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Request for an Administrative Stay of the Food and Drug Administration's Proposed Increase in the Color Certification Fee

Docket No. 2005N-0077. Color Additive Certification; Increase in Fees for Certification Service. 70 Fed. Reg. 15755 (29 March 2005).

Submitted to:
Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

27 April 2005

2005N-0077

PSA 1

PETITION FOR STAY OF ACTION

The undersigned submits this petition requesting that the Commissioner of Food and Drugs stay the effective date of the following matter:
Color Additive Certification; Increase in Fees for Certification Service. 70 Fed. Reg. 15755 (29 March 2005). Docket No. 2005N-0077.

A. Decision involved

The Food and Drug Administration (FDA) published an interim final rule on 29 March 2005 imposing an increase in the fee that it charges color additive manufacturers for certifying that certified additives that the agency regulates under 21 CFR Parts 74, 80, and 81 meet the agency's specifications. 70 Fed. Reg. 15755 (29 March 2005). The effective date for this interim final rule is 28 April 2005.

B. Action requested

The members of the International Association of Color Manufacturers (IACM), and other members of the color additive industry, respectfully request that the Commissioner stay the effective date of, and set aside, the pending interim final rule and conduct full notice and comment rulemaking on this matter of utmost importance to the certified color additive industry in accord with this petition for an administrative stay, and the concurrently filed Citizen Petition that is attached to this document, and incorporated by reference.

C. Statement of grounds

We respectfully request that the Commissioner stay the effective date of 28 April 2005 for this interim final rule because:

1. The FDA's use of an interim final rule rather than notice and comment rulemaking to increase the fee that the agency charges to provide color additive certification services violates the requirements of the Federal Food, Drug, and Cosmetic Act, and the Administrative Procedure Act.

2. The FDA is increasing the fee that it charges for color additive certification because the agency has mismanaged the color certification program and not because there is a legitimate need for additional funding. Therefore, the increase should be set aside and proposed only through full notice and comment rulemaking.

In this request for a stay, IACM summarizes the many serious issues associated with the FDA's management of the color certification program. These issues deserve serious exploration, discussion and consideration before any fee increase is implemented:

1. FDA's two relocations of the color certification laboratory incurred large, unnecessary costs. If the agency had managed the relocation properly, the laboratory would have been relocated only once to its permanent quarters in College Park, Maryland, at far less expense, thereby abrogating the need for a fee increase at this time.

2. If circumstances mandated that FDA relocate the laboratory twice, once to temporary quarters before a move to permanent quarters, and we assert that circumstances did not mandate two moves, then FDA should have relocated the laboratory to temporary quarters other than the unnecessarily expansive and enormously expensive facility in Chantilly, Virginia.

3. It appears from FDA reports that while the color certification laboratory has a current cash balance of "only" several hundred thousand dollars, it continues to maintain a reserve of $1 million dollars which could easily carry the laboratory through several years given the consistent significant income obtained through industry payments for certification services. Clearly, there is no need to rush to impose a fee increase.

4. FDA continues to support agency staff that work on issues other than color certification with funds collected from companies paying for certification services. Such funds should be used solely for the support of staff that perform services associated with color additive certification.

- FDA reports that it currently has thirty-four staff people allegedly working in the color certification laboratory. A number of these staff, according to FDA's own fee study, clearly work on projects and issues not associated with color certification such as cosmetic safety and regulation.
- As acknowledged in recent FDA correspondence, seven of these staff are fictitious "accounting devices."

5. The staffing level of the color certification laboratory (thirty-four people) appears to be far above what is required given the technology employed to analyze color additives for certification.

- IACM members routinely analyze the same color additives as FDA using the same technology and do so with far fewer people at far less expense.

6. The fee increase is based substantially on the large, unjustified expenses associated with the relocations of the certification laboratory. This basis is contrary to the expressed wishes of Congress as demonstrated by statements included in the records of the House and Senate Appropriations Committees.

An additional critically important issue that simply cannot be adequately addressed in the brief period of time allotted by the agency under the interim final rule is the issue of whether FDA should continue to certify color additives at all.

- Color additive certification is not generally required in other countries and is unlikely to be part of global food standards under development.
- Section 721 of the Federal Food, Drug, and Cosmetic Act states only that FDA (as delegated to by the Secreray) shall "by regulation provide for the certification" of

color additives. While this has been interpreted to mean that FDA should solely provide certification services, it leaves open the possibility of industry/agency cooperation perhaps with industry providing certification services under FDA oversight.

- If color additive certification is to be changed, it also seems appropriate to consider whether to suggest to Congress that the Act be amended to delete the requirement for certification.

The International Association of Color Manufacturers (IACM)

IACM is the international association of color additive manufacturers. IACM's members manufacture and market color additives (certified and exempt from certification) that are incorporated into foods, drugs and cosmetics. These color additives are extensively regulated by the U.S. Food and Drug Administration (FDA) as described at 21 C.F.R. Parts 73, 74, 80, and 81, and have been thoroughly evaluated to assure that they are safe for inclusion in foods, drugs, and cosmetics.

The FDA's Use of an Interim Final Rule Violates the Requirements of the Administrative Procedures Act

FDA violated the Administrative Procedure Act (APA) by issuing an interim final rule to increase the fees for its color additive certification program, without providing the public with notice and an opportunity for comment on the proposed fee increase prior to its imposition. The rationales offered by the FDA for invoking the "good cause" exception to the prior notice and comment requirement are plainly defective and do not justify the agency's failure to honor its most basic procedural obligation under the APA. Accordingly, FDA's action is illegal because it is "without observance of procedure required by law." 5 U.S.C. § 706(2)(D). *See Union of Concerned Scientists v. NRC*, 711 F.2d 370 (D.C. Cir. 1983).

FDA's provision for post hoc comment on the fee increase does not cure its failure to follow the notice and comment requirements under 5 U.S.C. § 553. *E.g., New Jersey Dept. of Envtl. Prot. v. EPA*, 626 F.2d 1038, 1049 (D.C. Cir. 1980). FDA therefore should revoke the illegal interim final rule and give the public a meaningful opportunity for comment prior to imposing any fee increase.

IACM is requesting in this petition through FDA's regulations regarding administrative practices and procedure (21 CFR Part 10; Section 10.35) that the agency stay the effective date of 28 April 2005 for the color additive certification fee increase, and then, based on IACM's Citizen Petition filed concurrently with this petition, propose a fee increase, should the agency determine that an increase is indeed necessary, and provide a complete rationale and explanation within full notice and comment rulemaking. Notice and comment rulemaking will provide the color additive industry the opportunity to fully explore the many serious issues associated with FDA's management of the color certification program.

A full explanation of the issues associated with FDA's violation of the Administrative Procedure Act is contained in the attached Citizen Petition and we request that the contents of the Citizen Petition be incorporated into this request for a stay.

The FDA Is Increasing the Certification Fee Because FDA Has Mismanaged the Color Certification Program and Not Because There Is a Legitimate Need for Additional Funds

Background

1. FDA's Regulation of Color Additives

Congress provided in the Federal Food, Drug, and Cosmetic Act (FFDCA) that the Food and Drug Administration (FDA), through authority delegated by the Department of Health and Human Services, has authority to regulate the sale and marketing of color additives. FFDCA Section 721. The FDA is provided with this explicit pre-market approval authority to determine whether color additives are safe for human and animal consumption before any color additive can be marketed. The statute and the agency's implementing regulations provide that FDA may "list" (approve) color additives when they are determined to meet the agency's criteria for safety.

Congress also provided FDA with the authority to determine that certain color additives should be subject to an additional requirement, a requirement of "certification" in which the agency analyzes a sample from each batch of these color additives to assure that they meet the agency's mandated specifications. Therefore, there are two classes of color additives, color additives exempt from certification (See 21 CFR Part 73) and color additives subject to batch certification (See 21 CFR Parts 74, 80, and 81). In general, color additives that may be produced from "natural" sources using "natural" processes are regulated as color additives exempt from certification, and color additives produced through chemical synthesis are regulated as certified color additives. However, several color additives exempt from certification with significant use in food such as B-carotene (21 CFR Sec. 73.95) and titanium dioxide (21 CFR Sec. 575) may be prepared using synthetic processes, as may other color additives exempt from certification such as synthetic iron oxide (21 CFR 73.200).

A large amount of scientific information generated since the Color Additive Amendments of 1960 added Section 721 to the FFDCA demonstrate that there is no difference in the safety of color additives exempt from certification and certified color additives. In fact, one can readily assert that the safety of the certified color additives is more thoroughly documented than the safety of most natural products due to the extensive battery of scientific safety studies required by FDA as a condition of their approval.

It is important to note that the certified color additives regulated by FDA under the requirements of 21 CFR Parts 74, 80, and 81 remain the only food ingredients that FDA "certifies." The vast majority of substances included in food as food additives and GRAS substances are regulated by FDA simply through industry compliance with specifications promulgated by FDA (See e.g. FDA's food additive regulations for food

additives such as preservatives and a wide variety of multipurpose substances at 21 CFR Part 172). In fact, FDA no longer even certifies human pharmaceutical preparations such as insulin and antibiotics, those certification programs having been discontinued during the 1990s.

A strong argument can easily be made that FDA's authority to certify color additives is an antiquated artifact of another time. Over forty years of experience under the current certification program has demonstrated that color additive certification is not necessary as a public health protection measure. Color additive certification is not widely employed in other countries – most countries elect to treat color additives as any other food constituent by establishing a specification by regulation that must be met by manufacturers. As countries signatory to the WTO Treaties continue to develop global food standards, the certification of color additives is not contemplated as a measure to be included.

Color additive certification as managed by FDA is an unnecessary and costly measure with no public health benefit that adds a significant cost to certified color additives. Certification fees of $0.30 per pound may add from 5% to 20% to the per pound cost of a color additive. Of course, this added cost works its way through the supply chain to the ultimate consumer.

2. Fees that FDA Charges for Color Certification Services

FFDCA Section 721(c) provides that FDA, through authority delegated by the Department of Health and Human Services, shall provide for the certification of color additives listed by the agency as conforming to the agency's specification requirements. The Act allows the FDA to charge a reasonable fee to "provide, maintain, and equip an adequate service" for certification of batches of color additives for which certification is required. Since 1994, the agency has charged parties submitting samples of certified color additives a fee of $0.30 per pound for certification services. The recently announced fee increase calls for an increase of $0.05/pound to $0.35, an increase of almost 17%.

Up until the past few years, the FDA's management of the color certification program could be characterized as conservative from a fiscal perspective, and in the view of the industry, appropriate. In past years, FDA staff were in close communication with the color additive industry, and the funds accumulated by FDA were closely monitored by both parties. When a significant surplus was accumulated in the certification fund, refunds were twice provided to parties who had certified color additives during the relevant period of time apportioned to the amount of color certified during that time. There was an acknowledgement by FDA that the agency should only collect and retain funds needed for the maintenance of a sound certification program, and that significant surpluses should not be accumulated.

<u>The 1994 Fee Increase</u>

From time to time, FDA has implemented increases in the certification fee. The most recent increase was implemented in 1994 with an increase of $0.05 from $0.25 to

$0.30 with an effective date of 29 December 1994. 59 Fed. Reg. 60898 (29 November 1994); 61 Fed. Reg. 3571 (1 February 1996).

This increase was accomplished through the agency's publication of an interim final rule on 29 November 1994 (59 Fed. Reg. 60898) to which IACM and other color additive manufacturers did not object in regards to the legal form of the notice (i.e. interim final rule vs. a proposed rule). IACM did not object in that instance to the agency's use of an interim final rule because of the extensive discussions underway at that time with FDA staff. During these discussions, it became evident that the color certification program had a legitimate need for an increase in the certification fee – the cash balance in the certification fund had fallen to a little more than $200,000.

However, IACM did object to certain proposed actions in the interim final rule other than the fee increase, most important of which was the proposed automatic annual fee escalator. IACM demonstrated to FDA that the use of an automatic fee escalator would result in an undue burden on the color additive industry through the collection of fees far beyond the needs of the certification program. IACM demonstrated that an automatic escalator would result in the rapid accumulation of unneeded surplus funds through the normal growth in annual pounds of color certified and the increasing efficiency of the certification analyses through advances in technology.

As noted in the FDA's final rule, the agency agreed with IACM's comments regarding the association's opposition to the automatic annual fee increase that FDA had proposed in the interim final rule. FDA summarized IACM's argument against the automatic fee escalator as follows:

> In support of its objection to the escalator provision, IACM stated that it was opposed to an automatic annual increase in the certification fees because it was contrary to section 721(e) of the act. <u>IACM argued that Congress clearly intended that such fee increases would have to be specified in a proposed regulation with an opportunity for public notice and comments.</u> 61 Fed. Reg. 3571. (Emphasis added).

FDA concluded in the final rule,

> <u>After due consideration FDA finds that it is persuaded by IACM's comments in support of its objection to the escalator provision, and the agency will not implement this provision</u>. The agency will continue with its past policy of monitoring color certification costs and set fees as required by section 721(e) of the act . . . FDA will continue to closely monitor the certification fee structure and will continue with its policy of refunding any excess of funds in proportion to workload of each company that sought color certification. 61 Fed. Reg. 3571. (Emphasis added).

Since 1996, FDA Has Not Managed the Color Additive Certification Program in a Sound and Fiscally Responsible Manner

In the years between the last fee increase in 1994 (implemented in final in February 1996) and the present, IACM has closely monitored the financial performance of the FDA's color certification fund and had close contact with the FDA staff responsible for managing the color certification program. IACM regularly had discussions with the laboratory staff to track the time it takes staff to complete their certification analyses and report the results to the manufacturers. IACM also carefully watched as the certification program accumulated a large cash surplus as a result of the 1994 increase in the certification fee.

In late 2000, IACM learned that the certification fund cash balance with the Treasury Department as of 1 October 2000 was $3,541,000. It is significant to note that if FDA had implemented its proposed automatic fee escalator in 1994, the cash surplus would have been even larger. IACM began discussions with FDA staff about the possibility of a refund of the surplus to color manufacturers upon learning of the large accumulated cash surplus. IACM was optimistic about a refund because in the past the agency had provided refunds on similar, and even smaller, cash balances. It was in late 2000 that IACM first learned of FDA's plans to relocate the color certification laboratory.

1. The Relocation of the Color Certification Laboratory

In late 2000, IACM learned that the FDA planned to relocate the color certification laboratory from Federal Building 8 in Southwest Washington, D.C. to its planned campus in College Park, Maryland sometime in 2002. IACM initiated a series of meetings and discussions with FDA staff to learn more about the relocation, and to discuss a refund of the surplus fees.

In mid-2001, IACM was informed that appropriated funds were not adequate to construct a building for the entire FDA Center for Food Safety and Applied Nutrition in College Park, and that because the Office of Colors and Cosmetics, including the color certification laboratory, had its own dedicated revenue stream (color certification fees), FDA decided to move the color certification laboratory to separate long-term rental space in the College Park area.

IACM raised a number of issues with the FDA's relocation plans related to the timing of the move and its possible cost, and also raised a significant fundamental issue – why should the color industry be required to finance the relocation of the color certification laboratory at great cost to the industry for the simple convenience of FDA. After all, the statute provides that the agency shall provide the certification service and allows the FDA to charge a reasonable fee to "provide, maintain, and equip an adequate service." Nothing in the statute or legislative history allows FDA to move on its own initiative, for its own convenience, and charge the entire cost of the relocation to the industry. This seems especially egregious when FDA staff admitted that the relocated laboratory would not, and in fact did not, result in any improvement in the services provided.

In August 2001, and after extensive discussions with FDA staff, IACM received a proposal from the agency providing some details on the agency's relocation plans, and offering a refund from the color certification fund surplus of about $1 million to be shared among all companies that had used the agency's certification services in recent years. As of 30 September 2001, FDA stated that the color certification fund had a balance of $4,693,000, the largest fund balance that IACM had ever been aware of.

Discussions with FDA related to the laboratory relocation and the pending refund continued throughout late 2001 with IACM suggesting that it appeared that the large surplus could be used to provide a larger refund to color additive manufacturers while still easily meeting the needs of the agency. IACM members eventually accepted FDA's offer to refund approximately $1 million to individual companies and these funds were disbursed near the end of the year in 2001. IACM continued to assert that a larger refund was appropriate given the information that IACM had been provided by FDA regarding the status of the surplus and the estimated costs for the laboratory relocation.

IACM became even more concerned in early 2002 as discussions regarding the laboratory relocation continued. At that time, FDA representatives provided cost estimates to IACM regarding the moving and "build-out" costs that ranged from $5 million to more than $7 million, greatly exceeding the surplus funds that FDA had accumulated. Also at that time, FDA staff mentioned the possible need for an increase in the certification fee of $0.10 from $0.30 to $0.40, an increase of 33%, in the middle of a severe economic recession affecting nearly every industry in the U.S.

Also at this time, IACM received a surprising piece of news – FDA now believed that the color certification laboratory would not be able to move to a facility in College Park but that the laboratory would have to be relocated to a temporary facility until late 2004 when FDA's new facility in College Park would be available. FDA staff informed IACM that the appropriate space that they had identified was a recently vacated state-of-the-art laboratory that was occupied by the Drug Enforcement Administration (DEA) in Chantilly, Virginia near Dulles International Airport, more than 25 miles from the laboratory's former location in Washington, D.C., and even further from College Park, Maryland. Therefore, FDA informed IACM that the laboratory would be moved twice, not once as originally expected.

2. The Move to Chantilly, Virginia

According to information that IACM received from FDA, the color additive certification laboratory requires about 12,000 square feet of space. The former DEA facility in Chantilly that FDA moved the laboratory to was approximately 35,000 square feet at $52/square foot – nearly three times the space needed at more than twice the square foot cost that FDA had been paying. When IACM asked why such extensive and expensive space was secured for the certification laboratory, FDA replied that the former DEA space was the only appropriate space available in the Washington metro area.

It is interesting that FDA's current fee study, referenced in the interim final rule, notes that the certification laboratory now pays rent on 21,303 square feet of space, nearly twice the estimated square footage previously identified as used by the laboratory. We plan to investigate this in more detail since personal observation of the new College Park facility by IACM representatives is inconsistent with this larger estimate.

The move to Chantilly was completed in December 2002. IACM worked closely with FDA staff during the move to assure that there was no significant interruption in the certification service – FDA staff deserve much credit for working to assure that consistent certification services were maintained during the move.

Even though the former DEA laboratory can be accurately characterized as state-of-the-art, there was no improvement in the services provided by FDA, and the cash surplus that the agency had was further reduced to pay for this enormous facility.

While the move was in preparation during the late 2002, IACM noted that FDA continued to maintain more than $3 million in the certification fund reserve, more than enough to accomplish the move according to the then current FDA estimates, and far less than the initial estimates of $5 million to $7 million provided earlier by the agency. IACM was informed that FDA would not consider an additional refund of surplus funds until after the final move to permanent quarters in College Park was completed.

3. Congress Addressed the FDA's Management of the Color Certification Laboratory and Provided Instructions to FDA on the Determination of Reasonable Fees for the Certification Service

Congress investigated the FDA's management of the color certification laboratory and expressed its concern through the Appropriations Committees of the House of Representatives and the Senate. The report of the House Appropriations Committee issued on 25 June 2003 stated:

> The Committee understands that fees paid by the color certification industry have been used to pay rent on a much larger facility than is needed in fiscal year 2003, due to logistics of using temporary space, and that the same situation is expected in the budget year. The Committee is concerned that this temporary rent increase will be the basis for an increase in assessed fees for the industry. The Committee expects FDA to calculate fees based on reasonable expenses, excluding the anomaly of increased rent in the current and budget years. The Committee notes that augmentation of the FDA budget by the color certification fees is allowable only to offset reasonable expenses of running the color certification function, and that a separate accounting of the fees and expenses must be kept.

The report of the Senate Appropriations Committee issued on 17 July 2003 stated:

> The Committee is aware that the color certification function, performed by FDA and paid for by user fees from the certified color industry, moved into new temporary space in October 2002, and is planning on moving into permanent space in the fall of 2004. Increased rent and security costs for the temporary space, which is much larger than necessary and significantly more expensive, are being paid by the color certification user fees. The Committee is aware that color certification user fee assessments have not increased since 1993, and that the industry received a rebate of $1,000,000 from FDA in fiscal 2002. However, the Committee is concerned that the industry must pay for space and security costs above necessary levels. The Committee is also concerned about the apparent lack of consultation with the industry as this office move was contemplated. The Committee directs FDA to provide a report on the steps that will be taken to ensure that there will not be any future excessive fluctuations in the cost of the program.

The House report instructed FDA to "calculate fees based on reasonable expenses, excluding the anomaly of increased rent" from the laboratory's time at the Chantilly facility. It is clear that the current fee increase is intended to recoup the excessive sums paid for rent and security at the Chantilly facility for the two years that the certification laboratory was housed there, and equally clear that the fee increase is contrary to the expressed wishes of the House Appropriations Committee. Furthermore, contrary to the wishes of the Senate Appropriations Committee, FDA has not taken steps that will "ensure that there will not be any future excessive fluctuations in the cost of the program" and in fact has done just the opposite by announcing on 29 March 2005 an increase in the certification fee of nearly 17%.

4. The Financial Basis for the Current Proposed Increase in the Color Certification Fee

In its recent interim final rule, FDA notes regarding the basis for the fee increase that, "All cost estimates are described in the '2003 Color Certification Fee Study.' A copy of this document is on file at the Division of Dockets Management (see ADDRESSES)." 70 Fed. Reg. 15755 (29 March 2005). In the section entitled "ADDRESSES" the reader is instructed to go to an FDA website (www.fda.gov/ohrms/dockets/default.htm) for background information, presumably to include the sole document cited by the agency in support of the fee increase, the 2003 fee study. As of today, the study was still not available as described by the agency. Fortunately, IACM obtained a copy by facsimile from FDA staff on 4 April 2005. It is worth noting that other members of the public would likely have had a difficult time in obtaining the study, especially given the brief 30-day period provided between the publication of the final rule (29 March 2005) and the effective date (28 April 2005). We

have no way of knowing if other important documents were also not included in the public docket.

The fee study cited in the interim final rule is misleading in that it describes the status of the certification program and fund as of September 2004, and makes projections going forward into 2005, but does not explain how the certification fund balance reached its current depleted state. It attempts to explain the agency's cost basis for the color certification program but succeeds only in raising more questions than it answers.

5. Recent Communication Between IACM and FDA

On 8 November 2004, IACM wrote to FDA seeking more information on costs associated with the move to Chantilly and the pending move to permanent quarters in College Park. In its letter, IACM requested an explanation for how the certification fund held a balance of $4,444,000 as of 1 October 2003 and as of 30 September 2004 held only $692,359, according to FDA's own accounting.

FDA addressed the issue of the severe depletion of the certification fund surplus in its response dated 21 December 2004 by explaining that,

> While most expenses have remained fairly constant or experienced minor increases, the cost of rent and utilities, and relocation costs have increased dramatically. Relocating from FB-8 has been extremely expensive, rent has increased, on average, $1.4 million per year for FY03 and FY04 from FY01 and FY02. In addition, $1.5 million from color certification funds was used to build out the laboratory space at University Station (College Park).

It is important to note that the dramatically increased costs that FDA refers to were undertaken by FDA over IACM's objections, and are solely attributable to the move to the expensive and unnecessarily large temporary space in Chantilly, Virginia, and the build out at College Park – IACM consistently objected to both.

For some time, IACM has been concerned about the staffing of the color certification laboratory. IACM has been aware that a number of staff are supported by the color certification fund although they do not work solely on color certification activities. For example, salaries for the Director of the Office of Colors and Cosmetics and the Administrator of the Office's Division of Programs and Enforcement comes solely from funds obtained for certification services. This is contrary to the intent of the agency's collection of user fees to support the activities of the certification laboratory – color certification fees should be used only to support staff that perform functions solely related to the color certification program.

In response to IACM's inquiry on a description in an FDA document describing staffing of the laboratory, FDA stated in the same 21 December 2004 letter,

> In answer to your inquiry about the seven positions billed as certification payroll offset, these positions have no job

> titles associated with them. They are used as an accounting device to offset overhead expenses associated with the administrative costs of running the certification program and providing services to Certification employees. (Emphasis added).

In other words, these apparently are fictitious employees. It seems likely that this "accounting device" would not be acceptable under generally accepted accounting principles. The staffing level of the color certification laboratory (thirty-four people) appears to be above what is required given the technology employed to analyze color additives for certification. IACM members routinely analyze the same color additives as FDA using the same technology and do so with fewer people at less expense. IACM has been reluctant to raise these issues in the past because its members expressed concern that the agency may retaliate against them through the certification program.

6. The 25 March 2005 FDA Letter

The color additive certification laboratory was moved from Chantilly, Virginia to its permanent quarters in College Park, Maryland in late 2004. Once again, as with the move from FB-8 to Chantilly, FDA staff deserves credit for accomplishing the move with no significant interruption in certification services.

FDA had informed IACM several years before that no further refund of surplus fees would be considered until after the move to College Park was completed. Consistent with this concept, IACM began exploring with FDA the status of the balance in the certification fund, among other issues related to the financial management of the program.

IACM made a series of inquiries in a letter to FDA dated 3 February 2005, to which FDA responded in a letter dated 25 March 2005. Unlike many communications in the past in which IACM felt that FDA staff at least made a good-faith effort to respond to inquiries given the well-recognized difficulties in deciphering federal government accounting, in this letter FDA simply refused to respond in a helpful way. As the letter states:

> It would be impractical to explain every line item in the budget but would rather cite our long relationship and the trust that has been established for quality work and responsible stewardship of color certification monies. I do hope we have put your concerns to rest and that we can get on with the business of certifying colors to better protect the health of our consumers.

The inquiries IACM made were straightforward and related to how the agency spends and accounts for funds that the certified color industry provides. FDA's response suggests that the agency does not have an explanation for "every line item in the budget" as is required of all Federal agencies, and any private business. While the color industry has had a long relationship with FDA, its trust in FDA has been tested by recent events.

IACM also noted that there is no mention in FDA's 25 March letter of a funding emergency for the certification fund. The letter also did not mention the interim final rule that was published in the Federal Register only four days later, nor did anyone at FDA call, or otherwise contact IACM, to provide the courtesy of letting the association know about the fee increase.

7. Financial Effect of the Two Moves

The two relocations of the color certification laboratory resulted in a large, negative financial impact on the certification program. Based on information provided by FDA, costs attributed to the rental of laboratory space for 2003 and 2004, the two years during which the laboratory was located in the Chantilly space, were $1,741,630 and $1,681,915, respectively, compared to an estimate of $1,028,180 for the current year in the laboratory's permanent quarters in College Park. The difference between two years in Chantilly and two years in College Park would be $1,367,185. Add to that sum the estimate provided by FDA that each move cost approximately $500,000 and a total unjustified expense of $1,867,185 can be determined (the difference in costs between Chantilly and College Park and the expense of one move).

Therefore, if FDA had managed the certification program in a responsible manner, the laboratory would have been moved only once and there would have been no need to pay the exorbitant costs associated with the Chantilly facility saving the agency (and therefore the certified color industry) $1,867,185, a sum that would clearly render the need for a fee increase unnecessary. Furthermore, if FDA had been able to secure space in place of Chantilly, and even if the laboratory had to be moved twice, a total of $1,367,185 would have been saved if the space was at a cost roughly equivalent to the laboratory's permanent quarters in College Park.

In addition to costs associated with the two moves, FDA also charged the certification fund approximately $1.5 million for the build-out of the laboratory in College Park. IACM has maintained throughout its discussions with FDA that build-out expenses should be borne by FDA, and not taken out of the certification fund. After all, the laboratory is owned and operated by FDA.

Another way to analyze the effect of the moves is to analyze the laboratory's costs for analyzing a batch of color. Using FDA's information, we constructed this table:

Fiscal Year	$ Spent on certification	# of Batches	Cost/Batch
2000	$ 4,315,000	3962	$ 1,089
2001	$ 3,930,000	4197	$ 936
2002	$ 5,040,000	4711	$ 1,069
2003	$ 7,855,000	4900	$ 1,603
2004	$ 6,128,000	5179	$ 1,178

We note the obvious bulge in the cost per batch in 2003 reflecting the costs associated with the Chantilly move and the College Park build out – this is a difference of 36% compared to 2004. If the 2003 cost per batch was held to the average of the 2002 and 2004 levels the fund would have an additional $2.3 million.

In the interim final rule, FDA describes events – the gradual escalation of costs – that have occurred since 1994, a lengthy period of time. There is no emergency or other sudden change in circumstances concerning public health and safety that justify the issuance of an interim final rule as opposed to notice and comment rulemaking. FDA could have issued a notice of proposed rulemaking at any time since the current fee schedule was established setting forth the price increases that have been incurred and seeking public comment on the proper revision of the fee schedule to address those costs. FDA failed to do so despite having many years in which it could have acted.

The problem of the financial status of the certification fund, as it is characterized by the agency, is one of the agency's own creation by its failure to manage the program properly, or at the very least to initiate a rulemaking at some prior point before now. FDA cannot use its own delays as an escape hatch to avoid its procedural obligations.

In summary, FDA's mismanagement has cost over $3 million, which the industry is now being asked to pay in the form of increased fees. It is clear that if these funds had not been spent, there would be no need for an increase in the certification fee for many years, and in fact FDA would now be discussing a refund with the certified color industry and not a fee increase.

Conclusion and Request for Action

IACM respectfully requests that the Commissioner of Food and Drugs stay the effective date of 28 April 2005 for the increase in the fee for the certification of color additives, and as requested in the attached Citizen Petition propose this and any future fee increases in a manner consistent with the Administrative Procedure Act employing full notice and comment rulemaking.

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4/27/05
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Attachment – Citizen Petition

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Citizen Petition Requesting that the Food and Drug Administration Conduct Notice and Comment Rulemaking for Proposed Increases in the Color Certification Fee

Docket No. 2005N-0077. Color Additive Certification; Increase in Fees for Certification Service. 70 Fed. Reg. 15755 (29 March 2005).

Submitted to:
Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane
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Rockville, Maryland 20852

27 April 2005

CITIZEN PETITION

The undersigned submits this petition under Sections 701 and 721 of the Federal Food, Drug, and Cosmetic Act, as amended, to request the Commissioner of Food and Drugs to promulgate any and all increases in the fee that the Food and Drug Administration charges for color certification services only by notice and comment rulemaking as required by the Administrative Procedure Act.

A. Action requested

By this Citizen Petition, the International Association of Color Manufacturers (IACM), and other members of the color additive industry, request that the Food and Drug Administration (FDA) 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 violates the requirements of the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act and does not allow for a full and appropriate exploration of the complicated issues associated with an increase.

IACM has submitted a separate request (attached) that the Commissioner stay the effective date of 28 April 2005 of the recently announced increase in the color additive certification fee. 70 Fed. Reg. 15755 (29 March 2005). Docket No. 2005N-0077.

Therefore, through the submission of a request for an administrative stay of action under 21 CFR Sec. 10.35, filed concurrently with this Citizen Petition and attached hereto, IACM respectfully requests that the Commissioner stay the effective date of 28 April 2005 for the recently announced fee increase, and then as requested in this Citizen Petition set aside the announced fee increase and determine that this and any future fee increase will be proposed through full notice and comment rulemaking as required by the Administrative Procedure Act should the agency find that a certification fee increase is indeed warranted.

B. Statement of grounds

We respectfully request that, after staying the effective date for the fee increase of 28 April 2005, the Commissioner set aside the announced fee increase and propose this and any future fee increase through full notice and comment rulemaking as required by the Administrative Procedure Act should the agency find that a certification fee increase is indeed warranted. The use of notice and comment rulemaking is required in this instance because:

1. The use of an interim final rule violates the requirements of the Administrative Procedure Act, as explained fully below.

2. Notice and comment rulemaking allows for more careful consideration of important issues such as this fee increase, and permits a full exploration of views. The use of an interim final rule effectively foreclosed any significant discussions between the agency

and the regulated community due to the short thirty-day period between issuance and the effective date, and in effect results in an outcome similar to the automatic fee escalator that FDA formally rejected in 1996.

3. The FDA is increasing the fee that it charges for color additive certification because the agency has mismanaged the color certification program and not because there is a legitimate need for additional funding. Therefore, the increase should be set aside and proposed only through full notice and comment rulemaking. The many serious issues associated with FDA's management of the color certification program are explored in the request for a stay of the effective date for the fee increase (attached), and should be considered during that rulemaking.

The International Association of Color Manufacturers (IACM)

IACM is the international association of color additive manufacturers. IACM's members manufacture and market color additives (certified and exempt from certification) that are incorporated into foods, drugs and cosmetics. These color additives are extensively regulated by the U.S. Food and Drug Administration (FDA) as described at 21 C.F.R. Parts 73, 74, 80, and 81, and have been thoroughly evaluated to assure that they are safe for inclusion in foods, drugs, and cosmetics.

The FDA's Use of an Interim Final Rule Violates the Requirements of the Administrative Procedures Act

FDA violated the Administrative Procedure Act ("APA") by issuing an interim final rule to increase the fees for its color additive certification program, without providing the public with prior notice and an opportunity for comment on the proposed fee increase prior to its imposition. The rationales offered by the FDA for invoking the "good cause" exception to the prior notice and comment requirement are plainly defective and do not justify the agency's failure to honor its most basic procedural obligation under the APA. Accordingly, FDA's action is illegal because it is "without observance of procedure required by law." 5 U.S.C. § 706(2)(D). *See Union of Concerned Scientists v. NRC*, 711 F.2d 370 (D.C. Cir. 1983).

FDA's provision for post hoc comment on the fee increase does not cure its failure to follow the notice and comment requirements under 5 U.S.C. § 553. *E.g., New Jersey Dept. of Envtl. Prot. v. EPA*, 626 F.2d 1038, 1049 (D.C. Cir. 1980). FDA therefore should revoke the illegal interim final rule and give the public a meaningful opportunity for comment prior to imposing any fee increase.

The "Good Cause" Exception to the Notice and Comment Requirement.

FDA's authorizing statute, 21 U.S.C. § 379(e), provides that the listing and certification of color additives "shall be performed only upon payment of such fees, which shall be specified in regulations, as may be necessary to provide, maintain and equip an adequate service for such purposes." (Emphasis added). Thus, FDA is required to issue a regulation before it may increase the fees for its certification services.

In general, the APA requires that prior to promulgating a regulation, the FDA must provide the public with prior notice and an opportunity for public comment. 5 U.S.C. § 553(b)-(c). The APA does provide a narrow exception that allows an agency to depart from the normal notice and comment requirement in situations:

> When the agency the agency "for good cause finds . . . that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest. 5 U.S.C. § 553(b)(3)(B).

The "good cause" exception is "narrowly construed and only reluctantly countenanced." *New Jersey Dept. of Envtl. Prot.*, 626 F.2d at 1045. It is "a safety valve to be used where delay would do real harm. It should not be used . . . to circumvent the notice and comment requirement whenever an agency finds it inconvenient to follow them." *Id.* at 1047, quoting *United States Steel Corp. v. EPA*, 595 F.2d 207, 214 (5th Cir. 1979).

> The exemption of situations of emergency or necessity is not an "escape clause" in the sense any agency has discretion to disregard its terms or the facts. A true and supported or supportable finding of necessity or emergency must be made and published. *New Jersey Dept. of Envtl. Prot.*, 626 F.2d at 1046, quoting S. Doc. No. 248, 79th Cong., 2d Sess. 200 (1946).

The law in the District of Columbia Circuit is clear: use of the "good cause" exception is limited to "emergency" situations. *Assoc. Builders & Contractors, Inc. v. Herman*, 976 F. Supp 1, 6 (D.D.C. 1997). Thus, a reviewing court may sustain a "good cause" claim <u>only</u> if the agency can demonstrate that it is responding to circumstances beyond its control and if it can show that a public health or safety emergency or an environmental crisis exists. *See, e.g., Council of the Southern Mountains, Inc. v. Donovan*, 653 F.2d 573 (D.C. Cir. 1981); *Assoc. Builders & Contractors*, 976 F. Supp. at 6.

With respect to this rule, none of the justifications for invocation of the "good cause" exception is present. FDA has not carried its burden of proving circumstances amounting to a public health or safety emergency. The rationales that the agency advanced in the Preamble to the interim final rule are inadequate to justify the extreme step of dispensing with prior notice and a meaningful opportunity for comment that lie at the core of the APA's requirement of reasoned decision-making.

<u>The Rationales Offered by FDA Do Not Justify an Interim Final Rule</u>.

In the preamble to the interim final rule, FDA offers three rationales for proceeding with an interim final rule and not offering the public a prior opportunity for comment. None of these purported reasons can justify the FDA's illegal action.

1. FDA states that the costs of the certification program have increased significantly since 1994 and that the current fee level is insufficient to provide an adequate certification service. 70 Fed. Reg. at 15755. Assuming this statement is valid, it would not provide a legitimate basis for dispensing with prior notice and comment and raising the fees through an interim final rule.

This rationale describes events – the gradual escalation of costs – that have occurred over a lengthy period of time. There is no emergency or other sudden change in circumstances concerning public health and safety that alone might justify issuance of an interim final rule. FDA could have issued a Notice of Proposed Rulemaking at any time since the current fee schedule was established – years or months ago -- setting forth the price increases that have been incurred and seeking public comment on the proper revision of the fee schedule to address those costs. FDA failed to do so despite having many years in which it could have acted.

Accordingly, assuming that "an immediate increase is necessary" as FDA asserts, *id.*, the problem is one of the agency's own creation by its failure to initiate a rulemaking at some point since the current fee schedule was instituted. FDA cannot use its own delays as an escape hatch to avoid its procedural obligations under the APA.

2. FDA asserts that the setting of a fee schedule to pay for certification services "is a matter particularly within the purview and expertise of the agency." *Id.* Such a rationale usually is offered in support of an agency argument that its action is not subject to judicial review, because the "agency action is committed to agency discretion by law," within the meaning of 5 U.S.C. § 701(a)(2). To the extent that FDA suggests such an argument here, its claim is erroneous as a matter of law.

Needless to say, FDA does <u>not</u> enjoy any special exemption from the APA requirements. Under the APA, there is a strong presumption of reviewability of agency actions. *E.g., Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 670 (1986). In order for an agency action to fall outside the scope of judicial review as an action "committed to agency discretion," the authorizing statute must be drawn in such broad terms that there literally is no law to apply. *E.g., Webster v. Doe*, 486 U.S. 592 (1988). In this case, however, Section 379(e) explicitly provides a standard to be applied: whether a fee increase is necessary "to provide, maintain and equip an adequate service . . . ." Therefore, this rationale cannot provide a basis for escaping FDA's obligation under the APA to provide for prior notice and comment.

3. In the Preamble, FDA attempts to justify the interim final rule by asserting: It is necessary to implement the fee increase as soon as possible to preserve adequate funds for the program. A delay could result in the fund being exhausted before the end of the fiscal year. 70 Fed. Reg. at 15756.

This claim provides no support for FDA's issuance of this interim final rule. The interim final rule was published in the Federal Register on 29 March 2005, more than six months before the end of the fiscal year. FDA has not demonstrated, either in the preamble to the rule or in the material in the rulemaking record, that there is any risk that the certification program would run out of money by 1 October if the imposition of the fee increase were deferred for the short period of time necessary for the agency to carry out its obligation to afford the public prior notice and an opportunity for comment.

In fact, the Preamble states that the increased revenues generated by the fee increase would be $849,626 per year, or approximately $70,800 per month. The Appendix to the Budget for FY 2006, released by the President earlier this year, states that the Revolving Fund for Certification and Other Services was estimated to have a $1 million unobligated balance, or surplus, at the end of FY 2005. Given that the Revolving Fund has a $1 million reserve, FDA's own figures demonstrate that there is no meaningful risk that the Fund would run out of money during the short period of time necessary to permit public comment.

Indeed, the Budget Appendix states that in fiscal year 2006, there will be a $1 million increase in "Offsetting collections from non-federal sources" – a fee increase. Since the Budget numbers are proposed by the agencies in the fall and finalized by the Office of Management and Budget in December of each year, this statement reveals that FDA had planned such a fee increase for several months prior to promulgation of the interim final rule. In other words, FDA has consciously delayed any increase in the certification fees for months to manufacture an "emergency" that does not exist.

This prior planning effort conclusively demonstrates that FDA had ample time to provide the public with notice and comment prior to promulgating any fee increase. Even if there were any meaningful risk that the Revolving Fund might be depleted by 1 October (and, as shown above, there is not), that risk would be a creation of FDA's own delay in providing the required notice under the APA of a step that it had discussed within the Administration many months beforehand.

Accordingly, even assuming that the monthly revenues of the certification program now exceed FDA's monthly outlay, that fact cannot justify promulgation of an interim final rule, given the large reserve that the program has generated and FDA's inexcusable delay in providing notice to the public of its intentions.

The 1994 Fee Increase

From time to time, FDA has implemented increases in the certification fee. The most recent increase was implemented in 1994 with an increase of $0.05 from $0.25 to $0.30 with an effective date of 29 December 1994. 59 Fed. Reg. 60898 (29 November 1994); 61 Fed. Reg. 3571 (1 February 1996).

This increase was accomplished through the agency's publication of an interim final rule on 29 November 1994 (59 Fed. Reg. 60898) to which IACM and other color additive manufacturers did not object in regards to the legal form of the notice (i.e. interim final rule vs. a proposed rule). IACM did not object in that instance to the agency's use of an interim final rule because of the extensive discussions underway at that time with FDA staff. During these discussions, it became evident that the color certification program had a legitimate need for an increase in the certification fee – the cash balance in the certification fund had fallen to a little more than $200,000.

However, IACM did object to certain proposed actions in the interim final rule other than the fee increase, most important of which was the proposed automatic annual

fee escalator. IACM demonstrated to FDA that the use of an automatic fee escalator would result in an undue burden on the color additive industry through the collection of fees far beyond the needs of the certification program. IACM demonstrated that an automatic escalator would result in the rapid accumulation of unneeded surplus funds through the normal growth in annual pounds of color certified and the increasing efficiency of the certification analyses through advances in technology.

As noted in the FDA's final rule, the agency agreed with IACM's comments regarding the association's opposition to the automatic annual fee increase that FDA had proposed in the interim final rule. FDA summarized IACM's argument against the automatic fee escalator as follows:

> In support of its objection to the escalator provision, IACM stated that it was opposed to an automatic annual increase in the certification fees because it was contrary to section 721(e) of the act. IACM argued that Congress clearly intended that such fee increases would have to be specified in a proposed regulation with an opportunity for public notice and comments. 61 Fed. Reg. 3571. (Emphasis added).

FDA concluded in the final rule,

> After due consideration FDA finds that it is persuaded by IACM's comments in support of its objection to the escalator provision, and the agency will not implement this provision. The agency will continue with its past policy of monitoring color certification costs and set fees as required by section 721(e) of the act . . . FDA will continue to closely monitor the certification fee structure and will continue with its policy of refunding any excess of funds in proportion to workload of each company that sought color certification. 61 Fed. Reg. 3571. (Emphasis added).

Based on FDA's statements in the 1996 final rule, IACM has operated under the assumption that any future fee increases would be proposed through full notice and comment rulemaking. The use of an interim final rule without adequate discussion is tantamount to the automatic fee escalator that FDA eventually rejected during the 1994-1996 fee increase process. The use of an interim final rule with only thirty days between issuance and the effective date forecloses any possibility of a thorough exploration of the issues associated with a fee increase, and can be viewed as a mechanism to "ram through" a fee increase that industry would oppose.

As the D.C. Circuit stated in *New Jersey Dept. of Envtl. Prot.*:

> Permitting the submission of views after the effective date is no substitute for the right of interested persons to make their views known to the agency in time to influence the

> rule making process in a meaningful way . . . We doubt that persons would bother to submit their views or that the Secretary would seriously consider their suggestions after the regulations are fait accompli . . . Were we to allow the (agency) to prevail on this point we would make the provisions of Sec. 553 virtually unenforceable. An agency that wished to dispense with pre-promulgation notice and comment could simply do so, invite post-promulgation comment, and republish the regulation before a reviewing court could act. 626 F.2d at 1047, *citing* United States Steel Corp. v. EPA, 595 F.2d 207, 214-215 (5th Cir. 1979).

The FDA is Increasing the Certification Fee Because FDA Has Mismanaged the Color Certification Program and Not Because There is a Legitimate Need for Additional Funds

Issues associated with the FDA's management of the color additive certification program are explored in the request for a stay of the 28 April 2005 effective date for the fee increase (attached). These serious issues are described in summary in the request for a stay and deserve more thorough exploration and discussion. However, FDA's use of an interim final rule to impose the fee increase effectively forecloses any significant exploration of these issues in the short thirty-day period allotted for comments, and provides no effective means for objecting to the increase.

IACM asserts that a fee increase would not be necessary if FDA had managed the color certification program properly. This assertion deserves to be heard and fairly evaluated before any fee increase is implemented. We respectfully request that the information contained in the request for a stay of the effective date be taken into account during the Commissioner's consideration of this Citizen Petition.

C. Environmental impact

A claim for categorical exclusion is made in accordance with 21 CFR Sec. 25.30 (2005).

D. Economic impact

To be submitted only upon request by the Commissioner in accordance with 21 CFR Sec. 10.30 (2005).

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petiton relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

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4/27/05

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Attachment – Request for administrative stay