DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-310/S-011

U.S. Surgical\ Tyco Healthcare
Attn: Daniel Campion
Regulatory Affairs Associate II
150 Glover Ave
Norwalk, CT 06856

Dear Mr. Campion:

Please refer to your new drug application (NDA) dated May 10, 2007, received May 11, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lymphazurin 1% (Isosulfan Blue).

We acknowledge receipt of your submissions dated May 10, June 5, October 16 and 22, 2007.

This "Changes Being Effected" supplemental new drug application provides for changes to the Warnings and Precautions section of the labeling as referenced in the FDA clinical facsimile of April 11, 2007.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions indicated in the enclosed labeling.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling. These revisions are terms of the approval of this application.

Please submit an electronic version of the FPL (PLR-SPL format) 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 supplement NDA 18-310/S-011**." Approval of this submission by FDA is not required before the labeling is used.

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 requirement for this application.

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

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 Ms. Thuy Nguyen, M.P.H., Regulatory Health Project Manager, at (301) 796-2050.

Sincerely,
{See appended electronic signature page}
Rafel Dwaine Rieves, M.D.
Acting Division Director
Division of Medical Imaging
and Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure: Labeling

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

/s/

Rafel Rieves

10/29/2007 04:18:03 PM