Recommendation:-

The MDAC (Dental) deliberated the proposals on 17.07.2013 and recommended the following:-

Agenda No.	File No.	Name of the Firm& Name of the Proposed product	Recommendations
1.	29/Misc/14/2011-DC	M/s Max Neeman Medical International Limited, Max House, Ground Floor, 1 Dr. Jha Marg, Okhla Phase –II, New Delhi Easy Graft Crystal & Easy Graft	The committee again reviewed and deliberated the proposal made by M/s. Maxneeman for conducting phase IV study with the product easy graft and Easy Graft Crystal and recommended the following:- 1. To drop immediate post-operative CBCT and only two CBCT will be required, one pre-operation and another after 150 days of surgery and bone grafting as the committee raised the concern of total cumulative radiation dose to each patient. The investigator had agreed upon it. 2. The committee felt that post grafting biopsy from both sites will not give any benefit to the patient. In fact it is an invasive procedure which does not contribute any diagnostic and therapeutic benefit to the patient. The committee recommended that the biopsy should be dropped from the study and only CBCT should be the basis of the evaluation of efficacy of

			bone grafting in increasing the bone weight, length and width etc. 3. The committee suggested that the investigator should use FOV limited to the site of mandible. 4. The study cannot be allowed to conduct in private clinic. The clinical Trial site should be a multispecialty hospital. The Committee recommended that the applicant may be asked to submit the revised protocol after incoraporating the above suggestions. It was decided by the committee that the revised protocol should be circulated to the experts for evaluation and there is no need for further meeting

Recommendation:-

The MDAC (Dental) deliberated the proposals on 28.10.2013 and recommended the following:-

Agenda No.	File No.	Name of the Firm& Name of the Proposed product	Recommendations	
1.	CLAA/MD/Orissa/01/2008-DC	M/s I.F.G.L Refractories Ltd., Sector-A, Kalunga Industrial Estate, P.O. Kalunga - 770031 Orissa. Name of product :- Biograft CPC putty Biograft nano Biograft HABG and Biograft New	Name of products	Comments
			Biograft CPC Putty	The committee recommended for the grant of manufacturing permissions
			Biograft Nano	The committee felt that the biocompatibility study submitted by the firm is incomplete and in-vivo animal testing is not properly documented and is not authentic. The firm has to submit the complete Biocompatibility study report and duly authentic in-vivo animal testing data for further examination of committee.
			Biograft HABG and Biograft New	The committee has recommended that the firm should conduct a clinical trial.

				Accordingly the clinical trial protocol etc. as per schedule Y needs to be submitted for further review by the committee.

Recommendations:-

The MDAC (~~Cardiovascular~~ Dental) deliberated the proposals on 12/11/2014 and recommended the following:-

Agenda No.	File No.	Name of the Firm & Name of the Proposed product	Recommendations
1.	**4-MD/CT-124/2014-DC**	M/s. Maulana Azad Institute of Dental Sciences, New Delhi. applied to the O/o DCG(I) to conduct A Multicentric Randomized Controlled Non-inferiority Clinical Trial to evaluate the efficacy and safety of CSIR – NMITLI Dental Implant an "Endosseous Root Form Dental Implant".	The proposed trial will be conducted on a total of 387 subjects screned as per the inclusion & exclusion criteria. The subjects will be followed a minimum of 1 year after delivery of prosthesis Under this project, the dental implant was designed on the basis of scientific rationale and experimentally optimized to serve treatment needs as an edentulous or partially edentulous Indian patient. The prototypes were developed at the in-house facility of IIT-Delhi. The implants were duly tested for biocompatibility studies (as per ISO-10993) norms and engineering tests for fatigue (Bose-USA) and other mechanical testing were done at IIT Delhi. To evaluate the survival rate of the study implant (NMITLI) at 1 year in function and evaluate the marginal bone loss of the study implant in comparison to the control implant. **Secondary Outcomes:** To evaluate the presence or absence of complications like perimucositis, periimplantitis and other non destructive mechanical complications and prosthetic failures along with mechanical parameters of implant stability and the aesthetic outcome. The proposed dental implant contains the following components Straight Abutment; Cover Screw; Implant Analogue, Healing Abutment; Angulated Abutment 15 degrees; Long abutment Screw; Hex Driver; Implant Driver; Surgical instrumentation.

			The committee deliberated the matter and recommended that the proposed trial may be permitted in the country subject to the submission of the certificates of sterility studies conducted after packaging and gamma sterilization and also the EC approval & PI's undertaking from CDC (Ludhiana) Center. Dr. Mahesh Verma being the Principal investigator of the trial at MAIDS, recused from the deliberation.

S.No.	Name & Designation of MDAC (Dental) experts	Signatures
1.	**Prof. Mahesh Verma,** Principal and Director of Prosthdontist, Maulana Azad Institute of Dental Sciences, New Delhi	
2.	**Prof. Naseem Shah,** Chief Center for Dental Education and Research, AIIMS, New Delhi	12-11-14
3.	**Dr. V. K. Gautam** Director, Prof. , Orthopaedics, MAMC, New Delhi.	12.11.14
4.	**Prof. Sangeeta Talwar,** MAIDS, New Delhi	12/11/2014