

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-076

ENVIRONMENTAL ASSESSMENT

1.3.1.8 ENVIRONMENTAL ASSESSMENT**Request for Categorical Exclusion**

In accordance with 21 CFR §25.1, this section provides the environmental assessment for Locoid® (hydrocortisone butyrate) Lotion, 0.1%. The action requested is a claim of categorical exclusion as provided for in the July 1998 "Guidance for Industry: Environmental Assessment of Human Drug and Biologics Applications" which states that "... NDAs, abbreviated applications, and supplements to such applications [are categorically excluded] if FDA's approval of the application increases the use of the active moiety, but the estimated concentration of the substance at the point of entry into the aquatic environment will be below 1 part per billion (ppb)"

The requested action for approval of this application meets the requirements for categorical exclusion from preparation of an environmental assessment in accordance with 21 CFR §25.31(b) and, to the best of the applicant's knowledge, no extraordinary circumstances exist (21 CFR §25.15(d)). The request for exclusion is based on a calculation that was performed to show that the estimated concentration of the new drug substance, hydrocortisone butyrate, at the point of entry into the aquatic environment will be below 1 part per billion (1 ppb). The assumptions and conclusion of this evaluation are outlined in the table below.

Information regarding sales projections and the calculation of the Expected Introduction Concentration (EIC), if divulged, would provide competitors confidential information on the projected market share of the drug product. Accordingly, the information provided in this section is claimed as confidential and not for public disclosure.

U.S. Market Projections for Locoid® (hydrocortisone butyrate) Lotion, 0.1%

Year	Qty. 2 oz. Bottles	Qty. 4 oz. Bottles	Total Bulk Drug Product (Kg)	Total Drug Substance (Kg)
2007				
2008				
2009				
2010				
2011				

b(4)

Calculation

EIC-Aquatic (ppb) = A x B x C x D where:

b(4)

b(4)

Conclusion

Since the potential introduction concentration is far less than this product qualifies for a Tier 0 approach and categorical exclusion from preparation of an environmental assessment.

b(4)

Excipients

Butylated Hydroxytoluene NF (CAS: 128-37-0)
Butylparaben NF (CAS: 94-26-8)
Ceteth-20 (CAS: 9004-95-9)
Cetostearyl Alcohol NF (CAS: 8005-44-5)
Citric Acid USP, Anhydrous (CAS: 77-92-9)
Light Mineral Oil NF (CAS 8012-95-1)
White Petrolatum USP (CAS 8009-03-8)
Propylparaben NF (CAS: 94-13-3)
Safflower Oil USP (CAS: 8001-23-8)
Sodium Citrate USP, Dihydrate (CAS: 6132-04-3)
Purified Water USP (CAS: 7732-18-5)