

Color Certification Online User's Guide

Office of Cosmetics and Colors (OCAC)

v 1.0 January 24, 2006

v 2.0 April 7, 2008

Adam Rixey
Applications Developer

Ali Jaffrey
Applications Developer

Raymond L. Decker
Director of Office of Cosmetics and Color

- About Color Certification Online 1
- Connecting to Color Certification Online..... 2
- Color Certification Main Menu 3
 - 1. Navigation Bar 3
 - 2. Company Information..... 3
 - 3. Folders..... 3
 - 4. Messages from OCAC HQ 4
 - 5. Submit Color Additive Request..... 4
 - 6. FedEx Tracking Information..... 4
- Updating Company Profile 5
- Updating Online Preferences 6
- Submitting Color Additives 7
 - Straight Color Additive..... 7
 - Receipt 8
 - Lake Color Additive 9
 - Repack Color Additive 11
- Queue and Pending Folders 12
 - Modifying a Color Request..... 12
- FedEx Tracking Information..... 13

About Color Certification Online

The Color Certification Online system is a new web interface that allows companies to submit color additives requests to the Office of Cosmetics and Colors (OCAC) without the need for paper forms. While a company must still mail the physical samples to the FDA for analysis, advance knowledge of the incoming samples can help expedite the testing process. It will also allow the companies to better track their color additives through the certification process.

Note that this document is intended for the companies submitting color additive requests. U.S. Agents representing foreign companies will have a different interface and set of options available to them.

Connecting to Color Certification Online

Open up your web browser and go to the following login screen at:

<https://info1.cfsan.fda.gov/color>

At the login screen, type in your user name and password. Select the agreement stating that you understand that 18 U.S.C. 1001 code, and then select the Log In button.

1906-2006
FDA
Centennial

U.S. Food and Drug Administration

Department of Health and Human Services

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

[FDA Home Page](#) | [CFSAN Home](#) | [Search/Subject Index](#) | [Q & A](#) | [Help](#)

Office of Cosmetics and Colors
Color Certification Online

*** Account Login** [Forgot your password?](#)

User Name:

Password:

[OMB Burden Statement](#)
[Browser Requirements](#)

Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

I understand

** Data entry session times out after 60 minutes of inactivity.*

[CFSAN Home](#) | [CFSAN Search/Subject Index](#) | [CFSAN Disclaimers & Privacy Policy](#) | [CFSAN Accessibility/Help](#)
[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#)

Figure 1 - Color Certification Online Login Screen

Color Certification Main Menu

The screenshot shows the main menu of the Color Certification Online system. At the top, the FDA logo and the text 'U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition Office of Cosmetics and Colors' are visible. The navigation bar includes links for 'Update Profile', 'Update Preferences', 'Send Feedback', and 'Log Out'. The user's account information is displayed, including the company name 'OCAC TEST COMPANY, limited', a balance of \$74,344.63, and 70/32 bottles LG/SM. There are four folders: 'In Queue (50)', 'Pending (47)', 'Certified (1)', and 'Reports'. A 'Submit Color Additive Request' section has buttons for 'Straight', 'Lake', and 'Repack'. A 'Messages from OCAC HQ' box shows a message: 'There are no recent messages from the OCAC HQ.' with a 'View old messages...' link. A 'FedEx Tracking Information' link is also present. At the bottom, there is a link to the 'Color Certification Online User Guide (274kb PDF)'.

Figure 2 – The Color Certification Online Main Menu

The main menu for the Color Certification Online program contains five key areas that you need to be aware of.

1. Navigation Bar

The navigation bar along the top of the screen contains links that allow you to update your company's profile and your online preferences. There is also a link to send feedback to the Office of Cosmetics and Colors (OCAC), as well as a button to log out of the Color Certification Online system.

All other pages of Color Certification Online include a "Menu" link in the navigation bar. Selecting that link will bring you back to this main menu.

2. Company Information

This box provides a brief snapshot of your current account balance with the OCAC. If you have received any sample bottles from the OCAC, they will also be displayed here. Below the box is a link to request more bottles.

3. Folders

These folders contain samples that you have submitted to the Color Certification Online system. A folder may not appear if it does not have any contents. If the FDA is currently analyzing a sample, it may temporarily not appear in any folders until our work is completed.

The following folders are possible:

- **In Queue** Samples in the queue are those that have been submitted online, but not yet received by the FDA.

- **Pending** Pending samples have been received by the FDA, but have not yet been analyzed.
- **Certified** Certified samples are those that have finished analysis and been certified by the FDA.
- **Unaccepted** Unaccepted samples are those that have not been accepted by the U.S. Agent. (Foreign companies only)
- **Reports** Selecting the reports folder will let you download a report of your company's account and sample information.

4. Messages from OCAC HQ

Important notices from the Office of Cosmetics and Colors will be displayed here.

5. Submit Color Additive Request

Selecting one of these buttons will allow you to enter information for a new color additive.

6. FedEx Tracking Information

This link allows you to enter in the FedEx tracking numbers for color sample packages that you ship to the FDA.

Updating Company Profile

Select the "Update Profile" link on the main menu to arrive at this screen. Here you can update your contact information, email address, and password. Once finished making changes, select the **Update** button.

Menu » Update Profile							
Company Name	OCAC TEST COMPANY						
Account Name	TEST						
Prefix	<input type="text" value="Mr."/>						
First Name	<input type="text" value="Raymond L."/>						
Last Name	<input type="text" value="Decker, Jr."/>						
Title	<input type="text" value="Commander"/>						
Phone	<table border="0"> <tr> <td>Area Code</td> <td>Phone Number</td> <td>ext.</td> </tr> <tr> <td><input type="text" value="123"/></td> <td><input type="text" value="436-1141"/></td> <td><input type="text" value="012"/></td> </tr> </table>	Area Code	Phone Number	ext.	<input type="text" value="123"/>	<input type="text" value="436-1141"/>	<input type="text" value="012"/>
Area Code	Phone Number	ext.					
<input type="text" value="123"/>	<input type="text" value="436-1141"/>	<input type="text" value="012"/>					
Fax	<table border="0"> <tr> <td>Area Code</td> <td>Phone Number</td> <td>ext.</td> </tr> <tr> <td><input type="text" value="132"/></td> <td><input type="text" value="654-3210"/></td> <td><input type="text"/></td> </tr> </table>	Area Code	Phone Number	ext.	<input type="text" value="132"/>	<input type="text" value="654-3210"/>	<input type="text"/>
Area Code	Phone Number	ext.					
<input type="text" value="132"/>	<input type="text" value="654-3210"/>	<input type="text"/>					
Email	<input type="text" value="adam.rixey@cfstan.fda.gov"/>						
Password	<input type="password" value="••••••••"/>						
Password (confirm)	<input type="password" value="••••••••"/>						

Figure 3 - Update Profile

Updating Online Preferences

Select the "Update Preferences" link on the main menu to arrive at this screen. Here you can change whether you prefer metric or imperial measurements. You can also set up alerts so that you will be notified if your account balance or remaining bottles fall below your desired values. When finished, select the **Update** button.

Menu » User Preferences

Units	<input type="radio"/> lbs <input checked="" type="radio"/> kgs
Balance Minimum	Alert when falls below <input type="text" value="\$60,000.00"/>
Small Bottles	Prompt for reorder when <input type="text" value="85"/> remaining
Large Bottles	Prompt for reorder when <input type="text" value="80"/> remaining

Figure 4 - User Preferences

Submitting Color Additives

On the main menu, select one of the three buttons to create a Straight, Lake, or Repack color additive request. There are slight differences to each of the three types of color additives, so we will start with the simplest of the three.

Straight Color Additive

Step 1: Enter Color Additive Information

The first step is to enter the basic color information. The following fields are required:

- **Straight** The color additive.
- **Batch #** Your company's batch number.
- **Weight** The batch weight. Enter in the units (pounds or kilograms) that you specified when updating your preferences.
- **Bottle Size** Size of the bottle containing the sample you send to the FDA.
- **Manufactured By** Company that manufactured this color additive.
- **Storage Method** How you are storing the color additive while it is pending certification.
- **Location** Where you are storing the color additive.

There is also an optional **Notes** field where you may enter any additional information that you wish to include with your submission.

Next

* Required Field

* Straight	* Batch #	* Weight
<input type="text" value="D&C GREEN No. 5"/>	<input type="text" value="XXXX-1"/>	<input type="text" value="750"/> kgs
* Bottle Size	<input type="radio"/> Large (81 remaining) <input checked="" type="radio"/> Small (57 remaining)	
* Manufactured By	<input type="text"/>	
* Storage Method	<input type="text"/>	
Notes	<input type="text"/>	
* Location	5001 Paint Branch Parkway College Park, MD 20704 Change	

Color Use Statement

Drugs and Cosmetics - generally, including those intended for use in the area of the eye, in amounts consistent with current good manufacturing practice. Nylon 6 sutures, not to exceed 0.6% by weight of the suture -- for general surgery only.

Balance	\$40529.56
Fee	- \$578.81
New balance	= \$39950.75

Figure 5 - Color Additive Information

The **Manufactured By**, **Storage Method**, and **Location** fields will each remember the values that you enter, to make future submissions easier. The first time you enter a submission, you will need to type in the value.

The next time you enter a submission, you will be able to select your previous choice from a pull-down menu. To create a new value, select the first option from the pull-down menu, such as "New Location". A text box will appear and allow you to enter in the new information. When finished, select the Update **Update** button. If you have

accidentally chosen an incorrect value, you can select the **Change** **Change** button to make the pull-down menu reappear.

Figure 6 - Location Pull-Down Menu

When you have filled out all the required fields for the color additive, select the **Next** **Next** button.

Step 2: Verification

Straight color additives do not require any additional information, so you arrive at a page to verify that all data is accurate. Select the **Previous** **Previous** button to make any changes to your information, or select the **Submit Request** **Submit Request** button to send the request to the Office of Cosmetics and Colors.

Verification of Sample Request

To make any changes, select the *Previous* button.

Dye	Batch #	Weight
D&C GREEN No. 5	XXXX-1	750 kgs (1653.75 Lbs)

Bottle Size	Small
Manufactured By	GloboChem Petrochemical Manufacturing, Inc.
Storage Method	Sealed PVC barrels, stacked in our warehouse.
Location	5001 Paint Branch Parkway College Park, MD 20704

Balance	\$40,529.56
Fee	- \$578.81
New balance	\$39,950.75

Figure 7 - Step 2: Verification

Receipt

Once a request has been submitted, you will be presented with a receipt that you may print out for your records. If you wish to submit another color additive request of the same type, select the **Add More** **Add More** button. You will be taken back to Step 1 of a new entry. As a time-saving measure, all information other than the **Batch #** and **Weight** will be exactly the same as the request that you just completed.

Lake Color Additive

Step 1: Initial Information

Lakes start out the same as entering a straight. You must enter the same basic information about the color additive, where it is stored, etc. The only changes are that the list of color additives is now made up of lakes instead of straights, and there is a new header at the top of the screen to show your position in the process.

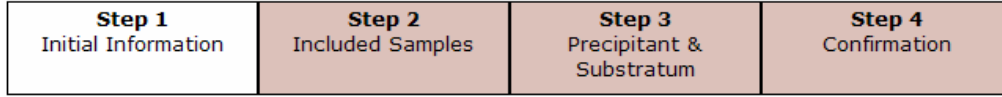


Figure 8 - Lake Header

Step 2: Included Samples

The second step is to add one or more samples included in the lake. Some lakes, such as all approved for use in foods, require a certified FDA Lot # to be used in the new lake. Others will accept either a Lot # or the name of the color. Depending upon the color additive that you have selected in Step 1, you will see one of two different forms.

Previous Next

This page is optional when submitting lakes.

Enter Color Used:

Lot #	<input type="text"/>	Weight	<input type="text"/>	kgs
--------------	----------------------	---------------	----------------------	------------

Add

Figure 9 - Certified FDA Lot # Required

To enter a certified FDA Lot #, type the value into the text box. Then type in the weight and select the **Add** button to enter the sample.

Previous Next

This page is optional when submitting lakes.

Enter Color Used:

<input checked="" type="radio"/> Lot #	<input type="text"/>	<input type="radio"/> Name	<input type="text"/>	Weight	<input type="text"/>	kgs
---	----------------------	-----------------------------------	----------------------	---------------	----------------------	------------

Add

Figure 10 - Certified FDA Lot # or Color Name Allowed

To enter a certified FDA Lot # or Color Name, first select the button next to the appropriate label (**Lot #** or **Name**). Then type in the value and weight, and then select the **Add** button to enter the sample.

Once you enter a color, the screen will refresh to show a list of colors added to this sample. If you make a mistake, you can select the **Edit** button next to a color to alter it or the **Delete** button to remove that color.

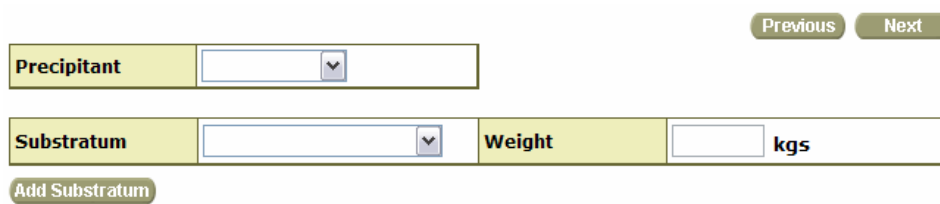
	Name of Color	Weight (kgs)
<input type="button" value="Edit"/> <input type="button" value="Delete"/>	D&C RED # 34	500

Figure 11 - Added Color List

When ready, select the **Next** button to continue on to the next stage of the process.

Step 3: Precipitant and Substratum

The third step allows you to enter the precipitant and substratum used in creating the lake. Select the values from the pull-down menus, enter the weight of the substratum, and then select the **Add Substratum** button. Note that depending upon the color chosen in Step 1, you may be able to add more than one substratum; however, you can only have one precipitant.



The form consists of a header with 'Previous' and 'Next' buttons. Below is a 'Precipitant' dropdown menu. Underneath is a row with 'Substratum' and 'Weight' dropdown menus, and a text input field followed by 'kgs'. At the bottom left is an 'Add Substratum' button.

Figure 12 - Precipitant and Substratum

When finished, select the **Next** button.

Step 4: Confirmation

This is just like the confirmation screen used when creating a straight color additive, only it now displays the included samples, precipitant, and substratum information. To make any changes, select the **Previous** button to go back in the process. (As a shortcut, you may also select a completed step in the header to jump directly to that page; for instance, selecting "Step 1: Initial Information" will take you back to the beginning.)

When you are ready to submit the data to the FDA, select the **Submit Request** button.

Repack Color Additive

Repacked color additives are handled similarly to lakes, only there are now three steps instead of four.

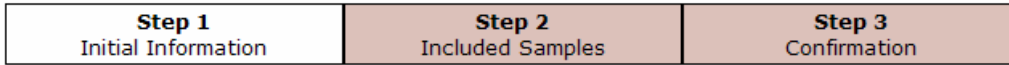


Figure 13 - Repack Header

Step 1: Initial Information

This first step is exactly the same as when submitting straights and lakes.

Step 2: Included Samples

The second step behaves the same as Step 2 for lakes; however, with repacks you must always supply a certified FDA Lot #. The total weight of repacked samples must also match up with the weight that you specified in Step 1.

Step 3: Confirmation

When you are ready to submit the data to the FDA, select the **Submit Request** **Submit Request** button.

Queue and Pending Folders

Selecting the **In Queue** or **Pending** folders on the main menu will allow you to view your samples sent to the FDA. While neither folder contains samples that have been analyzed, there is one very important distinction to make: items in the queue can *still be edited*, while those that are pending *cannot be edited*. If you submit a color additive request and then realize that you made a mistake, you can still go in and change it so long as it is still in the queue¹.

To view either the queue or pending color requests, select their folder from the main menu. If there are a large number of records, you will be able to filter by Batch # and/or Color Additive.

Menu » Color Requests		Queue Pending Certified		
Batch #	Color Additive			
<input type="text"/>	<input type="text"/>	<input type="button" value="Filter"/>		
<< Previous		record 1 to 20 of 35	page 1 2 all pages	Next >>
Batch #	Color Additive	Weight (kgs)	Fee	Date
XXXX-1	D&C GREEN No. 5	750	\$578.81	01/24/06
G3ALT	D&C RED No. 6 LAKE	900	\$694.57	01/20/06
ASDF1	D&C ORANGE No. 5 LAKE	123	\$224.00	01/17/06
ASDF	D&C RED No. 27 LAKE	100	\$224.00	01/11/06

Figure 14 - Color Requests in the Queue

Modifying a Color Request

To modify a color request, click on its Batch # in the queue. You will be taken back to Step 1 for that particular color type (straight, lake, or repack). Go through the steps as you normally would and make any necessary changes, and then re-submit on the confirmation page to update the sample request.


¹ Note that foreign companies must make any changes before their U.S. Agent accepts the sample request; once the Agent accepts responsibility for a sample, even if that sample is still in the queue, it may no longer be modified.

FedEx Tracking Information

[Menu](#) » **FedEx Tracking Information**

Enter New Tracking Information

Please only enter shipping information if you use the FDA's FedEx account to send color samples for testing.

Tracking #:	<input type="text"/>
Date Sent:	<input type="text"/> 

Submit

Figure 15 - FedEx Shipment Information

Select the **FedEx Tracking Information** link on the front page to enter information about your shipments to the FDA. There you can enter in your tracking numbers and the date sent. You do not need to specify which color samples are in each package.

If you have not yet received the FedEx account number, please contact Ray Decker at (301) 436-1148.