश, 2012

2- इन्चार्ज, सर्वर रूम को भेजकर लेख है कि आप उक्त पत्र को विभागीय वेबसाइट पर डालने का कष्ट करें।

औषधि नियंत्रक
राज 0 जयपुर