

F.No.4-14/97-DC (WCR)

From:-

The Drugs Controller General (India),
Directorate General of Health Services

FDA Bhawan, Kotla Road,
New Delhi-110002.

Dated 12 1 JUL 2009

To,

✓ M/s Wellquest Clinical Research,
(A Division of Nicholas Piramal India Ltd.)
4th floor, Mirra Kamsetty Mall,
Ramanthapur, R.R. Dist, Hyderabad-500013.

Sub: Approval of Bioavailability/Bioequivalence Study—regarding.

Sir,

Please refer to your letter no. Nil dated 2nd January 2009 and 10th July 2009 on the above subject.

This Directorate will continue to accept the bioavailability/bio-equivalence protocols and the report of the studies with the new drugs from your laboratory situated at M/s Wellquest Clinical Research, (A Division of Nicholas Piramal India Ltd.) 4th floor, Mirra Kamsetty Mall, Ramanthapur, R.R. Dist, Hyderabad-500013, subject to the condition that specific protocol for conducting BE/BA studies be got approved by Institutional Ethics Committee and then from this Directorate on case to case basis.

Yours faithfully,



(A.B.RAMTEKE)

Joint Drugs Controller (India)
For Drugs Controller General (I)

Copy to:-

The Dy. Drugs Controller (I),
CDSCO (South Zone),
2nd Floor, Shastri Bhawan Annexe,
26, Haddows Road, Chennai-6

F.No.4-14/97-DC (WCR)
Directorate General Of Health Services
Office of Drug Controller General (India)
(Drugs Control Section)

FDA Bhawan, Kotla Road,
New Delhi-110002.

Dated

5 APR 2011

To,

M/s Piramal Clinical Research
4th Floor, Mirra Kamshetty Mall,
Ramanthapur, R.R District
Hyderabad-500013

Sub: Change of name of Bioavailability/Bioequivalence Study Centre—regarding.

Sir,

Please refer to your letter no. Nil dated 4th April, 2011 received by this Directorate vide FTS 21730/DCGI/2011 dated 4th April, 2011 on the subject mentioned above.

This Directorate has noted the change of name of your BA/BE study centre from M/s Wellquest Clinical Research to M/s Piramal Clinical Research subject to all other conditions of earlier letter 21 July 2009 remaining same.

Yours faithfully,



(Dr. Surinder Singh)
Drugs Controller General (India)

Copy To:-

The Asstt. Drugs Controller (I),
Central Drugs Standard Control Organisation,
Zonal Office, Central Drugs Bhawan,
Beside AP T.B Demonstration and Training Centre,
S.R. Nagar, Hyderabad-500038