APPENDIX 16.1.3.1

List of EC members and EC approval letter
CHL – APOLLO HOSPITALS – ETHICS COMMITTEE

November 15, 2010

To,
Dr. Jayesh Kothari,
Consultant Dermatologist
Skin Clinic, # 301, Manasa Bhavan,
RNT Marg, Indore - 452001

Reference: CDS1002: A Multicentre, randomized, Investigator Blind, Parallel Group, Three Arm Pilot Study to Evaluate the HPA Axis Suppression, Efficacy and Safety of Clobetasol Propionate Cream 0.025% Formulation 5 and Clobetasol Propionate Cream 0.025% Formulation 13 as Compared to Temovate E Emollient 0.05% (clobetasol propionate emollient cream (in Patients with Moderate to Severe Psoriasis for 28 Days.

Subject: Ethics Committee approval for the above referenced study and study documents.

Dear Dr. Kothari,

We have received from you 12 copies of each of the following study related documents for referenced protocol with your letter dated September 29, 2010.

The following documents were reviewed:

1. Protocol Version No. 1.0 Dated 04 Aug 2010
2. Investigator’s Brochure Edition 2: dated 02 Aug 2010
3. Informed Consent Form Version No. 1: English dated 04 Aug 2010
4. Informed Consent Form Version No. 1: English translated to Hindi dated 31 Aug 2010
5. Informed Consent Form Version No. 1: English translated to Tamil dated 09 Sep 2010
6. Informed Consent Form Version No. 1: English translated to Kannada dated 09 Sep 2010
7. Informed Consent Form Version No. 1: English translated to Urdu dated 31 Aug 2010
8. Informed Consent Form Version No. 1: English translated to Marathi dated 01 Sep 2010
9. Informed Consent Form Version No. 1: English translated to Malayalam dated 31 Aug 2010
10. Informed Consent Form Version No. 1: Hindi translated to English dated 08 Sep 2010
11. Informed Consent Form Version No. 1: Tamil translated to English dated 13 Sep 2010
CHL – APOLLO HOSPITALS – ETHICS COMMITTEE

12. Informed Consent Form Version No. 1: Kannada translated to English dated 09 Sep 2010
13. Informed Consent Form Version No. 1: Urdu translated to English dated 09 Sep 2010
14. Informed Consent Form Version No. 1: Marathi translated to English dated 08 Sep 2010
15. Informed Consent Form Version No. 1: Malayalam translated to English dated 08 Sep 2010
16. Informed Consent Form : Translation Certificates
17. Informed Consent Form : Back Translation Certificates
18. Patient Diary Card Version No.1: English dated 14 Sep 2010
19. Patient Diary Card Version No.1: English translated to Hindi dated 20 Sep 2010
20. Patient Diary Card Version No.1: English translated to Tamil dated 20 Sep 2010
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33. DCGI- Submission Letter (Acknowledgement)
34. Central Reference Laboratory – Investigator Manual Version 1.0 dated 30 Aug 2010
35. Case Report Form Version 1.0 dated 24 Sep 2010
36. Curriculum Vitae and Medical Registration Certificate of Principal Investigator
37. Investigator’s Undertaking
38. Clinical trial Agreement
39. Indemnity Statement
CHL – APOLLO HOSPITALS – ETHICS COMMITTEE

At the Ethics Committee meeting held on 10 November 2010, your referenced letter and the above documents were examined and discussed. After due consideration, the committee has decided to approve the conduct of the study and above-mentioned documents for the referenced study under your direction at Skin Clinic, Indore.

This Committee’s approval is granted to you subject to permission from the Drugs Controller General of India, New Delhi for the conduct of this study. We request you to submit a copy of the DCGI’s approval letter for the study as soon as you receive.

The members who attended the meeting held on 10 November 2010, at which your proposal was discussed are listed below:

| S. No | Name of the member with designation | Qualification | Gender | Primary scientific or non-scientific specialty | Affiliation |
|-------|--------------------------------------|---------------|--------|---------------------------------------------|-------------|
| 1     | Dr. C. P. Kothari, Chairman          | M.B.B.S, M.S. | Male   | Gastrointestinal & Laparoscopic             | No, Honorary Consultant |
| 2     | Dr. Rajesh Jain, Member Secretary    | M.B.B.S, M.D. | Male   | Internist & Cardiologist                    | Yes, Full time Consultant |
| 3     | Dr. C. S. Agrawal, Clinician         | M.B.B.S, M.D. | Male   | Echo Cardiologist                           | Yes, Full time Consultant |
| 4     | Dr. Vidhyut Jain, Clinician          | M.B.B.S, M.D. | Male   | Internist & Cardiologist                    | No, Honorary Consultant |
| 5     | Dr. Ablay Bhagwat, Clinician         | M.B.B.S, M.D. (Medicine), D.M. (Neurology) | Male   | Neurologist                                 | Yes, Full time Consultant |
| 6     | Dr. Sanjay Dhamuka, Clinician        | M.B.B.S, M.H.A | Male   | Intensivist & ICU In-charge                 | Yes, Full time Consultant |
| 7     | Dr. Vinija Kothari, Basic Scientist  | M.B.B.S, M.D. (Pathology) | Female | Microbiologist & Pathologist                | Yes, Full time Consultant |
| 8     | Mr. Udesh Dassani, Lawyer            | F.C.A, L.L.B. | Male   | Lawyer                                      | No |
| 9     | Mr. Naresh Choudhary, Lay person     | M. Com, L.L.B | Male   | Businessman                                 | No |
| 10    | Mrs. Anjali Khatri NGO               | M. Com        | Female | Social Worker                               | No |
CHL – APOLLO HOSPITALS – ETHICS COMMITTEE

It is to be noted that neither you nor any of your proposed study team members were present during the decision-making procedures of the Ethics Committee.

Please inform us in case any Serious Adverse Event is observed during the conduct of the study and also let us have a periodic report on the progress of the study annually.

We confirm that the CHL-Apollo Hospitals – Ethics Committee operates as per Schedule Y and ICH GCP guidelines. The Institutional Ethics Committee expects to be informed about the following:

- Progress of the study and a copy of the final report.
- Any SAE occurring during the course of the study
- Any deviations from, or changes in the protocol to eliminate immediate hazards to the study subject
- Changes that increase the risk to the participating subjects and/or those that significantly affect the conduct of the study
- Any changes in the study documents e.g. patient information / informed consent

Sincerely,

Dr. Rajesh Jain
Member Secretary, CHL-Apollo Hospitals – Ethics Committee
Date: October 13, 2010

AGENDA

We will review and discuss the following protocol during our meeting on Thursday October 14, 2010, at 4.00 pm at Clinicom, No.7, 17th ‘A’ Cross, Malleswaram West, Bangalore - 560055

Protocol No/Title: CDS1002: "A Multicenter, Randomized, Investigator Blind, Parallel Group, Three Arm Pilot Study To Evaluate The HPA Axis Suppression, Efficacy And Safety Of Clobetasol Propionate Cream 0.025% Formulation 5 And Clobetasol Propionate Cream 0.025% Formulation 13 As Compared To Temovate E Emollient. 0.05% (clobetasol propionate emollient cream) In Patients With Moderate To Severe Psoriasis For 28 Days".

Received from
Dr. Sandesh Gupta
PRINCIPAL INVESTIGATOR
Skin n Laser Center
F-12/10, Krishna Nagar
Delhi-110051

Cordially,
For CLINICOM,

[Signature]

Member Secretary

Date: October 13, 2010
Minutes of the meeting held on Thursday, October 14, 2010, at 4.00 pm at Clinicom, No.7, 17th ‘A’ Cross, Malleswaram West, Bangalore 560055

We discussed Protocol No/Title: CDS1002: “A Multicenter, Randomized, Investigator Blind, Parallel Group, Three Arm Pilot Study To Evaluate The HPA Axis Suppression, Efficacy And Safety Of Clobetasol Propionate Cream 0.025% Formulation 5 And Clobetasol Propionate Cream 0.025% Formulation 13 As Compared To Temovate E Emollient 0.05% (clobetasol propionate emollient cream) In Patients With Moderate To Severe Psoriasis For 28 Days”.

Received from
Dr. Sandesh Gupta
PRINCIPAL INVESTIGATOR
Skin n Laser Center
F-12/10, Krishna Nagar
Delhi-110051

The following members of CLINICOM were present:

1. Mr V V Raghavan, (Pharmaceutical Technologist & Clinical Trials Expert) Chairman
2. Dr. P H Prasad, (Medical Scientist), Vice Chairperson
3. Ms. Vidya Sury, (Layperson & Homemaker), Member Secretary
4. Dr. S Krishnamurthy, (Legal Expert), Member
5. Ms. Chetana Sudhir, (Counselor and Social Worker), Member
6. Ms. Renu Srinivasan, (Social Worker / Educationist), Member
7. Mr. Arun Madhavan, (Theologian), Member
8. Dr. K Venkatesan, (Scientist), Member
9. Ms. Vidhya Nuti, (Legal Expert), Member

Dr. Nandini Mundkur, (Medical Scientist & Pediatric Consultant), Member did not attend the meeting. However she has reviewed the protocol documents and has no objection to the conduct of the study.

We have the following query related to the study:

- In ICF English Version Point no 4 - Page 4 of 14 - Study Design it says: “This is an investigator-blind study which means that your doctor will not know which of the three study treatments you are receiving. You will strictly be instructed not to disclose the identity of the cream to the study doctor at anytime during visit for the duration of study and after the study ends”
The highlighted text in bold - What is the relevance of this when the previous para says that the subject will not know which formulation which s/he will get. Could it lead to confusion in the mind of the subject? Please let us know the labeling details of the cream.

- Please submit a copy of the DCGI approval letter before commencing any study related activity

Cordially,
For CLINICOM,

V.V. Raghavan
Chairperson

Date: October 14, 2010
Date: November 2, 2010

Our ref: 00115/14.10.2010

Dr. Sandesh Gupta
PRINCIPAL INVESTIGATOR
Skin n Laser Center
F-12/10, Krishna Nagar
Delhi-110051

Dear Dr Sandesh Gupta,

Sub: Approval - Conditional

Ref: Protocol No/Title: CDS1002: “A Multicenter, Randomized, Investigator Blind, Parallel Group, Three Arm Pilot Study To Evaluate The HPA Axis Suppression, Efficacy And Safety Of Clobetasol Propionate Cream 0.025% Formulation 5 And Clobetasol Propionate Cream 0.025% Formulation 13 As Compared To Temovate E Emollient 0.05% (clobetasol propionate emollient cream) In Patients With Moderate To Severe Psoriasis For 28 Days”

With reference to the above - CLINICOM met on Thursday, October 14, 2010, at 4.00 pm to review and discuss the following documents vide your letter dated October 1, 2010:

1. Protocol Version No.1.0 dated 04 Aug 2010
2. Investigator’s Brochure Edition 2: dated 02 Aug 2010
3. Informed Consent Form Version No.1: English dated 04 Aug 2010
4. Informed Consent Form Version No.1: English translated to Hindi dated 31 Aug 2010
5. Informed Consent Form Version No.1: English translated to Tamil dated 09 Sep 2010
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33. DCGI-Submission Letter (Acknowledgement)
34. Central Reference Laboratory-Investigator Manual Version 1.0 dated 30 Aug 2010
35. Case Report Form Version 1.0 dated 24 Sep 2010
36. Curriculum Vitae and Medical Registration Certificate of Principal Investigator
37. Investigator’s Undertaking
38. Clinical Trial Agreement
39. Insurance policy

The following members of CLINICOM were present at the meeting held on Thursday, October 14, 2010 at 4 pm at Clinicom, No. 7, 17th ‘A’ Cross, Malleswaram West, Bangalore – 560055

1. Mr V V Raghavan, (Pharmaceutical Technologist & Clinical Trials Expert) Chairman
2. Dr. P H Prasad, (Medical Scientist), Vice Chairperson
3. Ms. Vidyasuriy, (Layperson & Homemaker), Member Secretary
4. Dr. S Krishnamurthy, (Legal Expert), Member
5. Ms. Chetana Sudhir, (Counselor and Social Worker), Member
6. Ms. Renu Srinivasan, (Social Worker/Educationist), Member
7. Mr. Arun Madhavan, (Theologian), Member
8. Dr. K Venkatesan, (Scientist), Member
9. Ms. Vidhya Nuti, (Legal Expert), Member

Dr. Nandini Mundkur, (Medical Scientist & Pediatric Consultant), Member did not attend the meeting. However she has reviewed the protocol documents and has no objection to the conduct of the study.

This is only a conditional approval. No study related activity shall commence unless a copy of the DCGI approval is submitted to CLINICOM.

Please note that CLINICOM is organized and operates according to the requirements of the ICH-GCP, Indian Council of Medical Research and Schedule Y. We confirm that neither you nor your study team members participated in the deliberations of the ethics committee and did not vote on the proposal for this study.

Please follow the requirements given below for this study:
CLINICOM
Committee for Evaluation of Protocols for Clinical Research
“Bhooma”, No.7, 17 A Cross, Malleswaram West, Bangalore 560 085
Tel:+91-80-41279794 E-mail: clinicom@gmail.com

Chairperson
Mr. V V Raghavan
M.Sc.
Clinical Trials
Expert & Pharmaceutical
Technologist

Vice Chairperson
Dr. P H Prasad
MBBS, FCCP
Medical Scientist

Member Secretary
Ms. Vidyasury
B Sc, MBA, Dip.T&D
Layperson & Home Maker

Members:
Dr. S Krishnamurthy
LL.M, Ph.D,
LL.D.D.Lit
Legal Expert

Ms. Vidhya Nuti
BSc, LLB, PGDPRCL
Legal Expert

Dr K Venkatesan
M A, Ph D
Scientist

Dr. Nandini Mundkur
M D (Paed), MAMC
Medical Scientist & Paediatric Consultant

Mr Arun Madhavan
B Com, MBA
Theologian

Ms. Renu Srinivasan
M A, B.Ed
Social Worker/Educationist

Ms. Chetana Sudhir
M A, B.Ed
Counselor & Social Worker

- Do not implement any deviation from, or change to, the protocol approved by this ethics committee without the prior written approval of this ethics committee.
- Deviations/changes to the approved protocol may be implemented without prior approval of this ethics committee only when necessary to eliminate immediate hazards to subjects or when changes involve only logistical or administrative aspects of the trial [e.g. change of study monitor(s), telephone numbers(s)].

Promptly report to CLINICOM, the following:

1. Any changes to or deviations to the protocol approved by CLINICOM that you might implement to eliminate hazards to the trial subjects.
2. All serious adverse events
3. New information that may affect adversely the safety of the subjects or the conduct of the trial.

Please submit the status report of the study to CLINICOM at 6-month intervals. Also, provide us with a copy of the final study completion report.

Cordially,
For CLINICOM,

V.V. Raghavan
Chairperson

Date: November 2, 2010
Date: October 13, 2010

AGENDA

We will review and discuss the following protocol during our meeting on Thursday October 14, 2010, at 4.00 pm at Clinicom, No.7, 17th 'A' Cross, Malleswaram West, Bangalore - 560055

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Received from
Dr. D.N.Balraj,
Rajbal Skin Clinic,
#944/1, 7th Main Road,
Banaswadi, Subbayanapalya,
Bangalore-560 043.

Cordially,
For CLINICOM,

[Signature]

Member Secretary

Date: October 13, 2010
Minutes of the meeting held on Thursday, October 14, 2010, at 4.00 pm at Clinicom, No.7, 17th ‘A’ Cross, Malleswaram West, Bangalore 560 055

We discussed Protocol No/Title: CDS1002: “A Multicenter, Randomized, Investigator Blind, Parallel Group, Three Arm Pilot Study To Evaluate The HPA Axis Suppression, Efficacy And Safety Of Clobetasol Propionate Cream 0.025% Formulation 5 And Clobetasol Propionate Cream 0.025% Formulation 13 As Compared To Temovate E Emollient 0.05% (clobetasol propionate emollient cream) In Patients With Moderate To Severe Psoriasis For 28 Days”.

Received from
Dr. D.N.Balraj,
Rajbal Skin Clinic,
#944/1, 7th Main Road,
Banaswadi, Subbayanapalya,
Bangalore-560 043.

The following members of CLINICOM were present:

1. Mr V V Raghavan, (Pharmaceutical Technologist & Clinical Trials Expert) Chairman
2. Dr. P H Prasad, (Medical Scientist), Vice Chairperson
3. Ms. Vidya Sury, (Layperson & Homemaker), Member Secretary
4. Dr. S Krishnamurthy, (Legal Expert), Member
5. Ms. Chetana Sudhir, (Counselor and Social Worker), Member
6. Ms. Renu Srinivasan, (Social Worker / Educationist), Member
7. Mr. Arun Madhavan, (Theologian), Member
8. Dr. K Venkatesan, (Scientist), Member
9. Ms. Vidhya Nuti, (Legal Expert), Member

Dr. Nandini Mundkur, (Medical Scientist & Pediatric Consultant), Member did not attend the meeting. However she has reviewed the protocol documents and has no objection to the conduct of the study.

We have the following query related to the study:

- In ICF English Version Point no 4 - Page 4 of 14 - Study Design it says: “This is an investigator-blind study which means that your doctor will not know which of the three study treatments you are receiving. You will strictly be instructed not to disclose the identity of the cream to the study doctor at anytime during visit for the duration of study and after the study ends.”
The highlighted text in bold - What is the relevance of this when the previous para says that the subject will not know which formulation which s/he will get. Could it lead to confusion in the mind of the subject? Please let us know the labeling details of the cream.

- Please submit a copy of the DCGI approval letter before commencing any study related activity

Cordially,
For CLINICOM,

[Signature]

Chairperson

Date: October 14, 2010
Date: November 2, 2010

Our ref: 00115/14.10.2010

Dr. D.N.Balraj,
Rajbal Skin Clinic,
#944/1, 7th Main Road,
Banaswadi, Subbayanapalya,
Bangalore-560 043.

Dear Dr D N Balraj,

Sub: Approval - Conditional

Ref: Protocol No/Title: CDS1002 : “A Multicenter, Randomized, Investigator Blind, Parallel Group, Three Arm Pilot Study To Evaluate The HPA Axis Suppression, Efficacy And Safety Of Clobetasol Propionate Cream 0.025% Formulation 5 And Clobetasol Propionate Cream 0.025% Formulation 13 As Compared To Temovate E Emollient 0.05% (clobetasol propionate emollient cream) In Patients With Moderate To Severe Psoriasis For 28 Days”

With reference to the above - CLINICOM met on Thursday, October 14, 2010, at 4.00 pm to review and discuss the following documents vide your letter dated September 30, 2010:

1. Protocol Version No.1.0 dated 04 Aug 2010
2. Investigator’s Brochure Edition 2: dated 02 Aug 2010
3. Informed Consent Form Version No.1: English dated 04 Aug 2010
4. Informed Consent Form Version No.1: English translated to Hindi dated 31 Aug 2010
5. Informed Consent Form Version No.1: English translated to Tamil dated 09 Sep 2010
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35. Case Report Form Version 1.0 dated 24 Sep 2010
36. Curriculum Vitae and Medical Registration Certificate of Principal Investigator
37. Investigator’s Undertaking
38. Clinical Trial Agreement
39. Insurance policy

The following members of CLINICOM were present at the meeting held on **Thursday, October 14, 2010 at 4 pm** at Clinicom, No. 7, 17th ‘A’ Cross, Malleswaram West, Bangalore – 560055

1. Mr V V Raghavan, (Pharmaceutical Technologist & Clinical Trials Expert) Chairman
2. Dr. P H Prasad, (Medical Scientist), Vice Chairperson
3. Ms. Vidy Sury, (Layperson & Homemaker), Member Secretary
4. Dr. S Krishnamurthy, (Legal Expert), Member
5. Ms. Chetana Sudhir, (Counselor and Social Worker), Member
6. Ms. Renu Srinivasan, (Social Worker / Educationist), Member
7. Mr. Arun Madhavan, (Theologian), Member
8. Dr. K Venkatesan, (Scientist), Member
9. Ms. Vidhya Nuthi, (Legal Expert), Member

Dr. Nandini Mundkur, (Medical Scientist & Pediatric Consultant), Member did not attend the meeting. However she has reviewed the protocol documents and has no objection to the conduct of the study.

**This is only a conditional approval. No study related activity shall commence unless a copy of the DCGI approval is submitted to CLINICOM.**

Please note that CLINICOM is organized and operates according to the requirements of the ICH-GCP, Indian Council of Medical Research and Schedule Y. We confirm that neither you nor your study team members participated in the deliberations of the ethics committee and did not vote on the proposal for this study.

Please follow the requirements given below for this study:

- Do not implement any deviation from, or change to, the protocol approved by this ethics committee without the prior written approval of this ethics committee.
• Deviations/ changes to the approved protocol may be implemented without prior approval of this ethics committee only when necessary to eliminate immediate hazards to subjects or when changes involve only logistical or administrative aspects of the trial [e.g. change of study monitor(s), telephone numbers(s)].

Promptly report to CLINICOM, the following:

1. Any changes to or deviations to the protocol approved by CLINICOM that you might implement to eliminate hazards to the trial subjects.
2. All serious adverse events
3. New information that may affect adversely the safety of the subjects or the conduct of the trial.

Please submit the status report of the study to CLINICOM at 6-month intervals. Also, provide us with a copy of the final study completion report.

Cordially,
For CLINICOM,

V.V. Raghavan
Chairperson

Date: November 2, 2010
To,

Dr. Manjunath Shenoy
Professor and Head
Department of Dermatology,
Yenepoya Medical College Hospital
Deralakatte, Mangalore

Subject: Approval of Protocol of Study No. MA-CT-10-010 for Ethical Clearance

Date: 23.11.2010

The Yenepoya University Ethics Committee convened meeting on 10.11.2010.

After going through the following documents:

- Protocol Version No.1.0 dated 04Aug 2010
- Investigator’s Brochure Edition 2: dated 02 Aug 2010
- Informed Consent form version 1: English dated 4th Aug 2010
- Informed consent forms Version 1.0 translated into Hindi, Tamil, Kannada, Urdu, Marathi, Malayalam Languages.
- Informed consent translations from Hindi, Tamil, Kannada, Urdu, Marathi, Malayalam Languages back into English
- Informed Consent Form: Translational and Back Translation Certificates
- Patient Diary Card Version No.1:English dated 14 Sep 2010
- Patient Diary card : Version 1 English translated to Hindi, Tamil, Kannada, Urdu, Marathi, Malayalam Languages and back translations.
- Patient Diary card : Translation and Back Translation Certificates
- DCGI- Submission Letter (Acknowledgement)
- Central References Laboratory- Investigator Manual Version 1.0 dated 30 Aug 2010
- Case Report Form Version 1.0 dated 24 Sep 2010
- Curriculum Vitae and Medical Registration Certificates of Principal Investigator
- Investigator's Undertaking
- Clinical trial Agreement (Awaited)
- Indemnity Statement
The Yenepoya University Ethics Committee has conditionally approved the study titled "Multicenter, Randomized, Investigator Blind, Parallel Group, Three Arm Pilot Study To Evaluate The HPA Axis Suppression, Efficacy And Safety Of Clobetasol Propionate Cream 0.025% Formulation 5 And Clobetasol Propionate Cream 0.025% Formulation 13 As Compared To Temovate E Emollient 0.05% (Clobetasol propionate emollient cream) In Patients With Moderate To Severe Psoriasis For 28 Days.

The final approval from ethics committee will be given after the DCGI Approval letter, Insurance certificate for the study are furnished.

Following members attended the meeting:
Fr. Joy (Chairman) Outside member
Dr. Vina Vaswani (Secretary YUEC)
Dr. Shankar Bhat
Dr. S.N. Rao
Dr. Maji Jose
Dr. Sham Bhat
Dr. Arun Kumar M
Dr. Shankar Bhat
Dr. Deepak Rai
Dr. Vidya
Mr. Abdul Rahim
Ms. Vinitha Jacob
Mr. Chadrashankar, Outside member
Ms. Shwetha Rasquinha. Outside member

[Signature]

Dr. Vina R. Vaswani MD, M Phil, MA (Bioethics)
Secretary Yenepoya University Ethics Committee
Secretary
Yenepoya University Ethics Committee
Date: October 13, 2010

AGENDA

We will review and discuss the following protocol during our meeting on Thursday October 14, 2010, at 4.00 pm at Clinicom, No.7, 17th 'A' Cross, Malleswaram West, Bangalore - 560055

Protocol No/Title: CDS1002: "A Multicenter, Randomized, Investigator Blind, Parallel Group, Three Arm Pilot Study To Evaluate The HPA Axis Suppression, Efficacy And Safety Of Clobetasol Propionate Cream 0.025% Formulation 5 And Clobetasol Propionate Cream 0.025% Formulation 13 As Compared To Temovate E Emollient 0.05% (clobetasol propionate emollient cream) In Patients With Moderate To Severe Psoriasis For 28 Days".

Received from
Dr. FREDERICK MANUEL
SKIN CLINIC
CONSULTANT DERMATOLOGIST
22, Paper Mills Road, Perambur,
CHENNAI - 600 011.
Phone (C): 044 – 65166966

Cordially,
For CLINICOM,

[Signature]

Member Secretary

Date: October 13, 2010
Minutes of the meeting held on Thursday, October 14, 2010, at 4.00 pm at Clinicom, No.7, 17th ‘A’ Cross, Malleswaram West, Bangalore 560055

We discussed Protocol No/Title: CDS1002: “A Multicenter, Randomized, Investigator Blind, Parallel Group, Three Arm Pilot Study To Evaluate The HPA Axis Suppression, Efficacy And Safety Of Clobetasol Propionate Cream 0.025% Formulation 5 And Clobetasol Propionate Cream 0.025% Formulation 13 As Compared To Temovate E Emollient 0.05% (clobetasol propionate emollient cream) In Patients With Moderate To Severe Psoriasis For 28 Days”.

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22, Paper Mills Road, Perambur,
CHENNAI – 600 011.
Phone (C): 044 – 65166966

The following members of CLINICOM were present:

1. Mr V V Raghavan, (Pharmaceutical Technologist & Clinical Trials Expert) Chairman
2. Dr. P H Prasad, (Medical Scientist), Vice Chairperson
3. Ms. Vidya Sury, (Layperson & Homemaker), Member Secretary
4. Dr. S Krishnamurthy, (Legal Expert), Member
5. Ms. Chetana Sudhir, (Counselor and Social Worker), Member
6. Ms. Renu Srinivasan, (Social Worker / Educationist), Member
7. Mr. Arun Madhavan, (Theologist), Member
8. Dr. K Venkatesan, (Scientist), Member
9. Ms. Vidhya Nuti, (Legal Expert), Member

Dr. Nandini Mundkur, (Medical Scientist & Pediatric Consultant), Member did not attend the meeting. However she has reviewed the protocol documents and has no objection to the conduct of the study.

We have the following query related to the study:

- In ICF English Version Point no 4 - Page 4 of 14 - Study Design it says: "This is an investigator-blind study which means that your doctor will not know which of the three study treatments you are receiving. You will strictly be instructed not to disclose the identity of the cream to the study"
doctor at anytime during visit for the duration of study and after the study ends"

The highlighted text in bold - What is the relevance of this when the previous para says that the subject will not know which formulation which s/he will get. Could it lead to confusion in the mind of the subject? Please let us know the labeling details of the cream.

- Please submit a copy of the DCGI approval letter before commencing any study related activity

Cordially,
For CLINICOM,

V.V. Raghavan
Chairperson

Date: October 14, 2010
Date: November 2, 2010

Our ref: **00115/14.10.2010**

Dr. FREDERICK MANUEL  
SKIN CLINIC  
CONSULTANT DERMATOLOGIST  
22, Paper Mills Road, Perambur,  
CHENNAI - 600 011.  
Phone (C): 044 – 65166966

Dear Dr Frederick Manuel,

Sub: Approval - Conditional

Ref: Protocol No/Title: CDS1002 : “A Multicenter, Randomized, Investigator Blind, Parallel Group, Three Arm Pilot Study To Evaluate The HPA Axis Suppression, Efficacy And Safety Of Clobetasol Propionate Cream 0.025% Formulation 5 And Clobetasol Propionate Cream 0.025% Formulation 13 As Compared To Temovate E Emollient 0.05% (clobetasol propionate emollient cream) In Patients With Moderate To Severe Psoriasis For 28 Days”

With reference to the above - CLINICOM met on Thursday, October 14, 2010, at 4.00 pm to review and discuss the following documents vide your letter dated October 4, 2010:

1. Protocol Version No.1.0 dated 04 Aug 2010  
2. Investigator’s Brochure Edition 2: dated 02 Aug 2010  
3. Informed Consent Form Version No.1: English dated 04 Aug 2010  
4. Informed Consent Form Version No.1: English translated to Hindi dated 31 Aug 2010  
5. Informed Consent Form Version No.1: English translated to Tamil dated 09 Sep 2010  
6. Informed Consent Form Version No.1: English translated to Kannada dated 09 Sep 2010  
7. Informed Consent Form Version No.1: English translated to Urdu dated 31 Aug 2010  
8. Informed Consent Form Version No.1: English translated to Marathi dated 01 Sep 2010  
9. Informed Consent Form Version No.1: English translated to Malayalam dated 31 Aug 2010  
10. Informed Consent Form Version No.1: Hindi translated to English dated 08 Sep 2010
11. Informed Consent Form Version No.1: Tamil translated to English dated 13 Sep 2010
12. Informed Consent Form Version No.1: Kannada translated to English dated 09 Sep 2010
13. Informed Consent Form Version No.1: Urdu translated to English dated 09 Sep 2010
14. Informed Consent Form Version No.1: Marathi translated to English dated 08 Sep 2010
15. Informed Consent Form Version No.1: Malayalam translated to English dated 08 Sep 2010
16. Informed Consent Form: Translation Certificates
17. Informed Consent Form: Back Translation Certificates
18. Patient Diary Card Version No.1: English dated 14 Sep 2010
19. Patient Diary Card Version No.1: English translated to Hindi dated 20 Sep 2010
20. Patient Diary Card Version No.1: English translated to Tamil dated 20 Sep 2010
21. Patient Diary Card Version No.1: English translated to Kannada dated 20 Sep 2010
22. Patient Diary Card Version No.1: English translated to Urdu dated 20 Sep 2010
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29. Patient Diary Card Version No.1: Marathi translated to English dated 24 Sep 2010
30. Patient Diary Card Version No.1: Malayalam translated to English dated 24 Sep 2010
31. Patient Diary Card: Translation Certificates
32. Patient Diary Card: Back Translation Certificates
33. DCGI-Submission Letter (Acknowledgement)
34. Central Reference Laboratory-Investigator Manual Version 1.0 dated 30 Aug 2010
35. Case Report Form Version 1.0 dated 24 Sep 2010
36. Curriculum Vitae and Medical Registration Certificate of Principal Investigator
37. Investigator’s Undertaking
38. Clinical Trial Agreement
39. Insurance policy

The following members of CLINICOM were present at the meeting held on Thursday, October 14, 2010 at 4 pm at Clinicom, No. 7, 17th ‘A’ Cross, Malleswaram West, Bangalore – 560055

1. Mr V V Raghavan, (Pharmaceutical Technologist & Clinical Trials Expert) Chairman
2. Dr. P H Prasad, (Medical Scientist), Vice Chairperson
3. Ms. Vidya Sury, (Layperson & Homemaker), Member Secretary
4. Dr. S Krishnamurthy, (Legal Expert), Member
5. Ms. Chetana Sudhir, (Counselor and Social Worker), Member
6. Ms. Renu Srinivasan, (Social Worker / Educationist), Member
7. Mr. Arun Madhavan, (Theologian), Member
8. Dr. K Venkatesan, (Scientist), Member
9. Ms. Vidhya Nuti, (Legal Expert), Member

Dr. Nandini Mundkur, (Medical Scientist & Pediatric Consultant), Member did not attend the meeting. However she has reviewed the protocol documents and has no objection to the conduct of the study.

This is only a conditional approval. No study related activity shall commence unless a copy of the DCGI approval is submitted to CLINICOM.

Please note that CLINICOM is organized and operates according to the requirements of the ICH-GCP, Indian Council of Medical Research and Schedule Y. We confirm that neither you nor your study team members participated in the deliberations of the ethics committee and did not vote on the proposal for this study.

Please follow the requirements given below for this study:

- Do not implement any deviation from, or change to, the protocol approved by this ethics committee without the prior written approval of this ethics committee.
- Deviations/changes to the approved protocol may be implemented without prior approval of this ethics committee only when necessary to eliminate immediate hazards to subjects or when changes involve only logistical or administrative aspects of the trial [e.g. change of study monitor(s), telephone numbers(s)].

Promptly report to CLINICOM, the following:
1. Any changes to or deviations from the study protocol approved by CLINICOM should be reported to us to eliminate hazards to the trial subjects.
2. All serious adverse events
3. New information that may affect adversely the safety of the subjects or the conduct of the trial

Please submit the status report of the study to CLINICOM at 6-month intervals. Also, provide us with a copy of the final study completion report.

Cordially,
For CLINICOM,

[Signature]
V.V. Raghavan
Chairperson

Date: November 2, 2010
Date: October 13, 2010

AGENDA

We will review and discuss the following protocol during our meeting on Thursday October 14, 2010, at 4.00 pm at Clinicom, No.7, 17th ‘A’ Cross, Malleswaram West, Bangalore - 560055

Protocol No/Title: CDS1002 : “A Multicenter, Randomized, Investigator Blind, Parallel Group, Three Arm Pilot Study To Evaluate The HPA Axis Suppression, Efficacy And Safety Of Clobetasol Propionate Cream 0.025% Formulation 5 And Clobetasol Propionate Cream 0.025% Formulation 13 As Compared To Temovate E Emollient 0.05% (clobetasol propionate emollient cream) In Patients With Moderate To Severe Psoriasis For 28 Days”.

Received from
Dr. Rizwan Haq, Principal Investigator, Radiance Skin Clinic, Opp. Muslim Library, Tekdi Road, Sadar, Nagpur-440 001

Cordially,
For CLINICOM,

[Signature]

Member Secretary

Date: October 13, 2010
Minutes of the meeting held on Thursday, October 14, 2010, at 4.00 pm at Clinicom, No.7, 17th 'A' Cross, Malleswaram West, Bangalore 560055

We discussed Protocol No>Title: CDS1002: “A Multicenter, Randomized, Investigator Blind, Parallel Group, Three Arm Pilot Study To Evaluate The HPA Axis Suppression, Efficacy And Safety Of Clobetasol Propionate Cream 0.025% Formulation 5 And Clobetasol Propionate Cream 0.025% Formulation 13 As Compared To Temovate E Emollient 0.05% (clobetasol propionate emollient cream) In Patients With Moderate To Severe Psoriasis For 28 Days”.

Received from
Dr. Rizwan Haq,
Principal Investigator,
Radiance Skin Clinic,
Opp. Muslim Library,
Tekdi Road, Sadar,
Nagpur-440 001

The following members of CLINICOM were present:

1. Mr V V Raghavan, (Pharmaceutical Technologist & Clinical Trials Expert) Chairman
2. Dr. P H Prasad, (Medical Scientist), Vice Chairperson
3. Ms. Vidya Sury, (Layperson & Homemaker), Member Secretary
4. Dr. S Krishnamurthy, (Legal Expert), Member
5. Ms. Chetana Sudhir, (Counselor and Social Worker), Member
6. Ms. Renu Srinivasan, (Social Worker / Educationist), Member
7. Mr. Arun Madhavan, (Theologian), Member
8. Dr. K Venkatesan, (Scientist), Member
9. Ms. Vidhya Nuti, (Legal Expert), Member

Dr. Nandini Mundkur, (Medical Scientist & Pediatric Consultant), Member did not attend the meeting. However she has reviewed the protocol documents and has no objection to the conduct of the study.

We have the following query related to the study:

- In ICF English Version Point no 4 - Page 4 of 14 - Study Design it says: "This is an investigator-blind study which means that your doctor will not know which of the three study treatments you are receiving. You will strictly be instructed not to disclose the identity of the cream to the study"
doctor at anytime during visit for the duration of study and after the study ends"

The highlighted text in bold - What is the relevance of this when the previous para says that the subject will not know which formulation which s/he will get. Could it lead to confusion in the mind of the subject? Please let us know the labeling details of the cream.

- Please submit a copy of the DCGI approval letter before commencing any study related activity

Cordially,
For CLINICOM,

[V.V. Raghavan]
Chairperson

Date: October 14, 2010
Date: November 2, 2010

Our ref: **00115/14.10.2010**

Dr. Rizwan Haq,
Principal Investigator,
Radiance Skin Clinic,
Opp. Muslim Library,
Tekdi Road, Sadar,
Nagpur-440 001

Dear Dr Rizwan Haq,

Sub: Approval - Conditional

Ref: Protocol No>Title: CDS1002 : “A Multicenter, Randomized, Investigator Blind, Parallel Group, Three Arm Pilot Study To Evaluate
The HPA Axis Suppression, Efficacy And Safety Of Clobetasol Propionate Cream 0.025% Formulation 5 And Clobetasol Propionate
Cream 0.025% Formulation 13 As Compared To Temovate E
Emollient 0.05% (clobetasol propionate emollient cream) In Patients
With Moderate To Severe Psoriasis For 28 Days”

With reference to the above - CLINICOM met on Thursday, October 14, 2010, at 4.00 pm to review and discuss the following documents
vide your letter dated September 30, 2010:

1. Protocol Version No.1.0 dated 04 Aug 2010
2. Investigator’s Brochure Edition 2: dated 02 Aug 2010
3. Informed Consent Form Version No.1: English dated 04 Aug 2010
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Malayalam dated 31 Aug 2010
10. Informed Consent Form Version No.1: Hindi translated to English dated 08 Sep 2010
11. Informed Consent Form Version No.1: Tamil translated to English dated 13 Sep 2010
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33. DCGI-Submission Letter (Acknowledgement)
34. Central Reference Laboratory-Investigator Manual Version 1.0 dated 30 Aug 2010
35. Case Report Form Version 1.0 dated 24 Sep 2010
36. Curriculum Vitae and Medical Registration Certificate of Principal Investigator
37. Investigator’s Undertaking
38. Clinical Trial Agreement
39. Insurance policy

The following members of CLINICOM were present at the meeting held on Thursday, October 14, 2010 at 4 pm at Clinicom, No. 7, 17th ‘A’ Cross, Malleswaram West, Bangalore – 560055

1. Mr V V Raghavan, (Pharmaceutical Technologist & Clinical Trials Expert) Chairman
2. Dr. P H Prasad, (Medical Scientist), Vice Chairperson
3. Ms. Vidya Sury, (Layperson & Homemaker), Member Secretary
4. Dr. S Krishnamurthy, (Legal Expert), Member
5. Ms. Chetana Sudhir, (Counselor and Social Worker), Member
6. Ms. Renu Srinivasan, (Social Worker / Educationist), Member
7. Mr. Arun Madhavan, (Theologian), Member
8. Dr. K Venkatesan, (Scientist), Member
9. Ms. Vidhya Nuti, (Legal Expert), Member

Dr. Nandini Mundkur, (Medical Scientist & Pediatric Consultant), Member did not attend the meeting. However she has reviewed the protocol documents and has no objection to the conduct of the study.

This is only a conditional approval. No study related activity shall commence unless a copy of the DCGI approval is submitted to CLINICOM.

Please note that CLINICOM is organized and operates according to the requirements of the ICH-GCP, Indian Council of Medical Research and Schedule Y. We confirm that neither you nor your study team members participated in the deliberations of the ethics committee and did not vote on the proposal for this study.

Please follow the requirements given below for this study:
• Do not implement any deviation from, or change to, the protocol approved by this ethics committee without the prior written approval of this ethics committee.

• Deviations/changes to the approved protocol may be implemented without prior approval of this ethics committee only when necessary to eliminate immediate hazards to subjects or when changes involve only logistical or administrative aspects of the trial [e.g. change of study monitor(s), telephone numbers(s)].

Promptly report to CLINICOM, the following:

1. Any changes to or deviations to the protocol approved by CLINICOM that you might implement to eliminate hazards to the trial subjects.
2. All serious adverse events
3. New information that may affect adversely the safety of the subjects or the conduct of the trial.

Please submit the status report of the study to CLINICOM at 6-month intervals. Also, provide us with a copy of the final study completion report.

Cordially,
For CLINICOM,

V.V. Raghavan
Chairperson

Date: November 2, 2010
Our ref: 00016/15.04.2011 Date: April 21, 2011

Dr. Sandesh Gupta
Principal Investigator,
Skin Laser Centre,
Dermatology
F-10/9, Krishna Nagar
New Delhi 110051
India

Dear Sirs,

Sub: Approval of Amended Protocol No: CDS1002 : “A Multicenter, Randomized, Investigator Blind, Parallel Group, Three Arm Pilot Study To Evaluate The HPA Axis Suppression, Efficacy And Safety Of Clobetasol Propionate Cream 0.025% Formulation 5 And Clobetasol Propionate Cream 0.025% Formulation 13 As Compared To Temovate E Emollient E 0.05% (clobetasol propionate emollient cream) In Patients With Moderate To Severe Psoriasis For 28 Days”.

With reference to the above - CLINICOM met on Friday April 15, 2011, at 5.30 pm to review and discuss the following documents vide your letter dated 31.03.11

1. DCGI approval letter to conduct the study
2. Inform Consent Form Version 2.0 English dated 8-Dec-2010
3. Inform Consent Form Version 2.0 English translated to Hindi dated 11-Jan-2011
4. Inform Consent Form Version 2.0 English translated to Marathi dated 11-Jan-2011
5. Inform Consent Form Version 2.0 English translated to Kannada dated 11-Jan-2011
6. Inform Consent Form Version 2.0 English translated to Tamil dated 11-Jan-2011
7. Inform Consent Form Version 2.0 English translated to Malayalam dated 11-Jan-2011
8. Inform Consent Form Version 2.0 English translated to Urdu dated 11-Jan-2011
9. Inform Consent Form Version 2.0 Hindi translated to English dated 11-Jan-2011
10. Inform Consent Form Version 2.0 Marathi translated to English dated 25-Mar-2011
11. Inform Consent Form Version 2.0 Kannada translated to English dated 25-Mar-2011
12. Inform Consent Form Version 2.0 Tamil translated to English dated 25-Mar-2011
13. Inform Consent Form Version 2.0 Malayalam translated to English dated 25-Mar-2011
14. Inform Consent Form Version 2.0 Urdu translated to English dated 25-Mar-2011
The following administrative changes are made in the ICF

On page 12 point 13 of ICF earlier it was mentioned as “If you are taken ill or are injured resulting directly from participation in this study the sponsor will make available to you reasonable medical treatments. The study sponsor agrees to pay all medical expenses necessary to treat such injury (1) to the extent you are not otherwise reimbursed by medical insurance and (2) provided you have followed the directions of the study doctor. No other compensation will be made available from the study sponsor”.

Now it has been changed to "In case of trial related injury, M/s Manipal Acunova will provide medical care as well as compensation for the injury”

With reference to the above amendment, the Certificate of Liability Insurance held by Dr. Reddy’s Laboratories, inclusion of Manipal Acunova as an Additional Insured Broad Form Vendor where required by written contract (page 2) has been noted. Documenting the administrative change in the ICF, we hereby approve this amendment.

**Kindly send us the Insurance Policy of the same towards completion of the formality at the earliest.**

The following members of CLINICOM were present at the meeting held on **Friday, April 15, 2011, at 5.30 pm** at CLINICOM, “SUSHRUTA”, #1/1, 1st Temple Road, 15th Cross, Malleswaram, Bangalore 560 003:

1. **Dr. Sandhya R., M.B.B.S., M.S., DNB, FVR [Ophthalmology]**
   Chairperson Clinician
2. **Mr. V.V.Raghavan, M.Sc**
   Vice Chairperson, Clinical Trials Expert & Pharmaceutical Technologist
3. **Dr. Anuradha H.V., M.B.B.S., M.D. [Pharmacology]**
   PGDMLE Member, Medical Scientist
4. **Dr. P.K. Raju, M.B.B.S., M.S. Ortho, D Ortho**
   Member, Clinician / Medical Scientist
5. **Ms. Vijaya Suresh, B.A.LLB**
   Legal Expert
6. **Mr. Lakshminarayan P.S., MSW, M.Phil, LLB, PGDHRM**
   Educationist/Social Worker/Legal expert
7. **Ms. Vidya Sury, MBA, Dip in T & D**
   Member, Layperson
8. **Ms. S. Poornima**
   Member Secretary

Please note that CLINICOM is organized and operates according to the requirements of the ICH-GCP, Indian Council of Medical Research and Schedule Y. We confirm that neither you nor your study team members participated in the deliberations of the ethics committee and did not vote on the proposal for this study.

Please follow the requirements given below for this study:
Chairperson
Dr. Sandhya R., M.B.B.S., M.S., DNB
FVR [Ophthalmology] Clinician

Vice Chairperson
Mr. V.V. Raghavan M.Sc
Clinical Trials Expert & Pharmaceutical Technologist

Members:
Dr. Anuradha H.V., M.B.B.S., M.D.
[Pharmacology] PGDMLE Medical Scientist
Dr. P.K. Raju M.B.B.S., M.S. Ortho, D Ortho Clinician / Medical Scientist
Ms. Vijaya Suresh, B.A. LLB Legal Expert
Mr. Lakshminarayan P.S., MSW, M.Phil, LLB, PGDHRM Educationist/Social Worker/Legal expert
Ms. Vidya Sury B Sc, MBA, Dip. T&D Layperson

Member Secretary
Ms. S. Poornima

- Do not implement any deviation from, or change to, the protocol approved by this ethics committee without the prior written approval of the ethics committee.
- Deviations/changes to the approved protocol may be implemented without prior approval of this ethics committee only when necessary to eliminate immediate hazards to subjects or when changes involve only logistical or administrative aspects of the trial [e.g. change of study monitor(s), telephone numbers(s)].

Promptly report to CLINICOM, the following:

1. Any changes to or deviations to the protocol approved by CLINICOM that you might implement to eliminate hazards to the trial subjects.
2. All serious adverse events
3. New information that may affect adversely the safety of the subjects or the conduct of the trial.

Please submit the status report of the study to CLINICOM at 6-month intervals. Also, provide us with a copy of the final study completion report.

Cordially,
For CLINICOM,

[Signature]

Dr. Sandhya R
Chairperson

April 21, 2011
Our ref: 00017/15.04.2011  Date: April 21, 2011

Dr. Frederick Manuel,
Principal Investigator
No.22, Paper Mill Road,
Perambur,
Chennai-600011,
India

Dear Sirs,

Sub: Approval of Amended Protocol No: CDS1002 : "A Multicenter, Randomized, Investigator Blind, Parallel Group, Three Arm Pilot Study To Evaluate The HPA Axis Suppression, Efficacy And Safety Of Clobetasol Propionate Cream 0.025% Formulation 5 And Clobetasol Propionate Cream 0.025% Formulation 13 As Compared To Temovate E Emollient 0.05% (clobetasol propionate emollient cream) In Patients With Moderate To Severe Psoriasis For 28 Days”.

With reference to the above - CLINICOM met on Friday April 15, 2011, at 5.30 pm to review and discuss the following documents vide your letter dated 01.04.11

1. DCGI approval letter to conduct the study
2. Inform Consent Form Version 2.0 English dated 8-Dec-2010
3. Inform Consent Form Version 2.0 English translated to Hindi dated 11-Jan-2011
4. Inform Consent Form Version 2.0 English translated to Marathi dated 11-Jan-2011
5. Inform Consent Form Version 2.0 English translated to Kannada dated 11-Jan-2011
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13. Inform Consent Form Version 2.0 Malayalam translated to English dated 25-Mar-2011
14. Inform Consent Form Version 2.0 Urdu translated to English dated 25-Mar-2011
The following administrative changes are made in the ICF

On page 12 point 13 of ICF earlier it was mentioned as “If you are taken ill or are injured resulting directly from participation in this study the sponsor will make available to you reasonable medical treatments. The study sponsor agrees to pay all medical expenses necessary to treat such injury (1) to the extent you are not otherwise reimbursed by medical insurance and (2) provided you have followed the directions of the study doctor. No other compensation will be made available from the study sponsor”.

Now it has been changed to “In case of trial related injury, M/s Manipal Acunova will provide medical care as well as compensation for the injury”

With reference to the above amendment, the Certificate of Liability Insurance held by Dr. Reddy’s Laboratories, inclusion of Manipal Acunova as an Additional Insured Broad Form Vendor where required by written contract (page 2) has been noted. Documenting the administrative change in the ICF, we hereby approve this amendment.

Kindly send us the Insurance Policy of the same towards completion of the formality at the earliest.

The following members of CLINICOM were present at the meeting held on Friday, April 15, 2011, at 5.30 pm at CLINICOM, “SUSHRUTA”, #1/1, 1st Temple Road, 15th Cross, Malleswaram, Bangalore 560 003:

1. Dr. Sandhya R., M.B.B.S., M.S., DNB, FVR [Ophthalmology]  
Chairperson Clinician
2. Mr. V.V. Raghavan, M.Sc  
Vice Chairman Clinical Trials Expert & Pharmaceutical Technologist
3. Dr. Anuradha H.V., M.B.B.S., M.D. [Pharmacology] PGDMLE  
Member, Medical Scientist
4. Dr. P.K. Raju, M.B.B.S., M.S. Ortho, D Ortho  
Member, Clinician / Medical Scientist
5. Ms. Vijaya Suresh, B.A.LLB  
Member, Legal Expert
6. Mr. Lakshminarayan P.S., MSW, M.Phil, LLB, PGDRM  
Member, Education/Social Worker/Legal expert
7. Ms. Vidya Sury, MBA Dip in T & D  
Member, Layperson
8. Ms. S. Poornima  
Member Secretary

Please note that CLINICOM is organized and operates according to the requirements of the ICH-GCP, Indian Council of Medical Research and Schedule Y. We confirm that neither you nor your study team members participated in the deliberations of the ethics committee and did not vote on the proposal for this study.
Chairperson  
Dr. Sandhya R.,  
M.B.B.S., M.S., DNB  
FVR [Ophthalmology]  
Clinician  

Vice Chairperson  
Mr. V.V.Raghavan  
M.Sc  
Clinical Trials Expert &  
Pharmaceutical  
Technologist  

Members:  
Dr. Anuradha H.V.,  
M.B.B.S., M.D.  
[Pharmacology]  
PGDME  
Medical Scientist  
Dr. P.K. Raju,  
M.B.B.S., M.S. Ortho,  
D Ortho  
Clinician / Medical  
Scientist  
Ms. Vijaya Suresh,  
B.A. LLB  
Legal Expert  
Mr. Lakshminarayan  
P.S., MSW, M.Phil,  
LLB, PGDHRM  
Educationist/Social  
Worker/Legal expert  
Ms. Vidya Sury  
B Sc, MBA, Dip.T&D  
Layperson  

Member Secretary  
Ms. S. Poornima  

Committee for Evaluation of Protocols for Clinical Research  
"SUSHRUTA", #1/1, 1st Temple Road, 15th Cross, Malleswaram, Bangalore 560 003  
Tel: 91-80-23313377, 23567777 E mail: clinicom@gmail.com  

Please follow the requirements given below for this study:  

- Do not implement any deviation from, or change to, the protocol  
  approved by this ethics committee without the prior written approval  
  of this ethics committee.  
- Deviations/ changes to the approved protocol may be implemented  
  without prior approval of this ethics committee only when necessary  
  to eliminate immediate hazards to subjects or when changes involve  
  only logistical or administrative aspects of the trial [e.g. change of  
  study monitor(s), telephone numbers(s)].  

Promptly report to CLINICOM, the following:  

1. Any changes to or deviations to the protocol approved by CLINICOM  
   that you might implement to eliminate hazards to the trial subjects.  
2. All serious adverse events  
3. New information that may affect adversely the safety of the subjects  
   or the conduct of the trial.  

Please submit the status report of the study to CLINICOM at 6-month  
intervals. Also, provide us with a copy of the final study completion report.  

Cordially,  
For CLINICOM,  

Dr Sandhya R  
Chairperson  

April 21, 2011
Dear Sirs,

Sub: Approval of Amended Protocol No: CDS1002 : “A Multicenter, Randomized, Investigator Blind, Parallel Group, Three Arm Pilot Study To Evaluate The HPA Axis Suppression, Efficacy And Safety Of Clobetasol Propionate Cream 0.025% Formulation 5 And Clobetasol Propionate Cream 0.025% Formulation 13 As Compared To Temovate E Emollient 0.05% (clobetasol propionate emollient cream) In Patients With Moderate To Severe Psoriasis For 28 Days”.

With reference to the above - CLINICOM met on Friday April 15, 2011, at 5:30 pm to review and discuss the following documents vide your letter dated 31.03.11

1. DCGI approval letter to conduct the study
2. Inform Consent Form Version 2.0 English dated 8-Dec-2010
3. Inform Consent Form Version 2.0 English translated to Hindi dated 11-Jan-2011
4. Inform Consent Form Version 2.0 English translated to Marathi dated 11-Jan-2011
5. Inform Consent Form Version 2.0 English translated to Kannada dated 11-Jan-2011
6. Inform Consent Form Version 2.0 English translated to Tamil dated 11-Jan-2011
7. Inform Consent Form Version 2.0 English translated to Malayalam dated 11-Jan-2011
8. Inform Consent Form Version 2.0 English translated to Urdu dated 11-Jan-2011
9. Inform Consent Form Version 2.0 Hindi translated to English dated 25-Mar-2011
10. Inform Consent Form Version 2.0 Marathi translated to English dated 25-Mar-2011
11. Inform Consent Form Version 2.0 Kannada translated to English dated 25-Mar-2011
12. Inform Consent Form Version 2.0 Tamil translated to English dated 25-Mar-2011
13. Inform Consent Form Version 2.0 Malayalam translated to English dated 25-Mar-2011
14. Inform Consent Form Version 2.0 Urdu translated to English dated 25-Mar-2011
The following administrative changes are made in the ICF

On page 12 point 13 of ICF earlier it was mentioned as “If you are taken ill or are injured resulting directly from participation in this study the sponsor will make available to you reasonable medical treatments. The study sponsor agrees to pay all medical expenses necessary to treat such injury (1) to the extent you are not otherwise reimbursed by medical insurance and (2) provided you have followed the directions of the study doctor. No other compensation will be made available from the study sponsor”.

Now it has been changed to “In case of trial related injury, M/s Manipal Acunova will provide medical care as well as compensation for the injury”

With reference to the above amendment, the Certificate of Liability Insurance held by Dr. Reddy’s Laboratories, inclusion of Manipal Acunova as an Additional Insured Broad Form Vendor where required by written contract (page 2) has been noted. Documenting the administrative change in the ICF, we hereby approve this amendment.

Kindly send us the Insurance Policy of the same towards completion of the formality at the earliest.

The following members of CLINICOM were present at the meeting held on Friday, April 15, 2011, at 5.30 pm at CLINICOM, "SUSHRUTA", #1/1, 1st Temple Road, 15th Cross, Malleswaram, Bangalore 560 003:

1. **Dr. Sandhya R.,** M.B.B.S., M.S., DNB, FVR [Ophthalmology]
   **Chairperson** Clinician

2. **Mr. V.V.Raghavan, M.Sc**
   **Vice Chairperson** Clinical Trials Expert & Pharmaceutical Technologist

3. **Dr. Anuradha H.V.,** M.B.B.S., M.D. [Pharmacology]
   **PGDMLE**
   **Medical Scientist**

4. **Dr. P.K. Raju,** M.B.B.S., M.S. Ortho, D Ortho
   **Clinician / Medical Scientist**

5. **Ms. Vijaya Suresh,** B.A.LLB
   **Legal Expert**

6. **Mr. Lakshmimarayan P.S.,** MSW, M.Phill, LLB, PGDHRM
   **Educationist/Social Worker/Legal expert**

7. **Ms. Vidya Sury,** BSc, MBA, Dip.T&D
   **Layperson**

8. **Ms. S. Poornima**
   **Member Secretary**

Please note that CLINICOM is organized and operates according to the requirements of the ICH-GCP, Indian Council of Medical Research and Schedule Y. We confirm that neither you nor your study team members participated in the deliberations of the ethics committee and did not vote on the proposal for this study.

Please follow the requirements given below for this study:
Chairperson
Dr. Sandhya R.,
M.B.B.S., M.S., DNB
FVR [Ophthalmology]
Clinician

Vice Chairperson
Mr. V. V. Raghavan
M. Sc.
Clinical Trials Expert &
Pharmaceutical
Technologist

Members:
Dr. Anuradha H.V.,
M.B.B.S., M.D.
[Pharmacology]
PGDMLE
Medical Scientist

Dr. P.K. Raju,
M.B.B.S., M.S. Ortho,
D Ortho
Clinician / Medical
Scientist

Ms. Vijaya Suresh,
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P.S., MSW, M.Phil,
LLB, PGDHRM
Educationist/Social
Worker/Legal expert

Ms. Vidya Sury
B Sc, MBA, Dip.T&D
Layperson

Member Secretary
Ms. S. Poornima

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3. New information that may affect adversely the safety of the subjects or the conduct of the trial.

Please submit the status report of the study to CLINICOM at 6-month intervals. Also, provide us with a copy of the final study completion report.

Cordially,
For CLINICOM,

[Signature]
Dr. Sandhya R
Chairperson

April 21, 2011
Our ref: 00015/15.04.2011          Date: April 21, 2011

Dr. Rizwan Haq
Principal Investigator,
Radiance Skin Clinic,
Opp. Muslim Library
Near City Survey Office
Tekadi Road Nagpur
Nagpur-440013

Dear Sirs,

Sub: Approval of Amended Protocol No: CDS1002 : "A Multicenter, Randomized, Investigator Blind, Parallel Group, Three Arm Pilot Study To Evaluate The HPA Axis Suppression, Efficacy And Safety Of Clobetasol Propionate Cream 0.025% Formulation 5 And Clobetasol Propionate Cream 0.025% Formulation 13 As Compared To Temovate E Emollient 0.05% (clobetasol propionate emollient cream) In Patients With Moderate To Severe Psoriasis For 28 Days".

With reference to the above - CLINICOM met on Friday April 15, 2011, at 5.30 pm to review and discuss the following documents vide your letter dated 31.03.11

1. DCGI approval letter to conduct the study
2. Inform Consent Form Version 2.0 English dated 8-Dec-2010
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13. Inform Consent Form Version 2.0 Malayalam translated to English dated 25-Mar-2011
14. Inform Consent Form Version 2.0 Urdu translated to English dated 25-Mar-2011
The following administrative changes are made in the ICF

On page 12 point 13 of ICF earlier it was mentioned as "If you are taken ill or are injured resulting directly from participation in this study the sponsor will make available to you reasonable medical treatments. The study sponsor agrees to pay all medical expenses necessary to treat such injury (1) to the extent you are not otherwise reimbursed by medical insurance and (2) provided you have followed the directions of the study doctor. No other compensation will be made available from the study sponsor".

Now it has been changed to "In case of trial related injury, M/s Manipal Acunova will provide medical care as well as compensation for the injury"

With reference to the above amendment, the Certificate of Liability Insurance held by Dr. Reddy's Laboratories, inclusion of Manipal Acunova as an Additional Insured Broad Form Vendor where required by written contract (page 2) has been noted. Documenting the administrative change in the ICF, we hereby approve this amendment.

Kindly send us the Insurance Policy of the same towards completion of the formality at the earliest.

The following members of CLINICOM were present at the meeting held on Friday, April 15, 2011, at 5.30 pm at CLINICOM, “SUSHRUTA”, #1/1, 1st Temple Road, 15th Cross, Malleswaram, Bangalore 560 003:

1. Dr. Sandhya R., M.B.B.S., M.S., DNB, FVR [Ophthalmology] 
   Chairperson Clinician
2. Mr. V.V.Raghavan, M.Sc 
   Vice Chairman, Clinical Trials Expert & Pharmaceutical Technologist
3. Dr. Anuradha H.V., M.B.B.S., M.D. [Pharmacology] PGDMLE 
   Member, Medical Scientist
4. Dr. P.K. Raju, M.B.B.S., M.S. Ortho, D Ortho 
   Member, Clinician / Medical Scientist
5. Ms. Vijaya Suresh, B.A.LLB 
   Member, Legal Expert
6. Mr. Lakshminarayan P.S., MSW, M.Phil, LLB, PGDHRM 
   Member, Educationist/Social Worker/Legal expert
7. Ms. Vidya Sury, MBA Dip in T & D 
   Member, Layperson
8. Ms. S. Poornima 
   Member Secretary

Please note that CLINICOM is organized and operates according to the requirements of the ICH-GCP, Indian Council of Medical Research and Schedule Y. We confirm that neither you nor your study team members participated in the deliberations of the ethics committee and did not vote on the proposal for this study.

Please follow the requirements given below for this study:
Committee for Evaluation of Protocols for Clinical Research
"SUSHRUTA", #1/1, 1st Temple Road, 15th Cross, Malleswaram, Bangalore 560 003
Tel: 91-80-23567777 E mail: clinicom@gmail.com

Chairperson
Dr. Sandhya R.,
M.B.B.S., M.S., DNB
FVR [Ophthalmology]
Clinician

Vice Chairperson
Mr. V.V. Raghavan
M.Sc
Clinical Trials Expert &
Pharmaceutical
Technologist

Members:
Dr. Anuradha H.V.,
M.B.B.S., M.D.
[Pharmacology]
PGDMLE
Medical Scientist

Dr. P.K. Raju,
M.B.B.S., M.S. Ortho,
D Ortho
Clinician / Medical
Scientist

Ms. Vijaya Suresh,
B.A. LLB
Legal Expert

Mr. Lakshminarayan
P.S., MSW, M.Phil,
LLB, PGDHRM
Educationist/Social
Worker/Legal expert

Ms. Vidy Sury
B Sc, MBA, Dip.T&D
Layperson

Member Secretary
Ms. S. Poornima

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3. New Information that may affect adversely the safety of the subjects or the conduct of the trial.

Please submit the status report of the study to CLINICOM at 6-month intervals. Also, provide us with a copy of the final study completion report.

Cordially,
For CLINICOM,

[Signature]
Dr. Sandhya R
Chairperson

April 21, 2011
Dr. Jayesh Kothari  
M.Derm (Delhi)  
D.V.D. (K.E.M. Bom.)  

Dr. जयेश कोठारी  
एम. इर्म (दिल्ली)  
डी.वी.डी. (के.ई.एम. बॉम्बे)  

Name Age Sex  

To,  
The Member Secretary  
CHL Apollo Hospital Ethics Committee,  
CHL Apollo Hospital,  
AB Road, Indore – 452 001.  

Reference: Protocol No/Title : CSD 1002 : A Multicenter , Randomized , Investigator Blind , Parallel group , Three arm pilot study To Evaluate The HPA axis Suppression , Efficacy and safety Of Clobetasol Propionate Cream 0.025% Formulation 5 and Clobetasol Propionate Cream 0.025% Formulation 13 as compared to Temovate E Emollient 0.05% (Clobetasol Propionate emollient Cream ) In Patient With Moderate To Severe Psoriasis For 28 Days  

Subject: Application for Ethics committee Notification for Study No. CSD1002  

Dear Member Secretary,  

Kindly find enclosed the following documents 1 set for Ethics committee notification.  

1. DCGI approval letter to conduct the study  
2. Inform Consent Form Version 2.0 English dated 08-Dec-2010  
3. Inform Consent Form Version 2.0 English translated to Hindi dated 11-Jan-11  
4. Inform Consent Form Version 2.0 English translated to Marathi dated 11-Jan-11  
5. Inform Consent Form Version 2.0 English translated to Kannada dated 11-Jan-11  
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13. Inform Consent Form Version 2.0 Malayalam translated to English dated 25-Mar-11  
14. Inform Consent Form Version 2.0 Urdu translated to English dated 25-Mar-11  

Kindly acknowledge the receipt of the above documents. Please review and give your opinion on the proposed protocol to conduct the study in our institution.  

Thanks & regards,  

DR. Jayesh Kothari  
Principal Investigator
To,

The Chairman,
Yenepoya University Ethics Committee,
University Road, Deralakatte,
Mangalore - 575018

Reference: Protocol No/Title: CDS1002 : “A Multicenter, Randomized, Investigator Blind, Parallel Group, Three Arm Pilot Study To Evaluate The HPA Axis Suppression, Efficacy And Safety Of Clobetasol Propionate Cream 0.025% Formulation 5 And Clobetasol Propionate Cream 0.025% Formulation 13 As Compared To Temovate E Emollient 0.05% (clobetasol propionate emollient cream) In Patients With Moderate To Severe Psoriasis For 28 Days”.

Subject: Notification of DCGI approval letter and administrative change in ICF for the above ref. Study

Dear Sir,

Kindly find enclosed following for the above referenced study along with the soft copies in a CD.

1. DCGI approval letter to conduct the study
2. Inform Consent Form Version 2.0 English dated 8-Dec-2010
3. Inform Consent Form Version 2.0 English translated to Hindi dated 11-Jan-2011
4. Inform Consent Form Version 2.0 English translated to Marathi dated 11-Jan-2011
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13. Inform Consent Form Version 2.0 Malayalam translated to English dated 25-Mar-2011
14. Inform Consent Form Version 2.0 Urdu translated to English dated 25-Mar-2011

The following administrative changes are made in the ICF

On page 12 point 13 of ICF earlier it was mentioned as “If you are taken ill or are injured resulting directly from participation in this study the sponsor will make available to you reasonable medical treatments. The study sponsor agrees to pay all medical expenses necessary to treat such injury (1) to the extent you are not otherwise reimbursed by medical insurance and (2) provided you have followed
the directions of the study doctor. No other compensation will be made available from the study sponsor”.

Now it has been changed to “In case of trial related injury, M/s Manipal Acunova will provide medical care as well as compensation for the injury”

This is for your kind review and reference
Please revert to me if you require further information or clarifications.

Kindly acknowledge receipt for the same.

Thanking You,

Yours Faithfully,

Dr. Manjunath Shenoy
Department of Dermatology,
Yenepoya Medical College,
Deralakatte,
Mangalore-575 018

Received the IDC CHE approval letter along with informed consent forms (2 to 14) and have noted the changes on page 12 point 13.

Vivek Rai
Secretary 09/04/2011
Yenepoya University Ethics Committee
Our ref: 00095/27.05.2011  

Date: May 27, 2011

Dr. D.N. Balkraj, 
Principal Investigator 
Rajbal Skin Clinic, 
# 401, Ratnamahal Shreyas Building, 
4th B cross, 7 C main, 
1st Block, HRBR layout, 
Kalyan Nagar 
Bangalore-540043

Dear Sirs,

Sub: Approval of Protocol Version 1.0, Amendment 1 dated 13 May 2011

Reference: Protocol No. CDS1002: "A Multicenter, Randomized, Investigator Blind, Parallel Group, Three Arm Pilot Study To Evaluate The HPA Axis Suppression, Efficacy And Safety Of Clobetasol Propionate Cream 0.025% Formulation 5 And Clobetasol Propionate Cream 0.025% Formulation 13 As Compared To Temovate E Emollient 0.05% (clobetasol propionate emollient cream) In Patients With Moderate To Severe Psoriasis For 28 Days".

With reference to the above - CLINICOM met on Friday May 27, 2011, at 5.30 pm to review and discuss the following documents vide your letter dated 21 May, 2011.

1. Amended Protocol version 1.0 amendment 1 dated 13 May 2011

The following changes have been made to protocol number MA-CT-10-010 protocol version 1.0, dated 04 August, 2010:

| Sl. No. | Location in the protocol Version 1.0 | As per protocol version 1.0 dated 04 August 2010 | As per protocol version 1.0 amendment 1 dated 13 May 2011 |
|--------|-------------------------------------|-----------------------------------------------|----------------------------------------------------------|
| 1      | Page 2 of 66 Table 2nd row, 3rd column | Tel: +91 (0) 80 6691 5780                      | Tel: +91 (0) 80 6691 5775                                 |
| 2      | Page 2 of 66 Table 3rd row           |                                               |                                                          |
| 3      | Page 4 of 66                          |                                               |                                                          |

Dr. Nagendra N MD, DNB
Medical Monitor, 
Manipal AcuNova Ltd., 
Mobius Towers, SJR - I park, 
EPIP Zone, Whitefield, 
Bangalore - 560 066 
Tel: +91 (0) 80 6691 5780 
Fax: +91 (0) 80 6691 5719 
Mob: +91 (0) 9632444661 
Email: nagendra.n@ecronacunova.com

Dr. Sharath Rao, MBBS
Medical Monitor, 
Manipal AcuNova Ltd., 
Mobius Towers, SJR - I park, 
EPIP Zone, Whitefield, 
Bangalore - 560 066 
Tel: +91 (0) 80 6691 5771 
Fax: +91 (0) 80 6691 5719 
Mob: +91 (0) 9886122314 
Email: sharath.rao@ecronacunova.com

Approved by

Signature

(Dr. Ganesh Babu 
-Senior Manager, Medical affairs Manipal AcuNova Ltd.)

Signature

(Dr. Ganesh Babu 
-Head, Medical affairs Manipal AcuNova Ltd.)
| Sl. No. | Location in the protocol Version 1.0 | As per protocol version 1.0 dated 04 August 2010 | As per protocol version 1.0 amendment 1.0 dated 13 May 2011 |
|--------|-------------------------------------|-----------------------------------------------|-------------------------------------------------|
| 4      | Page 5 of 66 Table last row         | Dr Nagendra N, MD, DNB                         | Dr Sharath Rao, MBBS                             |
|        |                                     | Manipal AcuNova Ltd., Mobius Towers, SJR - I park, EPMP Zone, Whitefield, Bangalore - 560066 | Manipal AcuNova Ltd., Mobius Towers, SJR - I park, EPMP Zone, Whitefield, Bangalore - 560066 |
|        |                                     | Tel: +91 (0) 80 6691 5780 Fax: +91 (0) 80 6691 5719 Mob: +91 (0) 9632444661 Email: nagendra.n@ecronacunova.com | Tel: +91 (0) 80 6691 5771 Fax: +91 (0) 80 6691 5719 Mob: +91 (0) 9886122314 Email: sharath.rao@ecronacunova.com |
| 5      | Page 47 of 66 2nd paragraph         | Normal cortisol response and range (patient has to meet all of following criteria for study entry) | Normal cortisol response and range (patient has to meet all of following criteria for study entry) |
|        |                                     | 1. The control plasma cortisol level should exceed 5 micrograms /100 mL. | 1. The control plasma cortisol level should exceed 5 micrograms /100 mL. |
|        |                                     | 2. The 30-minute level should show an increment of at least 7 micrograms /100 mL above the basal level. | 2. The 30-minute level should exceed 18 micrograms /100 mL. |
|        |                                     | 3. The 30-minute level should exceed 18 micrograms /100 mL. |                                           |
| 6      | Page 54 of 66 Last line             | Tel: +91 (0) 80 6691 5780                      | Tel: +91 (0) 80 6691 5775                      |

The following members of CLINICOM were present at the meeting held on Friday, May 27, 2011, at 5.30 pm at CLINICOM, "SUSHRUTA", #1/1, 1st Temple Road, 15th Cross, Malleswaram, Bangalore 560 003:

1. **Dr. Sandhya R., M.B.B.S., M.S., DNB, FVR [Ophthalmology]**
   Chairperson, Clinician
2. **Mr. V.V. Raghavan, M.Sc**
   Vice Chairman, Clinical Trials Expert & Pharmaceutical Technologist
3. **Dr. Anuradha H.V., M.B.B.S., M.D. [Pharmacology]**
   PGDMLE Member, Medical Scientist
4. **Dr. P.K. Raju, M.B.B.S., M.S. Ortho, D Ortho**
   Member, Clinician / Medical Scientist
5. **Ms. Vijaya Suresh, B.A.LLB**
   Member, Legal Expert
6. **Mr. Lakshminarayan P.S., MSW, M.Phi, LLB, PGDHRM**
   Educationist/Social Worker/Legal expert
7. **Ms. Vidyadhar Sury, MBA Dip T & D**
   Member, Layperson
8. **Ms. S. Poornima**
   Member Secretary

We are pleased to inform you that we hereby approve the study in its present form.
Please note that CLINICOM is organized and operates according to the requirements of the ICH-GCP, Indian Council of Medical Research and Schedule Y. We confirm that neither you nor your study team members participated in the deliberations of the ethics committee and did not vote on the proposal for this study.

Please follow the requirements given below for this study:

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- Deviations/changes to the approved protocol may be implemented without prior approval of this ethics committee only when necessary to eliminate immediate hazards to subjects or when changes involve only logistical or administrative aspects of the trial [e.g. change of study monitor(s), telephone numbers(s)].

Promptly report to CLINICOM, the following:

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2. All serious adverse events

3. New information that may affect adversely the safety of the subjects or the conduct of the trial.

Please submit the status report of the study to CLINICOM at 6-month intervals. Also, provide us with a copy of the final study completion report.

Cordially,

For CLINICOM,

May 27, 2011
Our ref: 00096/27.05.2011 Date: May 27, 2011

Dr. Rizwan Haq
Principal Investigator,
Radiance Skin Clinic,
Opp. Muslim Library
Near City Survey Office
Tekadi Road Nagpur
Nagpur-440013

Dear Sirs,

Sub: Approval of Protocol Version 1.0, Amendment 1 dated 13 May 2011

Reference: Protocol No. CDS1002 : “A Multicenter, Randomized, Investigator Blind, Parallel Group, Three Arm Pilot Study To Evaluate The HPA Axis Suppression, Efficacy And Safety Of Clobetasol Propionate Cream 0.025% Formulation 5 And Clobetasol Propionate Cream 0.025% Formulation 13 As Compared To Temovate E Emollient 0.05% (clobetasol propionate emollient cream) In Patients With Moderate To Severe Psoriasis For 28 Days”.

With reference to the above - CLINICOM met on Friday May 27, 2011, at 5.30 pm to review and discuss the following documents vide your letter dated 21 May, 2011

1. Amended Protocol version 1.0 amendment 1 dated 13 May 2011

The following changes have been made to protocol number MA-CT-10-010 protocol version 1.0, dated 04 August, 2010:

| Sl. No. | Location in the protocol Version 1.0 | As per protocol version 1.0 dated 04 August 2010 | As per protocol version 1.0 amendment 1.0 dated 13 May 2011 |
|--------|-------------------------------------|-----------------------------------------------|----------------------------------------------------------|
| 1      | Page 2 of 66 Table 2nd row, 3rd column | Tel: +91 (0) 80 6691 5780 | Tel: +91 (0) 80 6691 5775 |
| 2      | Page 2 of 66 Table 3rd row | Dr Nagendra N MD, DNB Medical Monitor, Mobius Towers, SJR - I park, EPIP Zone, Whitefield, Bangalore - 560 066 Tel: +91 (0) 80 6691 5780 Fax: +91 (0) 80 6691 5719 Mob: +91 (0) 9632444661 Email: nagendra.n@ecronacunova.com Approved by | |
| 3      | Page 4 of 66 | Dr Sharath Rao, MBBS Medical Monitor, Mobius Towers, SJR - I park, EPIP Zone, Whitefield, Bangalore - 560 066 Tel: +91 (0) 80 6691 5771 Fax: +91 (0) 80 6691 5719 Mob: +91 (0) 9886122314 Email: sharath.rao@ecronacunova.com Approved by | |

Signature
(Dr. Ganesh Babu
-Senior Manager, Medical affairs Manipal AcuNova Ltd.)

Signature
(Dr. Ganesh Babu
-Head, Medical affairs Manipal AcuNova Ltd.)
We are pleased to inform you that we hereby approve the study in its present form.

Please note that CLINICOM is organized and operates according to the requirements of the ICH-GCP, Indian Council of Medical Research and Schedule Y. We confirm that neither you nor your study team members

The following members of CLINICOM were present at the meeting held on Friday, May 27, 2011, at 5.30 pm at CLINICOM, “SUSRUTA”, #1/1, 1st Temple Road, 15th Cross, Malleswaram, Bangalore 560 003:

1. Dr. Sandhya R., M.B.B.S., M.S., DNB, FVR [Ophthalmology]
   Chairperson, Clinician

2. Mr. V.V.Raghavan, M.Sc
   Vice Chairman, Clinical Trials Expert & Pharmaceutical Technologist

3. Dr. Anuradha H.V., M.B.B.S., M.D. [Pharmacology] PGDMLE
   Member, Medical Scientist

4. Dr. P.K. Raju, M.B.B.S., M.S. Ortho, D Ortho
   Member, Clinician / Medical Scientist

5. Ms. Vijaya Suresh, B.A.LLB
   Member, Legal Expert

6. Mr. Lakshminarayan P.S., MSW, M.Phil, LLB, PGDHRM
   Member, Educationist/Social Worker/Legal expert

7. Ms. Vidya Sury, MBA Dip in T & D
   Member, Layperson

8. Ms. S. Poornima
   Member Secretary
participated in the deliberations of the ethics committee and did not vote on the proposal for this study.

Please follow the requirements given below for this study:

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Promptly report to CLINICOM, the following:

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2. All serious adverse events

3. New information that may affect adversely the safety of the subjects or the conduct of the trial.

Please submit the status report of the study to CLINICOM at 6-month intervals. Also, provide us with a copy of the final study completion report.

Cordially,

For CLINICOM,

Dr Sandhya R
Chairperson

May 27, 2011
CHL – APOLLO HOSPITALS – ETHICS COMMITTEE

June 28, 2011

To,
Dr. Jayesh Kothari,
Consultant Dermatologist
Skin Clinic, # 301, Manasa Bhavan,
RNT Marg, Indore - 452001

Reference: CDS1002: A Multicentre, randomized, Investigator Blind, Parallel Group, Three Arm Pilot Study to Evaluate the HPA Axis Suppression, Efficacy and Safety of Clobetasol Propionate Cream 0.025% Formulation 5 and Clobetasol Propionate Cream 0.025% Formulation 13 as Compared to Temovate E Emollient 0.05% (clobetasol propionate emollient cream (in Patients with Moderate to Severe Psoriasis for 28 Days.

Subject: Ethics Committee approval of Protocol Amendment for the above referenced study

Dear Dr. Kothari,

With reference to the Clarification letter dated 28 Jun 2011, submitted by you for the above referenced protocol, in regards to Ethics Committee Approval letter dated 18 Jun 2011 for Amended Protocol Version 1.0 amendment 1 dated 13 May 2011:

The committee has decided to approve the amendments in the protocol for the conduct of the study for the referenced study under your direction at Kothari Skin Clinic, Indore. We approve the trial to be conducted in the present form subject to the condition that all other terms & conditions of earlier clinical trial approval granted vide letter dated 18 Jun 2011 will remain same.

We request you to submit a copy of the DCGI’s approval letter for the study as soon as you receive it.

Sincerely,

Dr. Rajesh Jain
Member Secretary, CHL-Apollo Hospitals – Ethics Committee

Convenient Hospitals Ltd.
Our ref: 00097/27.05.2011 Date: May 27, 2011

Dr. Sandesh Gupta
Principal Investigator,
Skin N Laser Centre,
Dermatology
F-10/9, Krishna Nagar
New Delhi 110051

Dear Sirs,

Sub: Approval of Protocol Version 1.0, Amendment 1 dated 13 May 2011
Reference: Protocol No. CDS1002: "A Multicenter, Randomized, Investigator Blind, Parallel Group, Three Arm Pilot Study To Evaluate The HPA Axis Suppression, Efficacy And Safety Of Clobetasol Propionate Cream 0.025% Formulation 5 And Clobetasol Propionate Cream 0.025% Formulation 13 As Compared To Temovate E Emollient 0.05% (clobetasol propionate emollient cream) In Patients With Moderate To Severe Psoriasis For 28 Days".

With reference to the above - CLINICOM met on Friday May 27, 2011, at 5.30 pm to review and discuss the following documents vide your letter dated 21 May, 2011

1. Amended Protocol version 1.0 amendment 1 dated 13 May 2011

The following changes have been made to protocol number MA-CT-10-010 protocol version 1.0, dated 04 August, 2010:

| Sl. No. | Location in the protocol | As per protocol version 1.0 dated 04 August 2010 | As per protocol version 1.0 amendment 1.0 dated 13 May 2011 |
|---------|--------------------------|-----------------------------------------------|----------------------------------------------------------|
| 1       | Page 2 of 66 Table 2nd row, 3rd column | Tel: +91 (0) 80 6691 5780 | Tel: +91 (0) 80 6691 5775 |
| 2       | Page 2 of 66 Table 3rd row | **Dr. Nagendra N MD, DNB**
Medical Monitor,
Manipal AcuNova Ltd.,
Mobius Towers, SJR - I park,
EPIP Zone, Whitefield,
Bangalore – 560 066
Tel: +91 (0) 80 6691 5780
Fax: +91 (0) 80 6691 5719
Mob: +91 (0) 9862444661
Email: nagendra.n@acronacunova.com
Approved by |
| 3       | Page 4 of 66 | **Dr. Sharath Rao, MBBS**
Medical Monitor,
Manipal AcuNova Ltd.,
Mobius Towers, SJR - I park,
EPIP Zone, Whitefield,
Bangalore – 560 066
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Mob: +91 (0) 9886122314
Email: sharath.rao@acronacunova.com
Approved by |

Signature
(Dr. Ganesh Babu
-Senior Manager, Medical affairs Manipal AcuNova Ltd.)

Signature
(Dr. Ganesh Babu
-Head, Medical affairs Manipal AcuNova Ltd.)
Committee for Evaluation of Protocols for Clinical Research
“SUSHRUTA”, #1/1, 1st Temple Road, 15th Cross, Malleswaram, Bangalore 560 003
Tel: 91-80-23567777 E mail: clinicom@gmail.com

Chairperson
Dr. Sandhya R., M.B.B.S., M.S., DNB
FVR [Ophthalmology] Clinician

Vice Chairperson
Mr. V.V. Raghavan M.Sc
Clinical Trials Expert & Pharmaceutical Technologist

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Ms. Vidya Sury B Sc, MBA, Dip.T&R Layperson
Ms. S. Poornima Member Secretary

As per protocol version 1.0 dated 04 August 2010

Dr Nagendra N, MD, DNB
Manipal AcuNova Ltd.,
Mobius Towers, SIR - I park,
EPID Zone, Whitefield,
Bangalore - 560066
Tel: +91 (0) 80 6691 5780
Fax: +91 (0) 80 6691 5719
Mob: +91 (0) 9632444661
Email: nagendra.n@ecronacunova.com

Normal cortisol response and range (patient has to meet all of following criteria for study entry)
7. The control plasma cortisol level should exceed 5 micrograms /100 mL
8. The 30-minute level should show an increment of at least 7 micrograms/100 mL above the basal level.
9. The 30-minute level should exceed 18 micrograms/100 mL.

As per protocol version 1.0 amendment 1.0 dated 13 May 2011

Dr Sharath Rao, MBBS
Manipal AcuNova Ltd.,
Mobius Towers, SIR - I park,
EPID Zone, Whitefield,
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May 27, 2011