DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

Waiver to Allow Participation in a Food and Drug Administration
Advisory Committee

DATE: February 13, 2009

TO: Randall W. Lutter, Ph.D.
Deputy Commissioner for Policy
Food and Drug Administration

THROUGH: Vince Tolino /s/
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

Michael F. Ortwerth, Ph.D. /s/
Director, Advisory Committee Oversight and Management Staff
Office of Policy, Planning, and Preparedness

FROM: Kathleen L. Walker s/
Chief, Integrity, Committee and Conference Management Branch
Division of Ethics and Management Operations, OMO
Center for Devices and Radiological Health

Name of Advisory Committee Member: David C. Musch, Ph.D., M.P.H.

Committee: Ophthalmic Devices Panel of the Medical Devices Advisory Committee

Meeting date: March 27, 2009

Description of the Facts on Which the Waiver is Based:

Type, Nature, and Magnitude of the Financial Interest(s):
David C. Musch, M.D., Ph.D., currently serves on the Ophthalmic Devices Panel, which reviews and evaluates data concerning the safety and effectiveness of marketed and investigational devices for use in the eye and makes appropriate recommendations to the Commissioner of Food and Drugs. Dr. Musch's institute, the University of Michigan, is a clinical site for the premarket approval application (PMA) study coming before the panel for discussion. He has no involvement nor receives any compensation. His employer has received between $100,000 – $150,000 toward this study over the course of 6 years. Dr.

Musch reports directly to Paul Lichter, M.D. (the study PI), Chair, Department of Ophthalmology and Visual Sciences.

Description of the Particular Matter to Which the Waiver Applies:
Dr. Musch has been asked to participate in the meeting to discuss, make recommendations, and vote on a PMA for the *IMT™ Implantable Miniature Telescope* sponsored by VisionCare Technologies, Inc. The IMT™ is a visual prosthetic device which, when combined with the optics of the cornea, constitutes a telephoto lens. The IMT™ is indicated to improve vision by monocular implantation in patients 65 or older with stable moderate (distance BCVA of $\leq$ 20/80) to profound (distance BCVA $\geq$ 20/800) vision impairment caused by bilateral central scotomas associated with end-stage age-related macular degeneration.

Additional Facts: None

Basis for Granting the Waiver:
Dr. Musch currently holds joint appointments in the University of Michigan Medical School as Professor in the Dept. of Ophthalmology and Visual Sciences and in the School of Public Health as an Associate Research Scientist in the Dept. of Epidemiology. Trained as an epidemiologist, Dr. Musch addresses treatment effectiveness, variation in measurement and diagnostic abilities, and medical outcomes in his research programs. He is involved as a consultant to several multicenter clinical trials of laser treatments for age-related macular degeneration, and serves on the Data and Safety Monitoring Committees for both NIH and industry-sponsored clinical trials. Another of his research interests is the development of validated questionnaires for measuring vision-related quality of life. For this panel meeting, his expertise with regard to vision-related quality of life is considered essential to ensure an in-depth discussion of the IMT™, intended for particular patients with end-stage macular degeneration. Dr. Musch is considered an expert in end-stage macular degenerations and there are no alternate SGE's with Dr. Musch's expertise, specifically, in quality of life issues. During the recruiting process for this meeting we encountered nine SGEs with ophthalmic experience who had schedule conflicts. A search was done through the CDRH rosters to find a similar quality of life expertise and an understanding of ophthalmic issues, however no such expertise was found. The Center believes Dr. Musch's expertise is critical to the panel discussion because a key endpoint for effectiveness of this trial design is quality of life. With his knowledge and experience he can assist other panelists to understand the intricacies of this endpoint. I believe that Dr. Musch's expertise greatly outweighs any of the perceived conflicts of interest and his presence will contribute greatly to the opinions and expertise represented on the Panel.

Thus we are requesting a wavier for Dr. David Musch, a temporary voting member, of the Ophthalmic Devices Panel, from the conflict of interest prohibitions of 18 U.S.C. § 208(a).

Certification:

___x_____ The individual may participate – The Regular Government Employee's financial Interest is not so substantial as to be deemed likely to affect the integrity of the services provided by that individual.

_____ The individual may participate – The need for the Special Government Employee's services outweighs the potential for a conflict of interest.

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Limitations on the Regular Government Employee's or Special Government Employee's Ability to Act:

_____ Non-voting

_____ Other (specify):

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_____ Denied – The individual may not participate.

s/
_____ _____3/2/2009_____
Randall W. Lutter, Ph.D. Date
Deputy Commissioner for Policy