

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**22-129**

**PROPRIETARY NAME REVIEW(S)**



**Department of Health and Human Services  
Public Health Service  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Surveillance and Epidemiology**

Date: March 4, 2009

To: Susan Walker, MD, Director  
Division of Dermatology and Dental Products

Thru: Kristina C. Arnwine, PharmD, Team Leader  
Denise P. Toyer, PharmD, Deputy Director  
Carol A. Holquist, RPh, Director  
Division of Medication Error Prevention and Analysis

From: Loretta Holmes, BSN, PharmD, Safety Evaluator  
Division of Medication Error Prevention and Analysis

Subject: Proprietary Name Review

Drug Name: (b) (Benzyl Alcohol) Lotion  
5%

Application Type/Number: NDA 22-129

Applicant: Sciele Pharma, Inc.

OSE RCM #: 2008-1128

**\*\*\* Note: This review contains proprietary and confidential information that should not be released to the public.\*\*\***

**21 pages of (b4) CCI/TS information  
was withheld after this page.**

-----  
**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
-----

/s/

-----  
Loretta Holmes  
3/4/2009 02:28:42 PM  
DRUG SAFETY OFFICE REVIEWER

Denise Toyer  
3/4/2009 03:33:25 PM  
DRUG SAFETY OFFICE REVIEWER

Carol Holquist  
3/4/2009 03:57:45 PM  
DRUG SAFETY OFFICE REVIEWER



**Department of Health and Human Services  
Public Health Service  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Surveillance and Epidemiology**

Date: July 3, 2008

To: Susan Walker, MD, Director  
Division of Dermatology and Dental Products (HFD-540)

Thru: Linda Y. Kim-Jung, PharmD, Team Leader  
Denise P. Toyer, PharmD, Deputy Director  
Carol A. Holquist, RPh, Director  
Division of Medication Error Prevention (HFD-420)

From: Loretta Holmes, BSN, PharmD, Safety Evaluator  
Division of Medication Error Prevention (HFD-420)

Subject: Division of Medication Error Prevention  
Proprietary Name Review

Drug Name: (b) (4)  
(Benzyl Alcohol) Lotion  
5%

Application Type: NDA 22-129

Applicant: Sciele Pharma, Inc.

OSE RCM #: 2008-463

**\*\*\* Note: This review contains proprietary and confidential information that should not be released to the public.\*\*\***

**16 pages of (b4) CCI/TS information was withheld after this page.**

-----  
**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
-----

/s/  
-----

Linda Kim-Jung  
7/3/2008 12:52:18 PM  
DRUG SAFETY OFFICE REVIEWER  
Also signing for Loretta Holmes.

Denise Toyer  
7/7/2008 10:12:16 AM  
DRUG SAFETY OFFICE REVIEWER

Carol Holquist  
7/9/2008 05:43:24 PM  
DRUG SAFETY OFFICE REVIEWER