DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-484/S-013 **SUPPLEMENT APPROVAL**

Celgene Corporation
Attention: Penny Ng, BSc, MBA, RAC
Manager, Regulatory Affairs
9900 West 109th Street, Building 70, Suite 300
Overland Park, KS 66210

Dear Ms. Ng:

Please refer to your supplemental new drug application dated December 10, 2009, received December 11, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Innohep® (Tinzaparin Sodium, Injection).

This "Prior Approval" supplemental new drug application provides for revisions to the boxed warning of your package insert

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon package insert text, which is identical to the content of package insert [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format submitted on December 10, 2009.

PROMOTIONAL MATERIALS

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at 301-847-8444:

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

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. 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.

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
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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 questions, contact Marcus Cato, Regulatory Project Manager, at (301) 796-3903.

Sincerely,

{See appended electronic signature page}

Rafel (Dwaine) Rieves, MD
Director
Division of Medical Imaging and Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20484	SUPPL-13	CELGENE CORP	INNOHEP(TINZAPARIN SODIUM)INJ 10,000IU/M

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

/s/

RAFEL D RIEVES
12/23/2009