DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-114 **NDA APPROVAL**

Anesiva, Inc.
650 Gateway Blvd.
South San Francisco, CA 94080

Attention: Carol Zoltowski, V.M.D.
Senior Director and Head of Regulatory Affairs

Dear Dr. Zoltowski:

Please refer to your new drug application (NDA) dated November 21, 2006, received November 24, 2006, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Zingo™ (lidocaine hydrochloride monohydrate) powder intradermal injection system, 0.5 mg.

We acknowledge receipt of your submissions dated January 4, March 2 and 12, April 13, May 7 and 17, June 15 and 22, July 20 and 24, and August 14 and 16, 2007.

This new drug application provides for the use of Zingo™ (lidocaine hydrochloride monohydrate) powder intradermal injection system for use on intact skin to provide topical local analgesia prior to venipuncture or peripheral intravenous cannulation in children 3-18 years of age.

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 enclosed agreed-upon labeling text and with the minor editorial revisions indicated in the enclosed labeling.

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 package insert). 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 22-114**."

Carton, Pouch, and Immediate Container Labels

Submit final printed carton, pouch, and immediate container labels that are identical to the enclosed carton, pouch, 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, Pouch, and Container Labels for approved NDA 22-114**." Approval of this submission by FDA is not required before the labeling is used.

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

Pediatric Research Equity Act (PREA)

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 are waiving the pediatric study requirements for birth to 3 years of age. We note that you have fulfilled the pediatric study requirement for ages 3 through 16 years for this application.

Promotional Materials

You may request advisory comments on proposed introductory advertising and promotional labeling. If you choose 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 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.

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
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

Stability/Shelf-Life

An expiration dating period of 24 months is granted for Zingo™.

Reporting Requirements

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, contact Geri Smith, Regulatory Project Manager, at geri.smith@fda.hhs.gov or (301) 796-2204.

Sincerely,

{See appended electronic signature page}

Sharon Hertz, M.D.
Deputy Director
Division of Anesthesia, Analgesia and
Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures: Package Insert
Immediate Container Label
Pouch Label
Carton Label

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

/s/

Sharon Hertz

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