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

January 16, 2007

Robert E. Brackett, Ph.D.
Director, Center for Food Safety & Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Re: Color Certification Fund Issues

Dear Dr. Brackett:

On behalf of the International Association of Color Manufacturers (IACM), I am writing to request your assistance with several issues related to the color certification fund. The IACM is the international association of color additive manufacturers. The IACM's members manufacture and market color additives (certified and exempt from certification) that are incorporated into foods, drugs and cosmetics. We are requesting your assistance in providing the following to the color additive industry:

- A refund of surplus deposits currently in the certification fund;
- Regular, detailed, and transparent financial status reports on the color certification fund;
- A response to the April 2005 citizen petitions filed on behalf of the color additive industry.

Refund of Surplus Advance Deposits in the Certification Fund

According to information provided to IACM representatives earlier this month, the surplus at the end of the fiscal year 2005-2006 in the color certification fund was $2,246,173.00. We believe that under the authority granted to the FDA in 21 CFR § 80.10, a significant portion of this surplus should be returned pro-rata to the companies that were charged for certification services.

FDA has at times maintained an excessive surplus in the certification fund at the expense of the certified color industry. We explained this in detail in the April 2005 citizen petition to the agency. Accordingly, we believe that an immediate refund of not less than $1,000,000.00 should be provided pro rata to the certified color industry. This refund would leave more than adequate funds for any anticipated contingencies that the program may encounter.

Regular Financial Reports

The IACM's recent effort to receive a financial report of the color certification fund is typical of past experiences. After several months of calls and emails to the Office of Cosmetics and Colors we finally received a one page report that contains about 12 different expense categories covering nearly $7 million in certification fees. Such limited and late reporting makes it difficult to assess how efficiently the program is being managed. We are requesting your assistance in having the agency provide timely, detailed and transparent quarterly financial reports to IACM representatives so that we can share them with the color additive industry.

Because these funds come from the color additive industry and not Congress, we have a unique stake in seeing that the funds are properly managed. In order for the industry to have confidence in how the program is being run we must receive timely, detailed and transparent financial reports. We would appreciate any assistance you can give us in obtaining these on a regular basis.

Response to April 2005 Citizen Petitions

In April 2005, the IACM submitted 2 citizen petitions to the FDA requesting an administrative stay of the proposed color certification fee increase, and requesting that the agency conduct notice and comment rulemaking for the proposed fee increases. At the time, the agency acknowledged receipt of these documents; however, there has never been a complete response to the petitions. Federal law and regulations require a response to our petitions and we would appreciate your assistance in providing one. Copies of both petitions are enclosed for your information.

The color certification program managed by the FDA is an important and unique Federal program. Because this program is funded through industry fees it is critical that we work cooperatively with the agency. Over the last few years several events have challenged the industry's confidence in FDA's ability to properly manage this program. If your office is able to address the above requests it will go a long way toward reassuring us that the program is being managed fairly and efficiently.

Sincerely,

Ellen Gardner
Executive Director

CC: Linda Katz, OCAC
Ray Decker, OCAC
Enclosures