



FDA, Maharashtra 02482-220731

By Regd. Post A.D.

No. RTI/ 415 /16/2

Office of the Assistant Commissioner,  
Food & Drug Administration (M.S.)  
1<sup>st</sup> floor, hotel vikas lodge,  
Plot no. P-18, addl. MIDC Area,  
Jalna-431 203.

Dated - 24 /02 /2016.

To,

Adv. Prashant Reddy T,  
C/O Lex One Partners, E-19, LGF,  
Jungpura Extension,  
New Delhi 110014.

Subject – Right To information Act 2005.

Information Regarding Criminal. Complaints & Judgments of 205/13, 196/13,  
195/13 at CJM Jalna .

- Ref: -1) Your application dated 7 December 2015 received to this office on 4/2/2016.  
2) Letter of Information officer , F.D.A. M.S. H.Q. No. RTI/630/268-15/15  
Dated 20/01/2016 received to this office on 4/2/2016  
3) Letter of Information officer F.D.A. M.S. A, bad.no.cen.Info/A.Div./241/2016/3  
Dated 05/02/2016 received to this office on 8/2/2016

R/Sir,

This is to informed with reference to above subject. I am sending herewith the copy of case No  
of 205/13, 196/13, 195/13 for information.

We are also informed that above cases are running in the Court at C.J.M. Jalna and no  
Judgement found.

Thanking you.

Your Faithfully,

(D.K. JAGTAP)

Information officer , and  
Assistant Commissioner(Drug)  
Food & Drug Administration (M.S.),  
Jalna.

Enclosed copy: (32 pages )

Copy To,

- 1) Information Officer Food and drug Administration ,M.S. Aurangabad
- 2) Information Officer Food and drug Administration ,M.S. Mumbai-51

**IN THE COURT OF HON'BLE CHIEF JUDICIAL MAGISTRATE AT JALNA**

In the matter of  
**Drugs and Cosmetics  
 Act, 1940 and Rules, 1945**

R.C.C. No. 205/2013

Date:- 21/3/2013

**State of Maharashtra ,**

At the instance of

Chandrakat Arjun More , Age 36 yrs.

Drugs Inspector,

Food and Drugs Administration,

Jalna.

----- **Complainant**

**V/s.**

- 1) Shri Promod Dhanraj Totala, Competent Person of  
 M/s. Samarth Agency, Wing no : 04, shop No : F-6 &  
 7 , APMC Market, Dawa Bajar, Jalna-431203.

..... **Accused No.1**

- 2) Shri. Desai Sarjerao Bajirao, Production Manager of  
 Colinz Laboratories Limited, R/o : C-2, 302, 3<sup>rd</sup> floor,  
 orchid Saibaba Vihar Complex, Near Muchala  
 Complex, Ghodbunder Raod, Thane West-400 706)


..... **Accused No.2**

- 3) Shri. S.G. Karkar, Ex-Plant Manager of M/s. Shefa  
 Heathcare Pvt.Ltd, R/o : 401, A-alahad Co-Op. Housing  
 society, Shivaji Chowk, kulgaon, Badlapur(E)  
 Dist.Thane Phone No : 9322395273

..... **Accused No.3**

- 4) Shri. V S Panshikar , Manage- quality Control of  
 M/s. Shefa Heathcare Pvt.Ltd, R/o : 7- Gajanan  
 Prasad, Near Bhanushali Hall, Nanadivali Road,  
 Dombivli (E) 421201

..... **Accused No.4**

  
 न्यायिक अधिकारी  
 अथवा अधिवक्ता आदित्य  
 अथवा अधिवक्ता प्रशासन, म. रा.  
 जालना.

- 5) Shri Arshad Mukhtar Nadvi, Managing Director of, M/s. Shefa Healthcare Pvt. Ltd, R/o: 301, al-Mahmood apartment, 37C, Perry Cross road, Bandra (W), Mumbai-400 050, Mobil No: 9821220390.

..... Accused No.5

- 6) Shri Sunil Sarmalkar, Technical Director of M/s. Shefa Healthcare Pvt. Ltd, R/o: B-1301, Raunak Tower, Gokhale road, Naupada Thane (W)-400 602 Mobile No : 9223222337

..... Accused No.6

- 7) M/s. Colinz Laboratories Limited, A/101, Pratik Estate, Next to Wockhardt Hospital, Mulund Link Road, Mumbai 400 078

..... Accused No.7

- 8) M/s. Shefa Healthcare Pvt Ltd, A-10/1 MIDC Taloja Industrial Area Taloja, Navi Mumbai, Pin 410 208

..... Accused No.8

**Place of Offences : Sadar Bajar Police Station, Jalna**


**Date Of Offences Disclosed: 08/10/2012**

**Charges:**

Section 17-a read with Section 16(1)(a) and Section 34 punishable under Section 27-d of Drugs and Cosmetics Act 1940.

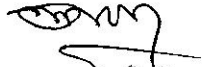
**Most respectfully sheweth as under**

- 1) That the complainant is an Inspector appointed under Section 21 of Drugs and Cosmetics Act 1940, (hereinafter referred to as the "Said Act") & presently working in the office of the Assistant Commissioner, Food & Drug Administration M.S. Jalna. (copy of order is attached)

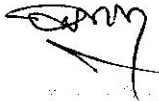
  
 अधिवक्ता प्रशासन, न. रा.  
 जालना.

- 2) That the complainant is authorized to institute this prosecution as per provisions of Section 32 of the said Act.
- 3) That the Accused No. 1 is the Competent Person and partner of M/s. Samarth Agency, Wing no : 04, shop No : F-6 & 7, APMC Market, Dawa Bajar, Jalna-431203, having the selling license in form 20B & 21B for the sale of drugs by the way of wholesale granted by the Assistant Commissioner, Food & Drug Administration M.S. Jalna.
- 5) That the accused No. 2 is the Production Manager of M/s. Colinz Laboratories Limited, and responsible person for the day to activity of the company, i.e. Accuse No.7, as contemplated under section 17 and 18 of said Act.
- 6) That the accused No 3 is the Plant Manager And Incharge chemist for Manufacturing M/s. Shefa Healthcare Pvt Ltd, A-10/1 MIDC Talaja Industrial Area Talaja, Navi Mumbai, i.e. Accuse No.8
- 7) That the accused No 4 is the Quality control Manager of M/s. Shefa Healthcare Pvt Ltd, A-10/1 MIDC Talaja Industrial Area Talaja, Navi Mumbai.
- 8) That the Accused No.5 is the Managing Director, M/s. Shefa Healthcare Pvt. Ltd, engaged in the day to day activities of the Company as per the section 34 of the said Act.
- 8) That the accused no. 6 is the Technical Director of M/s. Shefa Healthcare Pvt Ltd, A-10/1 MIDC Talaja Industrial Area Talaja, Navi Mumbai.
- 9) That the accused No 7. Is the Company engaged in the manufacturing of said drug under loan license bearing No. 25A-KD-221A & 28A-KD-2523A at the premises of Accused No.8 At. A-10/1 MIDC Talaja Industrial Area Talaja, Navi Mumbai, granted by the Licensing Authority (Kokan Div.) & having product permission to manufacture the "Pasam Drop",

- 10) That the Accused No. 8 is the Manufacturing Company engaged in the manufacturing the drugs for sale at his premises under the loan license in the name of Accused No.7 granted by the Joint commissioner (KD) Thane Food and drug Administration , M.S.,Thane.
- 11) That on 29/02/2012, the Complainant had drawn the sample as per the procedure & power vested him under the section 23 of the said Act of Drug namely "**PASAM Drops**", 10ml B.No. PS120101 Mfg- 01/2012, Dt. Of Exp- 12/2014 Mfg. By- M/s. Colinz Laboratories Ltd., At- A-10/1 MIDC, Taloja Industrial Area Taloja, Navi Mumbai -410208 (hereinafter referred to as the "Said Drug") for analysis in form 17, Dtd. 29/02/2012, from the premises of M/s. Samarth Agency i.e. Accused No.1.
- 12) That the said drug was sent for analysis under form 18 on 01/03/2012, to Government Analyst, Drugs Control Laboratory, Maharashtra State, Aurangabad as per the procedure of the said Act.
- 13) That the Government Analyst, M.S. Aurangabad had declared the said drug as of **Not Of Standard quality**, vide his report in Form 13 bearing no. NSQ/ AUR/20852/2012, dtd. 08.10.2012 (hereinafter referred to as the "Said Report"), for the reasons mentioned below:-
- "The Content of the Dicyclomine Hydrochloride in the sample is less(23.30% of the said amount) than the permissible limit. ( Permissible limit :- Not less than 90% of the said Amount.) "**
- 14) That the Complainant as per provision of Section 25(2) of the said Act handed over the one copy of Analytical Test Report in Form-13, vide office letter no. JLN/DI/ 20852 /NSQ/2294 Dtd. 09/10/2012 to Shri Promod Dhanraj Totala Partner and Competent Person of M/s. Samarth Agencies. i.e. Accused no 1.

  
 - अधिकारी  
 र. प्रशासनिक विभाग  
 अन्न व औषध प्रशासन, म. श.  
 मुंबई.

- 15) That the complainant under Section 18-A of the said act asked to accused no 1 vide above referred letter to disclose the name of the supplier, from whom he acquired the said drug, as per provision of Section 18-A of the said Act.
- 16) That the complainant sent the one copy of test report of subject drug as per the Section 25(2) vide office letter bearing no. औसौप्र / २३११/१२/१२ dated 10/10/2012 by speed post to accused No.7 which was delivered to them on 15/10/2012 as per the reply letter of colinz datd 30/10/2012
- 17) .That Accused No.1, vide his letter dtd. 09/10/2012 disclosed that, they had purchased the said drug from M/s. Colinz Laboratories Ltd i.e. Accused No.7 vide their invoice no. 11/ML/705 dt. 13/02/2012, 2012/ML/00080-dt.22/04/2012, 2012/ML/00168 dt-22/05/2012, 2012/ML/00346-dt.26/07/2012, 2012/ML/00393,dt-02/08/2012 & 2012/ML/00482 dt. 03/09/2012. Accused No.1 also submitted the self certified copy of these all purchase bills, and distribution details of the said drugs.
- 18) That the Complainant received the letter from Accused No.7 in reply of the letter sent to him & he told that he is not agree with the govt. analyst report since they were not used proper method for the testing of the sample.
- 19) That the Complainant sent a letter bearing No. D&C/NSQ/6500/12/2 Dt. 23/11/12 to accuse No.7 mentioning that if they were not agree with the G.A. Report, then they may apply for sending the Sample for reanalysis under Section 25(4) of the said Act to CDL Kolkata. Also complainant requested to send the required documents asked under Section 18-B of the said Act from accuse no.7.
- 20) That the Complainant has send the reminder-1 letter to accused o7 on dated 03/01/2013 औ.सै.प्र/अप्र/23-24/13/02 to submitt the document related to Not of standard Quality Said Drug & also sent the one sealed Counter part of sample as per the Section 25(3) of the said Act.




- 21) That the complainant received the letter from accused No.7 dated 7/01/2013 that they manufactured the said drug at the premises of accused no.8 but does not give a single document asked by the complainant under section 18-B of the said Act.
- 22) That the complainant received the document from the accused No.7 vide his letter dated 15 january 2013 regarding the details of them. And in that letter they directed to accuse no. 8 to send the documents regarding the manufacturing related of said drugs.
- 23) That Complainant received the documents of the Accused No.8 from accused no. 7 vide covering letter dated 19/02/2013 of, along with the certified copy of documents of Accuse No.8
- 24) That, the complainant received the Prosecution order from the joint Commissioner (Head Quarter) Food & Drug Administration M.S. bearing no. खटला/AUR/20852/2012/1741/12/10 dated 20/10/2012.
- 25) That the said drug is a drug as defined under Section 3(b)(i) of the said Act, which reads as follows:-

**Section 3: Definitions-** In this Act, unless there is anything repugnant in the subject or context, -

**(b) "Drug" includes-**

(i) all medicines for internal or external use of human being or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparation applied on human body for the purpose of repelling insects like mosquitoes.

- 26) That the said drug was declared as **Not of Standard Quality** by Government Analyst, Drugs Control Laboratory, Maharashtra State, Aurangabad vide said report.

  
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 राज्य सरकार, महाराष्ट्र, अ. व. स.  
 अहमदनगर

- 27) That the manufacturing of Not of Standard Quality drug is prohibited as per provision of Section 18-(a)(i) read with Section 16(1)(a) of the said Act.
- 28) Section 18(a)(i) reads as follows:

**Section 18. Prohibition of manufacture and sale of certain drugs and cosmetics-** no person shall himself or by any other person on his behalf-

(a) Manufacture for sale [or for distribution] or sell, or stock, or exhibit [ or offer] for sale or distribute -

(i) Any drug which is not of standard quality, or is misbranded, adulterated or spurious. ,

- 29) That Section 16(1)(a) reads as follows:

### Section 16. Standards of quality-

(1) For the purpose of this chapter, the expression "Standard Quality" means-

(a) in relation to a drug, that the drug complies with the standards set out in (second schedule).

- 30) That from the above facts, it is clear that the **Accused no. 1 to 6 had distributed & Sold the said drug on or before 08/10/2012**, which is not of standard quality and, thereby **contravened the Section 18 (a)(i) r/w Section 16(1)(a) and Section 34 punishable under Section 27(d) of Drugs and Cosmetics Act 1940.**

- 31) That from above facts, it is clear that the **Accused no 2 to 8** has **manufactured for sale and sold the said Drug** on or before 08/10/2012, which is Not of Standard Quality and thereby **contravened Section 18 (a)(i) r/w Section 16(1)(a) and Section 34 punishable under Section 27(d)** of Drugs and Cosmetics Act 1940.

Handwritten signature and date: 10/10/10



**PRAY:**

The complainant prays that the process be issued against the accused and they may be dealt as per law.

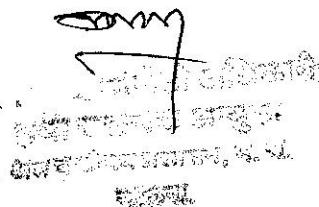
And for this Act of kindness, the complainant shall be duty bound ever pray.

Place: Jalna

Date: 21/3/2013



(Chandrakant A More)  
Complainant,  
Drugs Inspector,  
FDA, Jalna.



Drugs Inspector,  
Jalna

(9)


**List of witnesses IN THE R.C.C. NO. 205 | 2013**

- 1) Shri. D P Awashank, Government Analyst, Drug Control Laboratory, M.S. Aurangabad.

Any other witness with the permission of the Hon'ble Court.

Place: Jalna

Date: 21/2/2013

  
(Chandrakant A More)  
Complainant,  
Drugs Inspector,  
FDA, Jalna.


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**LIST OF DOCUMENTS ATTACHED IN THE R.C.C. No.- 205 /2013**

Sr. No.	Name of the Documents	Date	copy	Page No.
01	Copy of Gazette Notification of Complainant & transfer order	10-01-2012	Xerox	1 - 09
02	Office Copy of Form 17 inspection report	29-02-2012	Original	10-12
03	Purchase bill & payment receipt of sample	29-02-2012 & 9-11-2012	Original	13-14
04	Copy of Form 18 sent to Govt. Analyst	01-03-2012	original	15
05	Copy of Government Analyst Report in Form 13A	08-10-2012	original	16-18
06	Office Copy of Letter given to Accuse No 1	09-10-2012	original	19
07	Inspection report and letter along with documents given by the Accuse No.1	09-10-2012	original	20-29
08	Office copy of Letter sent to Accuse No.7	10-10-2012	original	30
09	Copy of letter received from Accuse No : 7	30-10-2012	original	31-32
10	Consent letter received from Joint Commissioner HQ to launch the prosecution	20-10-2012	original	33
11	Office copy of Letter sent to accuse No. 7	23-11-2012	Original	34
12	Office copy of Letter of Sec.32 & 25 compliance sent to Accused No.7	03/01/2013	Original	35
13	Letter received from accuse no 7	07-01-2013	Original	36
14	Letter along with documents received from Accuse No.7	15-01-2013	Original	37-117
15	Letter along with documents received from Accuse No.7	19/02/2013	Original	118-214

Place: Jalna

Date: 21/3/2013

  
(Chandrakant Arjun More)  
Complainant,  
Drugs Inspector,  
FDA, Jalna.

  
SUBST.