GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION

FROM

P.RAMBABU, B.PHARM
DRUGS INSPECTOR,
VIZIANAGARAM
VIZIANAGARAM DIST

TO

THE DIRECTOR GENERAL,
DRUGS AND COPYRIGHT,
DRUGS CONTROL ADMINISTRATION,
VENGALARAONAGAR,
HYDERABAD-38

Rc No. SA/08/NSQ /PRB / DI / VZM / 2012, Dated 07/06/2012.

Sir,

Sub: Drugs and Cosmetics Act 1940 and rules made there under – Tinidazole tablets I.P. 300mg, Batch no. 02,Mfg date: 11/09, Exp date: 10/11, Manufactured by M/s Quest Laboratories Pvt Ltd, P-63, Onkaar Marg, Gandhi Nagar,Indore-453112, Madhya Pradesh -Declared as Not of Standard Quality – Complaint filed Against the manufacturing firm and its Managing Director, in the Honourable Court of AJFCM, Vizianagaram on 07/06/2012 – Copy of Complaint submitted- Regarding.

Ref:
1. Cir Rc.No.035/Peshi/97-12 dated 19/9/2008 of the Director General, Drugs Control Administration, Hyderabad.
2. Memo Rc.No.7187/M1A/OS/2011 dated 12/08/2011 of Director General Drugs Control Administration, Hyderabad.

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As per the references cited above I have filed complaint against the subject firm and its Managing Director for manufacturing of the subject drug which was declared as Not of Standard Quality in the Honourable Court of Additional Judicial First Class Magistrate Court, Vizianagaram, Vizianagaram dist on 07/06/2012.

A copy of complaint is herewith submitted for your kind information.

Yours faithfully,

P. Ram 7/6/12
Drugs Inspector
Vizianagaram

Encl: Copy of complaint (6 papers)

Copy submitted to the Director, Drugs Control Administration, Hyderabad, for kind information

Copy submitted to the Joint Director, Drugs Control Administration, Hyderabad for kind information

Copy submitted to the Deputy Director, Drugs Control Administration, Visakhapatnam for kind information.

Copy submitted to the Assistant Director, Drugs Control Administration, Vizianagaram for kind information.

GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION

DIRECTOR GENERAL (Drugs & Copyrights) 18 JUN 2012 DGA Vengalrao Nagar, Hyderabad-38.

DIRECTORATE OF DRUGS CONTROL GOVERNMENT OF ANDHRA 008033 HYDERABAD 12/6/12

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P.RAMBABU, B.PHARM
DRUGS INSPECTOR,
VIZIANAGARAM
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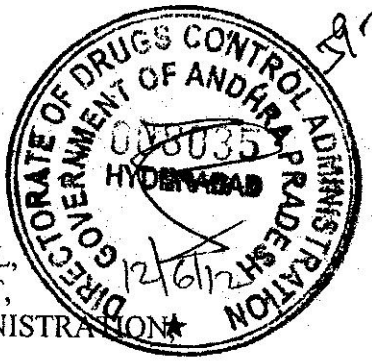
GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION



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P.RAMBABU, B.PHARM
DRUGS INSPECTOR,
VIZIANAGARAM
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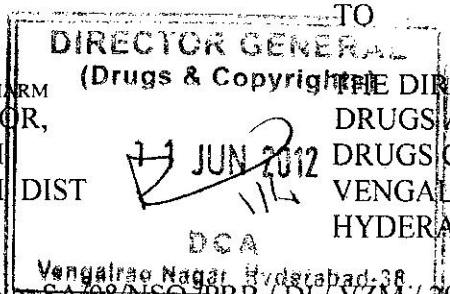

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IN THE HONOURABLE COURT OF JUDICIAL FIRST CLASS MAGISTRATE

AT VIZIANAGARAM

CC. No. /2012

Between

The State of Andhra Pradesh

Represented by Drugs Inspector,

Vizianagaram ... Complainant

And

1. M/s Quest Laboratories Pvt. Ltd,
   P-63, Onkaar Marg
   Gandhi Nagar,
   Indore-453112, Madhya Pradesh
   Represented by its Managing Director
   Mr. Anil Sabarwal ... A1
2. Mr. Anil Sabarwal,
   Managing Director,
   M/s Quest Laboratories Pvt Ltd,
   P-63, Onkaar Marg
   Gandhi Nagar,
   Indore-453112, Madhya Pradesh ... A2

SECTOINS CONTRAVENED: (a) Manufactured for sale and distributed a Not of standard quality drug. There by contravening Sec 18(a)(i) r/w Sec 16 Punishable U/s 27(d) of Drugs and Cosmetics Act, 1940

(b) Failed to furnish the constitution particulars and batch manufacturing records of the products as required U/s 24, 18-B and 22(1)(cca) of the Drugs and Cosmetics Act there by contravening section 24, 18-B and 22(1)(cca) of the Act punishable under section 28, 28-A and 22(3) of the Act respectively.

DATE OF OFFENCE: Sample picked up on 02/01/2010. Test report received on 20/07/2011

PLACE OF OFFENCE: Detected in the central drug stores, APHMHIDC, Cantonment, Vizianagaram

LIST OF PROPERTY DEPOSITED: Enclosed

LIST OF WITNESSES : Enclosed

BRIEF FACTS OF THE CASE:

It is submitted that the Complainant P. Rambabu, LW 1 is a Drugs Inspector appointed U/s 21 of the Drugs and Cosmetics Act, 1940 and is authorized to launch prosecution U/s 32

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of the said Act. At present he is working as Drugs Inspector, Vizianagaram with effect from 16-06-2008.

M/s Quest Laboratories Pvt Ltd, P-63, Onkaar Marg, Gandhi Nagar,Indore-453112, Madhya Pradesh Represented by its Managing Director, Mr. Anil Sabarwal, is a Drug manufacturing firm who got Manufacturing Drug Licenses to manufacture drugs under form 25 and 28, bearing no. 25/18/98.

Mr. Anil Sabarwal, A2 is the Managing Directorof the A1 firm who had manufactured Tinidazole tablets I.P. 300mg, Batch no. 02,Mfg date: 11/09, Exp date: 10/11, manufactured by the A1 firm, a Not of Standard Quality drug in their manufacturing premises M/s Quest Laboratories Pvt Ltd, P-63, Onkaar Marg, Gandhi Nagar,Indore-453112, Madhya Pradesh.

On 02/01/2010 the LW 1 has picked up a sample of Tinidazole tablets I.P. 300mg, Batch no. 02, Mfg date: 11/09, Exp date: 10/11, manufactured by the A1 firm, for test / analysis from the Central Drug Stores, APHMHIDC, Cantonment, Vizianagaram in the presence of LW2, and was sent to the Govt. Analyst, drugs Control Laboratory, Hyderabad, as per the provisions of Drugs and Cosmetics Act, 1940.

On 20/07/2011 the LW 1 has received the test report of the above drug sample from the Govt. Analyst, drugs Control Laboratory, Hyderabad in person, and the sample was declared as Not of Standard quality for the reason that sample does not meet the test for Disintegration.

On 21/07/2011 the LW 1 addressed a letter to LW4 duly enclosing the original Test Report of the above drug as required U/s 25(2) of the Drugs and Cosmetics Act, 1940 and was requested to furnish source of purchase and other particulars of the batch drug mentioned there in the letter as required U/s 18A and 18 B of the Act, which was received in person by LW3 on the same day.

On 28/07/2011 the LW 1 received a reply from the LW4 and in their reply dated 21/07/2011 they have stated that they procured the above batch drug from the manufacturer a quantity of 1, 00,000 tablets vide invoice no. 0503 dated 10/12/2009.

With the above information on 30/07/2011the LW 1 addressed a letter to A1 firm as required U/s 18A and 18B of the Drugs and Cosmetics Act, 1940, duly enclosing a copy of test report of the drug in Form 13 along with a sealed sample portion of the batch drug and also to furnish their drug license, list of approved products, constitution particulars, Batch

Contd... Page 3

manufacturing records and distribution particulars of the above drug. No reply has not received from the A1 firm

Further on 08/09/2011, LW 1 issued a reminder to A1 firm U/s 24 of the Act with a request to furnish their drug license, list of approved products, constitution particulars, Batch manufacturing records and distribution particulars of the above drug.

And also on 25/10/2011, LW 1 issued another reminder to A1 firm requesting them to furnish U/s 22(1) (cca) of the Act with a request to furnish their drug license, list of approved products, constitution particulars, Batch manufacturing records and distribution particulars of the above drug.

Further on 11/05/2012, LW 1 issued another reminder to A1 firm requesting them to furnish U/s 22(1) (cca) of the Act with a request to furnish their drug license, list of approved products, constitution particulars, Batch manufacturing records and distribution particulars of the above drug. But the A1 firm has not furnished the required information till date

All the above facts reveal that the subject Not of Standard quality drug was manufactured and distributed by A1 firm represented by its Managing Director A2

Further the above facts also reveal that A1 and A2 received all the notices given by LW 1 U/s 24, 18-B and 22(1) (cca) of the Act but failed to furnish their drug license, list of approved products, constitution particulars, Batch manufacturing records and distribution particulars of the above drug. Thus the A1 and A2:

(a) Manufactured for sale and distributed a Not of standard quality drug. There by contravening Sec 18(a)(i) r/w Sec 16 Punishable U/s 27(d) of Drugs and Cosmetics Act, 1940

(b) Failed to furnish the constitution particulars and batch manufacturing records of the products as required U/s 24, 18-B and 22(1)(cca) of the Drugs and Cosmetics Act there by contravening section 24, 18-B and 22(1)(cca) of the Act punishable under section 28, 28-A and 22(3) of the Act respectively.

Hence it is prayed that the case may kindly be taken on the file of the honourable court and dealt with the accused according to law.

P. Ram 7/6/12
COMPLAINANT
DRUGS INSPECTOR
VIZIANAGARAM

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LIST OF WITNESSES:

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Name and Address	Purpose
1. P. Rambabu Drugs Inspector, Vizianagaram	To speak about sampling and investigation etc., facts
2. K. Lakshmi Pharmacist, Gr-II, Central drug store, APHMHIDC, Vizianagaram	To speak about sampling etc., facts
3. B. Sanyasi Naidu Pharmacist, Gr-II, Central drug store, APHMHIDC, Vizianagaram	To speak about procurement and Distribution of the drug etc., facts
4. T.V.S.N. Reddy Executive Engineer, APHMHIDC (APMSIDC), Vizianagaram	To speak about procurement and Distribution of the drug etc., facts

P. Ram 7/6/12
COMPLAINANT
DRUGS INSPECTOR
VIZIANAGARAM

LIST OF DOCUMENTS RELIED UP ON:

1. Certified copy: Gazette notification of the appointment of LW 1
2. Certified copy: Transfer order of LW 1 for transfer to Vizianagaram district
3. Office copy: Form 17 dated 02/01/2010
4. Office copy: Form 18 dated 02/01/2010 addressed to Govt. Analyst, DCL, Hyderabad
5. Original: Postal Receipt No. 710 dated 04/01/2010 for registered parcel of sample

Contd... Page 5

6. Original: Postal Receipt No. 5015 dated 04/01/2010 for registered post of Form 18 / 69

7. Original: Form 13 Report No. 1452/DCL/2011 dated 15/07/2011 of the Govt. Analyst, DCL, Hyderabad

8. Office copy: Notice dated 21/07/2011 of LW 1 addressed to LW4

9. Original: Post Receipt No. 1697 dated 21/07/2011 and acknowledgement card received from A1 firm

10. Original: Reply dated 21/07/2011 of LW4 addressed to LW 1

11. Certified copy: Directions of Director General, Drugs & Copyrights, Drugs Control Administration, Hyderabad dated 19/04/2008.

12. Office copy: Notice dated 30/07/2011 of LW 1 addressed to A1 firm (3 sheets)

13. Original: Postal Receipts No.3103 dated 30/07/2011 addressed to the A1 firm

14. Office copy: Letter (Reminder) dated 08/09/2011 of LW 1 to A1 firm

15. Original: Registered Postal acknowledgment pertaining to the above reminder letter

16. Office copy: Letters (Reminders 2&3) dated 25/10/2011 & 11/05/2012 respectively of LW 1 to A1 firm

17. Original: Registered Postal acknowledgments pertaining to the above reminder letters

18. Certified copy: Form 26 bearing Drug License no. 25/18/98 of the A1 firm

P. Ram 7/6/12

COMPLAINANT
DRUGS INSPECTOR
VIZIANAGARAM