

# IACM

International Association  
of Color Manufacturers

www.iacmcolor.org

1620 I Street, N.W., Suite 925, Washington, D.C. 20006 Tel: (202) 293-5800 Fax: (202) 463-8998

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December 8, 2005

Lyle D. Jaffe  
Division of Dockets Management  
Office of Management Programs  
Office of Management  
U.S. Food and Drug Administration  
Rockville, MD 20857

Re: Docket Number 2005N-0077/CP 1

Dear Mr. Jaffe:

I am writing to inquire about the status of the FDA response to a citizen petition that I submitted as Executive Director of the International Association of Color Manufacturers (IACM). According to correspondence from your office, this petition was received by the agency on April 29, 2005. As of today, I have not received a response.

The petition requests that the Food and Drug Administration propose any and all increases in the fees for certification services through full notice and comment rulemaking. The use of an interim final rule to accomplish a fee increase with only thirty days between announcement and the effective date violated the requirements of the Federal Food, Drug, and Cosmetic Act and the Administrative Procedures Act. Under FDA regulations, we are entitled to a response to our petition.

Under the provisions of 21 CFR § 10.30(e) the Commissioner shall furnish a response to each petitioner within 180 days of receipt of the petition. The response will either: approve the petition, deny the petition, or provide a tentative response indicating why the agency has been unable to reach a decision on the petition. These provisions provide ample flexibility to the Commissioner for providing a timely response.

I would appreciate your assistance in determining the status of the Commissioner's response to my petition. Please feel free to contact me if you have additional questions.

Sincerely,



Glenn Roberts

2005N-0077

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