

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-717

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-717

ZARS, Inc.
1142 West 2320 South
Salt Lake City, UT 84119

Attention: Patricia J. Richards
Vice President, Regulatory Affairs

Dear Ms. Richards:

Please refer to your new drug application (NDA) dated November 14, 2003, received November 17, 2003, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for TRADENAME (lidocaine and tetracaine) 7%/7% Cream.

We acknowledge receipt of your submissions dated March 15, June 15, July 9, September 7, 10, 13, 14, and 15, 2004, April 18, and December 30, 2005, February 15, March 15, 21, and 31, May 17, 25, 26, and 30, June 8, 21, 23, and 27, 2006.

The December 30, 2005, submission constituted a complete response to our September 15, 2004, action letter.

This new drug application provides for the use of TRADENAME (lidocaine and tetracaine) 7%/7% Cream for use on intact skin in adults to provide topical local analgesia for superficial dermatological procedures such as dermal filler injection, pulsed dye laser therapy, facial laser resurfacing, and laser-assisted tattoo removal.

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

An expiration dating period of 24 months is granted for this product when stored at 2-8°C.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert, and immediate container and carton labels submitted June 27, 2006. Marketing the product with the FPL that is not identical to the approved labeling text may render the product misbranded and unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-717.**" Approval of this submission by FDA is not required before the labeling is used.

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. Submit any proprietary name to the Agency for our review prior to its implementation.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

We remind you of your agreement to address the following issues listed in your amendment dated September 10, 2004.

1. You will reevaluate the drug release specifications once data from multiple commercial batches are available during the first year of production.
2. You will provide the data on three validation batches demonstrating the correlation between assay homogeneity of the bulk drug product before it is packaged into  tubes with assay data on finished tubes to support the adequacy of assay testing only on the bulk drug product.
3. You will provide additional specifications if the data does not demonstrate the above correlation.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly 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

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

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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

If you have any questions, call Pratibha Rana, M.S., Regulatory Project Manager, at (301) 796-1277.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Director
Division of Anesthesia, Analgesia
and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

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

/s/

Bob Rappaport
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