



The Honorable Henry A. Waxman
Ranking Minority Member
Congress of the United States
House of Representatives
2157 Rayburn House Office Building
Washington, D.C. 20515-6143

Attention: Dr. Josh Sharfstein
Committee on Government Reform

CIBA Vision Corporation
Legal Department
11460 Johns Creek Parkway
Duluth, Georgia 30097-1556

R. Scott Meece
Vice President & General Counsel
Voice: 678-415-3054
Fax: 678-415-3018
scott.meece@cibavision.novartis.com

VIA FACSIMILE TO (202) 226-3348

August 27, 2002

Dear Congressman Waxman:

I read with great interest your letter dated August 26, 2002 to The Honorable Tommy G. Thompson. On behalf of CIBA Vision Corporation, I express our full support of your position that plano colored contact lenses should continue to be regulated by the FDA and prescribed by licensed eye care practitioners.

The manufacture and sale of contact lenses is the core of our business. Our business exists because consumers can safely wear our contact lenses, whether the lenses correct vision, provide cosmetic benefits or both. We firmly believe and consistently communicate that all contact lens wearers should visit their eye care practitioner for proper lens fitting, as well as wearing and cleaning instructions. In addition, every wearer should have regular, periodic examinations to ensure that their lenses continue to fit properly and that ocular health is not compromised. We believe this practice is important to our business, but more importantly, this practice is important for maintaining the ocular health and good vision of contact lens wearers.

You should know that we have initiated a project within our company - Project Healthy Eyes - whose goals are aligned with the position taken in your August 26 letter. Therefore, I offer our support of your position, and I invite you to contact me if you believe we can do anything further to support this effort.

Our company's guiding purpose is to improve, protect and preserve the eyesight of people around the world. We are truly proud of this purpose. We see your position on this issue as being in line with our goals, and on behalf of our employees and contact lens wearers, I thank you for your work.

Sincerely,

A handwritten signature in cursive script that reads "R. Scott Meece".

R. Scott Meece
Vice President & General Counsel



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VIA FACSIMILE TO (202) 226-3348

September 26, 2002

Dear Congressman Waxman:

I am writing to follow up on my letter to you dated August 27, 2002, expressing CIBA Vision Corporation's full support for your position that plano colored contact lenses should continue to be regulated by the FDA. CIBA Vision's endorsement of continued regulation is based entirely upon our interest in the public health, which we share with you and the medical community.

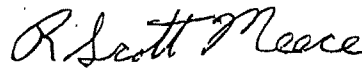
Recently, I realized that our letter could be misinterpreted as an endorsement of the legal position set forth in your August 26, 2002, letter to Secretary Thompson. CIBA Vision has not taken a public position regarding the various legal arguments related to this issue – either in my letter to you or in any other public forum. Instead, our position on continued regulation is based solely on the critically important public health issues raised and our concern for maintaining the ocular health and good vision of all contact lens wearers.

My letter to you was intended to express our support for your efforts to address what we believe would be an inappropriate policy and was not intended to address your legal arguments. Based upon an analysis of the precedents cited in your letter, as well as other relevant precedents, it is apparent that your letter is arguing for an extension of current law on "intended use" that can only be appropriately implemented by the United States Congress – not the FDA. The current governing law holds that no product is "intended for use" within the meaning of the FD&C Act unless the sponsor makes express claims about the product.

The Honorable Henry A. Waxman
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As the largest manufacturer of colored contact lenses, CIBA Vision remains committed to addressing the critical health aspects of this issue. Please contact me if there is anything CIBA Vision can do to further advance the important public health objectives that we both are pursuing.

Sincerely,



R. Scott Meece
Vice President & General Counsel

cc: The Honorable Tommy G. Thompson, Secretary, HHS
Eve Slater, Assistant Secretary, HHS
Lester M. Crawford, DVM, Ph.D., Deputy Commissioner, FDA
Daniel E. Troy, Esq., Chief Counsel, FDA
David W. Feigal, Jr., M.D., Director, CDRH, FDA
The Honorable Edward M. Kennedy, Chairman, Senate HELP Committee