

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-129

APPROVAL LETTER



NDA 22-129

NDA APPROVAL

Sciele Pharma, Inc.
Attention: Debra A. Hayes, RAC
Manager Regulatory Affairs
Five Concourse Parkway, Suite 1800
Atlanta, GA 30328

Dear Ms. Hayes:

Please refer to your new drug application (NDA) dated June 15, 2007, received June 15, 2007, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for TRADENAME (benzyl alcohol) Lotion, 5%.

We acknowledge receipt of your submissions dated July 19, August 31, September 17, September 21, September 28, October 12, November 19, November 26, December 10, December 12 and December 28, 2007; January 25, February 5, March 4, March 19, March 27, April 14, April 30, May 23, June 5, June 18, July 1, July 10, July 28, August 27, September 18, October 17, December 9, December 11, and December 29, 2008; February 10, March 30, and April 7, 2009.

The October 17, 2008 submission constituted a complete response to our July 14, 2008 action letter.

This new drug application provides for the use of TRADENAME (benzyl alcohol) Lotion, 5%, for the topical treatment of head lice infestation in patients 6 months of age and older.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling (text for the package insert, text for the patient package insert, and text for Patient Instructions). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 22-129."

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*.

Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 22-129.**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

PROPRIETARY NAME

If you intend to have a proprietary name for this product we recommend that you submit a request for a proposed proprietary name review. (See the draft Guidance for Industry, *Complete Submission for the Evaluation of Proprietary Names*, <http://www.fda.gov/cder/guidance/7935dft.pdf> and “PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 through 2012.”)

ADVISORY COMMITTEE

NDA 22-129 was not presented to the Dermatology and Ophthalmology Drugs Advisory Committee because the systemic exposure to benzyl alcohol following topical treatment with TRADENAME (benzyl alcohol) Lotion, 5%, was low and no concerning safety signals were documented. Benzyl alcohol is an active ingredient that can be marketed for over-the-counter use under a monograph and is an excipient in approved drug products including solutions for intravenous administration.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for age 0 to 1 month because the necessary studies would be impossible or highly impracticable. This is because there are too few children with the condition to study. We are also waiving the pediatric study requirement for ages 1 to 6 months because the product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in this age group and is not likely to be used in a substantial number of pediatric patients in this group. Head lice infestation is not prevalent in children younger than six months of age and the standard treatment for children that age is to shave the head.

We note that you have fulfilled the pediatric study requirement for ages 6 months to 18 years for this application.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

Please submit one market package of the drug product when it is available.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

MEDWATCH-TO-MANUFACTURER PROGRAM

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at www.fda.gov/medwatch/report/mmp.htm.

If you have any questions, call Nichelle Rashid, Regulatory Project Manager, at (301) 796-3904.

Sincerely,

{See appended electronic signature page}

Julie Beitz, M.D.
Director
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosures

Content of Labeling
Carton and Container Labels