F.No.4-14/2011/BA-BE/17 (TAAB)
Directorate General of Health Services
Office of Drug Controller General (India)
(Drugs Control Section)

FDA Bhawan, Kotla Road,
New Delhi-110002.
Dated 10 JUL 2017

To,

M/s Taab Biostudy Services,
77/2/1B/1, Bade Raipur Road,
Jadavpur, Kolkatta- 700 032

Sub:- Renewal for Approval of Bioavailability/Bioequivalence Study centre of M/s. TAAB Biostudy Services, 77/2/1B/1, Bade Raipur Road, Jadavpur, Kolkata- 700 032- regarding.

Sir,

Please refer to your letter no. nil dated 05/10/2016 received by this Directorate vide diary no. 55811 dated 07/10/2016 on the subject stated above.

As per documents submitted by you, this Directorate will accept the protocol and bioavailability / bioequivalence study reports of New Drugs from your facility having:

1. Clinical facility of 24 Beds at M/s. TAAB Biostudy Services, 77/2/1B/1, Bade Raipur Road, Jadavpur, Kolkatta- 700 032.
2. Bio Analytical Facility at 76/D, Ibrahimpur Road, Kolkata-700032.

Subject to following conditions:-

1. The study centre should ensure that the whole Informed Consent Process should be documented through Audio-Video means maintaining the principle of confidentiality as per GSR 611(E) dated 31.07.2015.
2. Specific protocol for conducting BE/BA studies with new drug formulation should be cleared by Institutional Ethics Committee and then get approval from this office on case to case basis.
3. This certificate shall remain valid for a period of three years from the date of issue. However, there will be periodical assessment of performance of said study centre for continued acceptance of protocol and reports in this regard.

Yours faithfully,

(Dr. S. Eswara Reddy)
Joint Drugs Controller (India)

Copy to:-

The Deputy Drugs Controller (I), Central Drugs Standard Control Organization, (East Zone), Nizam Palace, 1st MSO Building, 7th Floor, 234/4, A.J.C. Bose Road, Kolkata- 700020

F.No.4-14/2011/BA-BE/17 (TAAB)
Directorate General of Health Services
Office of Drug Controller General (India)
(Drugs Control Section)

FDA Bhawan, Kotla Road,
New Delhi-110002.
Dated
19 JAN 2016

To,

M/s Taab Biostudy Services,
77/2/18/1, Bade Raipur Road,
Jadavpur, Kolkatta- 700 032

Sub:- Renewal for Approval of Bioavailability/Bioequivalence Study Centre of M/s. Taab Bio study Services, 77/2/18/1, Bade Raipur Road, Jadavpur, Kolkatta- 700 032- regarding.

Sir,

Please refer to your application no. Nil dated 06.05.2015 vide FTS no. 25666/15 dated 15.5.2015 on the above subject.

As per documentation submitted by you, this Directorate will accept the protocol and bioavailability/ bioequivalence study reports of New Drugs from your study centre having:

a) Clinical facility of 24 beds at M/s. Taab Bio study Services, 77/2/18/1, Bade Raipur Road, Jadavpur, Kolkatta- 700 032.
b) Bio analytical facility at 76/D, Ibrahimpur Road, Kolkata-700032.

Subject to the following conditions:-

1. The study centre should ensure that the whole Informed Consent Process should be documented through Audio- Video means maintaining the principle of confidentiality as per GSR 611(E) dated 31.07.2015.
2. Specific protocol for conducting BE/BA studies with new drug formulation should be cleared by Institutional Ethics Committee and then got approved from this office on case to case basis.
3. After one year there will be assessment of performance of said study centre for continued acceptance of protocol and reports in this regard.

Yours faithfully,

(Dr. S. Eswara Reddy)
Joint Drugs Controller (India)

Copy to:-

The Deputy Drugs Controller (I), Central Drugs Standard Control Organisation, (East Zone), C.G.O. Building, Nizam Place, 2nd Floor, 234/4, A.J.C. Bose Road, Kolkata- 700020.

F.No.4-14/2011/BA-BE/17 (TAAB)
Directorate General of Health Services
Office of Drug Controller General (India)
(Drugs Control Section)

FDA Bhawan, Kotla Road,
New Delhi-110002.
Dated
16 MAY 2014

To,

M/s Taab Biostudy Services,
77/2/18/1, Bade Raipur Road,
Jadavpur, Kolkatta- 700 032

Sub:- Renewal for Approval of Bioavailability/Bioequivalence Study centre of M/s. Taab Biostudy Services, 77/2/18/1, Bade Raipur Road, Jadavpur, Kolkatta- 700 032- regarding.

Sir,

Please refer to your letter no. Nil dated 16/4/2014 vide diary no. 17295 dated 23/4/2014 on the above subject.

As per documentation submitted by you, this Directorate will accept the protocol and bioavailability/ bioequivalence study reports of New Drugs from your laboratory having:

a) Clinical facility (24 Beds) at M/s. Taab Biostudy Services, 77/2/18/1, Bade Raipur Road, Jadavpur, Kolkatta- 700 032.
b) Bio Analytical and Pharmacostatic analysis at 76/D, Ibrahimpur Road, Kolkata-700032.

Subject to the following conditions:-

1. The copy of registration of Ethics Committee is required to be submitted, as directed by this office vide letter no. F.No.4-14/2011/BA-BE/17 (TAAB) dated 02.07.2013
2. The study centre should ensure that the whole Informed Consent Process should be documented through Audio- Video means maintaining the principle of confidentiality.
3. Specific protocol for conducting BE/BA studies with new drug formulation should be cleared by Institutional Ethics Committee and then got approved from this office on case to case basis.
4. After one year there will be assessment of performance of said study centre for continued acceptance of protocol & reports in this regard.

Yours faithfully,

(Dr. V. G. Somani)
Joint Drugs Controller (India)

Copy to:-

1. Dy. Drugs Controller (I), Central Drugs Standard Control Organisation, (East Zone), C.G.O. Building, Nizam Place, 2nd Floor, 234/4, A.J.C. Bose Road, Kolkata- 700020. With request to check the compliance of the firm regularly, specifically, in one month & submit report with specific recommendations to this office.