



---

## USING SUPAC IR GUIDELINES TO CHANGE OPACODE® INK FORMULATIONS ON PREVIOUSLY APPROVED DRUGS

---

### Major Implications

- In certain situations, manufacturers will be able to make changes in components, composition, site, equipment, or process **WITHOUT PRIOR APPROVAL**.
- Annual reports will be sufficient documentation for *some* changes.
- For component and composition changes, a classification system will be used to establish test documentation required.

### Components and Composition LEVEL 1 Changes

- Level 1 changes are those that are unlikely to have any detectable impact on formulation quality and performance. (**NOTE:** Deletion of a colorant or flavor, or changing the ingredient of a printing ink to another approved ingredient, are considered Level 1 changes).

### What is required to make the change?

- Chemistry: Application/Compendial release requirements and stability testing (One batch on long-term stability with data reported in the annual report)
- Dissolution: **NONE** beyond application/compendial requirements
- In-Vivo Bioequivalence: **NONE**
- Filing: Annual Report (all information including long term stability data)

### What does all this mean?

- SUPAC provides opportunities to change the inks used on previously approved drugs with a minimal amount of work. Inks can be changed to newer formulas with different ingredients for improved performance or increased global acceptability.
- Changes can now be made **WITHOUT** pre-approval. The change only needs to be filed in the annual report.
- **NOTE:** This change cannot be made together with other changes.

### Outside the Scope of the Guidance

- It is recommended you consult CFRs, other CDER guidance's/guidelines, or contact the appropriate CDER review division
  1. for changes not specifically addressed in the SUPAC guidelines.
  2. for multiple changes submitted at one time or over a short period of time.
  3. when the number of batches needed for stability testing is not specified (Level 2 or 3).

**Questions** regarding SUPAC guidelines should be addressed to:

Nancy Seger  
FDA's Center for Drug Evaluation and Research  
Tel: 301-594-5629

**Questions** regarding Colorcon ink formulations should be addressed to:

Colorcon  
Technical Services Dept.  
Tel: 215-699-7733  
Fax: 215-661-2505



## March 2008

---

### World Headquarters

Colorcon

415 Moyer Blvd., P.O. Box 24, West Point, PA 19486-0024

Tel: 215-699-7733 Fax: 215-661-2605 Website: [www.colorcon.com/pharma](http://www.colorcon.com/pharma)

e-mail: [info@colorcon.com](mailto:info@colorcon.com)

---

Locations	Telephone	Facsimile	Locations	Telephone	Facsimile
<i>United States</i>			<i>Asia/Pacific</i>		
Santa Ana, California	714-549-0631	714-549-4921	Singapore	65-6438-0318	65-6438-0178
Indianapolis, Indiana	317-545-6211	317-545-6218	Fuji-gun, Shizuoka, Japan	81-5-4465-2711	81-5-4465-2730
Humacao, Puerto Rico	787-852-3815	787-852-0030	Shanghai, China	86-21-5442-2222	86-21-5442-2229
Stoughton, Wisconsin	608-887-8970	608-887-8984	Goa, India	91-832-288-3434	91-832-288-3440
<i>Canada</i>			Gyeonggi-do, Korea	82-31-296--2173	82-31-296-2178
St. Laurent, QC, Canada	514-337-8341	514-337-9159	<i>Latin America</i>		
<i>Europe</i>			Buenos Aires, Argentina	54-11-4552-1565	54-11-4552-3997
Dartford, Kent, England	44-1322-293000	44-1322-627200	Cotia, Brasil	55-11-4612-4262	55-11-4612-3307
Massey, France	33-1-6447-9750	33-1-6932-5983	Bogota, Colombia	571-418-1202	571-418-1257
Idstein, Germany	49-6126-9961-0	49-6126-9961-11	Caracas, Venezuela	58-212-237-9842	58-212-238-2259
Gallarate, Italy	39-0331-776932	39-0331-776831	Santa Fe, México	52-55-3000-5700	52-55-3000-5701 /02
Budapest, Hungary	36-1-200-8000	36-1-200-8010			
Istanbul, Turkey	90-216-465-0360	90-216-465-0361			
Barcelona, Spain	34-9-3589-3756	34-9-3589-3792			

The information contained herein, to the best of our knowledge is true and accurate. Any recommendations or suggestions are made without warranty or guarantee, since the conditions of use are beyond our control. Any information contained herein is intended as a recommendation for use of our products so as not to infringe on any patent.