



Regulatory Information Sheet

Regulatory Submissions

United States Drug Master Files (DMFs)

Colorcon maintains several U.S. DMFs that cover a wide range of Colorcon products. Some Colorcon DMFs apply to various product lines and some are specific to one product or product line.

Colorcon U.S. Type IV Drug Master Files	
No. 721	Formulated Coating Systems
No. 967	Phthalavin (polyvinyl acetate phthalate)
No. 9822	Surelease [®] Aqueous Ethylcellulose Dispersion
No. 2948	Lake Blends and Pigment Blends
No. 29329	StarCap 1500 [®] Co-Processed Starch Excipient

Note: Starch 1500[®] Partially Pregelatinized Maize Starch products and FD&C and D&C lakes are considered well characterized single component products and as such are not included in a DMF. These products are covered by compendial monographs or 21 CFR.

DMFs 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.). Products that contain ingredients not acceptable for drug use in the U.S. are not included in the DMF. U.S. DMFs are totally confidential and have no “open” part that can be reviewed by parties other than the FDA.

Customers preparing U.S. drug applications (NDA or ANDA) may request a letter of authorization to reference a Colorcon DMF for specific Colorcon products. When a letter of authorization is requested, Colorcon prepares a letter to the FDA authorizing the FDA, on behalf of that particular customer, to reference Colorcon’s DMF to assess the specific products included in the letter during NDA and ANDA reviews. A copy of the letter sent to FDA is provided to the customer for inclusion in their U.S. regulatory filings. Letters of authorization do not expire and updating them is not necessary. They are not specific to a particular drug product and can be used for any submission that utilizes the Colorcon product(s) referred to in the letter.

If information contained in the DMF is amended, customers that have received authorization to reference that information in the DMF in the past will be notified and a new letter of authorization referring to the amended information page will be sent to the FDA.

DMF reference letters may be requested by contacting Regulatory Affairs by or via the on-line request system on Colorcon’s web site.

Canadian Drug Master File

Colorcon also maintains several Canadian DMFs that cover various Colorcon products.

Colorcon Canadian Type III Drug Master Files	
No. PR-MF-6836	Formulated Systems
No. DMF-2006-006	Surelease [®] Aqueous Ethylcellulose Dispersion
No. DMF-2007-068	StarCap 1500 [®] Co-Processed Starch Excipient

The Canadian DMF system works similarly to the U.S. DMF system except that Colorcon must pay Health Canada a \$50 CAD administrative fee for each Colorcon product included in referenced in a letter of authorization.

Letters of authorization for Canadian DMFs may be requested in the same manner as described above for U.S. DMFs.

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.

The information contained in this document is proprietary to Colorcon, Inc. and may not be used or disseminated inappropriately.

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