UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

January 18, 2008

Docket No. 030-37578 License No. 37-31286-01
Control No. 141323

Elliott Gruskin
V.P. Biomaterials
Synthes Biomaterials, Inc.
1230 Wilson Drive
West Chester, PA 19380

SUBJECT: SYNTHES BIOMATERIALS, INC., NEW LICENSE, CONTROL NO. 141323

Dear Mr. Gruskin:

This refers to your request for an NRC license. Enclosed with this letter is the license. Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

When submitting future license amendments, please have the document signed by a management representative rather than the Radiation Safety Officer. The NRC views a letter signed by a management representative as indication that management has reviewed the application and concurs in the statements and representations contained therein. In addition, please note that NRC Form 313 requires the applicant, by signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or a certifying official of the licensee rather than a consultant.

The NRC is required to have your Taxpayer Identification Number in order to make payments (refunds). The self-addressed, stamped NRC Form 531, "Request for Taxpayer Identification Number," is enclosed.

The NRC expects licensees to conduct their programs with meticulous attention to detail and high standards of safety and compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NRC requirements, you must conduct your program according to NRC regulations, the conditions of your NRC license, and the representations made in your application. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify the NRC in writing of any change in mailing address.

3. In accordance with 10 CFR 30.36(d), notify the NRC, promptly, in writing, and request termination of the license

   a) when you decide to terminate all activities involving materials authorized under the license; or

   b) if you decide not to acquire or possess and use authorized material.

4. Request and obtain a license amendment before you:

   a) change Radiation Safety Officers;

   b) order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license; or

   c) add or change the areas of use, or addresses of use identified in the license application or on the license; or

   d) change the name or ownership of your organization.

5. Submit a complete renewal application or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations.

You will be periodically inspected by the NRC. Failure to conduct your program safely and in accordance with NRC regulations, license conditions, and the representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, imposition of a civil penalty, or an order suspending, modifying or revoking your license.

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material;** then **Regulations, Guidance, and Communications.** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

Thank you for your cooperation.

Sincerely,

Original signed by Elizabeth Ullrich

Betsy Ullrich
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
1. NRC Form 531
2. License No. 37-31286-01

cc:
Meredith Hans, Ph.D., Radiation Safety Officer

DOCUMENT NAME: C:\FileNet\ML080290130.wpd

SUNSI Review Complete: LRoldán

After declaring this document "An Official Agency Record" it **will** be released to the Public.

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DATE	01/18/08		01/18/08					

OFFICIAL RECORD COPY

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Synthes Biomaterials, Inc	3. License number 37-31286-01
2. 1230 Wilson Drive West Chester, Pennsylvania 19380	4. Expiration date January 31, 2018
	5. Docket No. 030-37578 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Hydrogen 3	A. Any	A. 100 millicuries
B. Carbon 14	B. Any	B. 50 millicuries
C. Phosphorus 32	C. Any	C. 25 millicuries
D. Sulfur 35	D. Any	D. 25 millicuries
E. Iodine 125	E. Any	E. 25 millicuries

9. Authorized use:

A. Through E. Research and development as defined in 10 CFR 30.4.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 1230 Wilson Drive, West Chester, Pennsylvania.

11. Licensed material shall be used by, or under the supervision of, Meredith Hans, Ph.D. License material listed in items A through D shall be used by, or under the supervision of Doug Buechter, Ph.D. and Melissa Brow. License material listed in item A shall be used by, or under the supervision of Lisa Hughes, Ph.D. and Shane Woods.

12. The Radiation Safety Officer for this license is Meredith Hans, Ph.D.

13. The licensee shall not use licensed material in or on human beings.

License Number
37-31286-01

Docket or Reference Number
030-37578

MATERIALS LICENSE
SUPPLEMENTARY SHEET

14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    A. Application dated November 11, 2007 [ML073241232]
    B. Facsimile dated January 8, 2008 [ML080110156]

For the U.S. Nuclear Regulatory Commission

Date January 18, 2008

By ***Original signed by Elizabeth Ullrich***

Elizabeth Ullrich
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406