DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-305/SLR-010

Draxis Specialty Pharmaceutical, Inc.
Attention: Charles Vachon
Senior Manager, Regulatory Affairs
167 Autoroute TransCanada Highway
Kirkland, Quebec Canada, H9H 4J4

Dear Mr. Vachon:

Please refer to your supplemental new drug application dated May 2, 2006, received May 3, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Name of Drug Product: Sodium Iodide I 131 Capsule USP, Diagnostic-Oral.

This "Changes Being Effected" supplemental new drug application provides for the relocation of the color band on the vial labels and the addition of a conversion table on the approved calendar.

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.

The final printed labeling (FPL) must be identical to the submitted labeling (immediate container and carton labels and color coded calendar submitted May 2, 2006).

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 supplement NDA 21-305/S-010**." Approval of this submission by FDA is not required before the labeling is used.

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

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. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

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 Renee Tyson, Regulatory Project Manager, at (301) 796-1476.

Sincerely,

{See appended electronic signature page}

George Q. Mills, M.D., M.B.A.
Director
Division of Medical Imaging and Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

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

/s/

George Mills
10/23/2006 10:56:09 AM