DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-810/S-001
NDA 50-810/S-002
NDA 50-810/S-005

Inspire Pharmaceuticals, Inc.
Attn: Kimberly A. Davis
Director, Regulatory Affairs
4222 Emperor Blvd., Suite 200
Durham, NC 27703

Dear Ms. Davis:

Please refer to your supplemental new drug applications submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Azasite (azithromycin ophthalmic solution) 1%:

S-001 dated April 14, 2008, received April 15, 2008
S-002 dated April 17, 2008, received April 18, 2008
S-005 dated May 23, 2008, received May 27, 2008

These applications are subject to the exemption provisions of section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

Your submission of October 29, 2008, constituted a complete response to our August 29, 2008, action letter.

Supplement 001 provides for minor changes to the package insert and for revised carton and container labeling. These changes reflect a change in the manufacturing information from Cardinal Health to Catalent Pharma Solutions, LLC.

Supplement 002 provides for the addition of a new Azasite 0.65 mL professional sample, for carton and container labeling for the 0.65 mL professional sample, and a patient instruction leaflet to be added to the cartons of the commercial and professional sample presentations.

Supplemental 005 provides for a patient instruction leaflet to be added to the cartons of the commercial and professional sample presentations.

We have completed the review of your applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text

Within 21 days of the date of this letter, submit 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 in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, designate these submissions "**SPL for approved supplement NDA 50-810/S-001, S-002 and S-005**." Approval of these submissions by FDA are not required before the labeling are used.

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 these submissions "**FPL for approved supplements NDA 50-810/S-001, S-002, and S-005**." Approval of is these submissions by FDA are not required before the labeling are used.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert, text for the patient instruction leaflet, and immediate container and carton labels submitted October 29, 2008.

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 the Division of Anti-Infective and Ophthalmology Products and two copies of both the promotional materials and the package inserts 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

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

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

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

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 Raphael R. Rodriguez, Regulatory Project Manager, at (301) 796-0798.

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:

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

/s/

Wiley Chambers

5/6/2009 01:08:00 PM