



REGULATORY SUBMISSIONS

United States Drug Master Files

- Colorcon maintains the following US Type IV Drug Master Files:
 - No. 721: Formulated Systems - Opadry[®], Opadry[®] II, Opadry[®] AMB, Opadry[®] ns-g, Opaglos[®] 2, Coateric[®], Sureteric[®], Opacode[®], Opalux[®], Opaspray[®] and others.
 - No. 967: Phthalavin[®] (Polyvinyl Acetate Phthalate)
 - No. 9822: Surelease[®]
 - No. 2948: Lake Blends, Pigment Blends
 - No. 20329: StarCap 1500[®]
 - **NOTE:** Starch 1500[®] products and High Tint lakes (HT[®]) are considered well characterized single component products and as such are not included in a DMF. They are covered by NF monographs or 21 CFR.
- DMF's are held by the FDA and contain quantitative formula information, raw material grades, facilities plans and general manufacturing information (i.e. equipment list, basic process and adjustment description, etc.).
- Type IV DMF's are totally confidential and have no "open" part that can be reviewed by parties other than the FDA.
- Customers may request a reference to a DMF for particular formulas. When a reference is requested, a letter is generated to the FDA authorizing the FDA, on behalf of that particular customer, to assess those particular formulas during NDA and ANDA reviews. A copy of the letter to the FDA, with a cover letter, is faxed and mailed to the customer. If the request is for a formula that is not currently in the DMF, the formula will be submitted to the FDA with the reference letter.
- If a formula is changed or amended in the DMF, customers that have received permission to reference that formula will be notified and given a letter of reference to the amended page.
- Letters of reference do not expire and updating them is not necessary. They are not specific to a particular drug application and can be used for any submission that utilizes the product.
- DMF reference letters may be requested by contacting Regulatory Affairs by phone, e-mail, letter or the Regulatory Request System at Colorcon's Internet site. When making a request, the customer's name, address, phone number, fax number, contact person and formula number(s) are required.
- Formulae that contain ingredients not acceptable for drug use in the U.S. are not normally included in the DMF. International formulations developed at other Colorcon sites may be included in the U.S. DMF if the product contains ingredients that can be used in the U.S.

Canadian Drug Master File

- Colorcon maintains the following Canadian Type III Drug Master Files:
 - No. PR-MF-6836: Formulated Systems
 - No. DMF-2006-006: Surelease[®]
 - No. DMF-2007-068: StarCap 1500[®]
- The Canadian Drug Master File works similarly to the U.S. DMF except that Colorcon must pay a \$50 CAD fee for each formula referenced.
- Letters of reference may be requested in the same manner as above.

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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

e-mail: 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.

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