

## MATERIALS LICENSE

Amendment No. 05

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.

OFFICIAL RECORD COPY

Licensee		In accordance with the letter dated July 22, 1996,	
1. Genzyme Corporation		3. License Number 20-28072-01 is amended in its entirety to read as follows:	
2. Genzyme Tissue Repair Division 64 Sidney Street Cambridge, Massachusetts 02139-4136		4. Expiration Date July 31, 2003	
		5. Docket or Reference No. 030-30124	
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. 50 millicuries	
D. Phosphorus 33	D. Any	D. 50 millicuries	
E. Sulfur 35	E. Any	E. 150 millicuries	
F. Iodine 125	F. Any	F. 50 millicuries	
9. Authorized use			
A. through F. Research and development as defined in 10 CFR 30.4.			

## CONDITIONS

10. Licensed material may be used only at the licensee's facilities at 64 Sidney Street, Cambridge, Massachusetts.
11. A. Licensed material shall be used by, or under the supervision and in the physical presence of individuals who have received the training described in application dated August 21, 1992 and have been approved in writing by the Radiation Safety Officer. The license shall maintain records of individuals designated as users for three years following the last use of licensed material by the individual.
- B. The Radiation Safety Officer for this license is Richard Mattila.
12. Licensed material shall not be used in or on human beings.
13. Radioactive waste generated under this license shall be stored in accordance with the statements, representations, and procedures included with the licensee's waste storage plan described in the licensee's letter dated May 21, 1993.

MATERIALS LICENSE  
SUPPLEMENTARY SHEET

License Number

20-28072-01

Docket or Reference Number

030-30124

Amendment No. 05

14. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days and sulfur-35 for decay-in-storage before disposal in ordinary trash, provided:
- A. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.
  - B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
  - C. A record of each such disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
15. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
16. 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 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 August 21, 1992
  - B. Letter dated May 21, 1993
  - C. Letter dated February 1, 1995
  - D. Letter dated May 2, 1995

Date

AUG 14 1996

For the U.S. Nuclear Regulatory Commission

Original Signed By:

John D. Kinneman

By

Nuclear Materials Safety Branch  
Region I

King of Prussia, Pennsylvania 19406

AUG 14 1996

Gary C. du Moulin, M.P.H., Ph.D.  
Director, Quality Systems  
Genzyme Corporation  
Genzyme Tissue Repair Division  
64 Sidney Street  
Cambridge, MA 02139-4136

Dear Dr. du Moulin:

This refers to your license amendment request. Enclosed with this letter is the amended license. Please note that as part of this amendment, in accordance with 10 CFR 30.36, effective February 15, 1996, the expiration date of your license has been extended by a period of five years. The new expiration date is stated in Item 4 of the license.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Thank you for your cooperation.

Sincerely,

**Original Signed By:**  
**John D. Kinneman**

John D. Kinneman, Chief  
Nuclear Materials Safety Branch 2  
Division of Nuclear Materials Safety

License No. 20-28072-01  
Docket No. 030-30124  
Control No. 123505

Enclosure:  
Amendment No. 05

DOCUMENT NAME: R:\WPS\MLTR\L2028072.01

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI	N				
NAME	SLodhi		J Kinneman					
DATE	08/01/96		08/2/96		08/ /96		08/ /96	

OFFICIAL RECORD COPY

ML 10

genzyme  
*tissue repair*

GENZYME CORPORATION  
64 SIDNEY STREET  
CAMBRIDGE, MA 02139-4136  
TEL 617-494-8484  
FAX 617-494-6561

22 July 1996

030-30124

License No. 20-28072-01

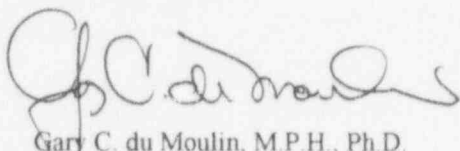
U.S. Nuclear Regulatory Commission  
Region I  
475 Allendale Road  
King of Prussia, PA 19406

Gentlemen:

Genzyme Corporation hereby requests amendment to License Number 20-28072-01 to reflect the impending departure of Olaniyi Kehinde, who is currently the Radiation Safety Officer on this license. We propose the responsibility of Radiation Safety Officer for this research and development license be assumed by Richard Mattila, the existing Radiation Safety Officer on license No 20-20334-01, the main Genzyme license. This license will continue to be operated as a separate entity with no change in operating procedures, but Mr. Mattila, who is responsible for all health and safety at Genzyme, will oversee the radiation safety issues here as he does for the rest of the company.

Enclosed is a check for \$610.00 covering the amendment fee under Category 3M in 10 CFR Part 170. Please contact F.X. Masse at 617-253-9217 if you have any questions.

Very Truly Yours,



Gary C. du Moulin, M.P.H., Ph.D.  
Director,  
Quality Systems



Richard Mattila, M.S.  
Radiation Safety Officer  
Genzyme Corporation

Attachments

OFFICIAL RECORD COPY

ML 10

123505

JUL 29 1996

(FOR LFMS USE)  
INFORMATION FROM LTS  
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ETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM  
AND  
REGIONAL LICENSING SECTIONS

PROGRAM CODE: 03620  
STATUS CODE: 0  
FEE CATEGORY: 3M  
EXP. DATE: 20030731  
FEE COMMENTS: -----  
DECOM FIN ASSUR REQD: N  
.....

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED  
APPLICANT/LICENSEE: GENZYME CORPORATION  
RECEIVED DATE: 960729  
DOCKET NO: 3030124  
CONTROL NO.: 123505  
LICENSE NO.: 20-28072-01  
ACTION TYPE: AMENDMENT

2. FEE ATTACHED  
AMOUNT: \$ 610.00  
CHECK NO.: 033903

3. COMMENTS

SIGNED M. A. Perkins  
DATE 7/31/96

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED 1)

1. FEE CATEGORY AND AMOUNT: 3M 9610

2. CORRECT FEE PAID- APPLICATION MAY BE PROCESSED FOR:  
AMENDMENT ✓  
RENEWAL \_\_\_\_\_  
LICENSE \_\_\_\_\_

3. OTHER \_\_\_\_\_  
\_\_\_\_\_

SIGNED \_\_\_\_\_  
DATE \_\_\_\_\_

Log	<u>Aug 6</u>
Revised	<u>GENZYME TISSUE REPAIR</u>
Check No.	<u>033903</u>
Amount	<u>4610</u>
Fee Category	<u>3M</u>
Type of Fee	<u>AMD</u>
Date of Fee	<u>8/6/96</u>
By	<u>AB</u>