

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-211

APPROVAL LETTER



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22-211

NDA APPROVAL

Sirion Therapeutics, Inc
Attention: Jeremy Brace
Vice President, Regulatory Affairs
9314 E Broadway Avenue
Tampa, FL 33619

Dear Mr. Brace:

Please refer to your new drug application (NDA) dated November 14, 2008, received November 17, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zirgan (ganciclovir ophthalmic gel) 0.15%.

We acknowledge receipt of your submissions dated January 6, February 2, 3, 5, and 19, March 19 and 25, June 24, August 6 and 31, and September 10 (two), 2009.

This new drug application provides for the use of Zirgan (ganciclovir ophthalmic gel) 0.15% for the treatment of acute herpetic keratitis (dendritic ulcers).

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.

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, submitted September 10, 2009. 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 22-211."

We acknowledge your September 10, 2009, submission containing final printed carton and container labels.

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels submitted September 10, 2009, 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 22-211.**" 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.

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. This drug product for this indication has an orphan drug designation, and therefore, you are exempt from this requirement.

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 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, 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 <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

In addition, we request that you submit one copy of the introductory promotional materials you propose to use for this product to this division. Please submit one market package of the drug product when it is available.

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 12B-05
5600 Fishers Lane
Rockville, MD 20857

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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 Lori Marie Gorski, Regulatory Project Manager, at (301) 796-0722.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Acting Director
Division of Anti-Infective and Ophthalmology
Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Package Insert, Carton and Container labels

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-22211

ORIG-1

SIRION
THERAPEUTICS

ZIRGAN (GANCICLOVIR
OPHTHALMIC GEL)0.15%

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

/s/

WILEY A CHAMBERS
09/15/2009