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

December 8, 2005

Docket No. 03019868 License No. 29-21169-01

Robert J. Broeze, Ph.D.
President
Laureate Pharma, Inc.
201 College Road East
Princeton, NJ 08540-6610

SUBJECT: INSPECTION 03019868/2005001, LAUREATE PHARMA, INC., PRINCETON, NEW JERSEY SITE AND NOTICE OF VIOLATION

Dear Dr. Broeze:

On November 16, 2005, Betsy Ullrich and Dennis Lawyer of this office conducted a safety inspection at the above address of activities authorized by your NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selected examination of representative records. Additional information provided by your staff was reviewed through November 23, 2005. The findings of the inspection were discussed with Mary Joan Hampson-Carlin and Christopher Ulriksen of your organization at the conclusion of the inspection on November 23, 2005.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed that categorizes the violation by severity level. You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

Within the scope of this inspection, one Non-Cited Violation (NCV) of 10 CFR 20.1101(c) was identified. Specifically, your staff indicated that, prior to November 2005, an annual review of the radiation safety program had not been performed since at least 2002. This was a non-repetitive, licensee-identified and corrected violation and is being treated as an NCV in accordance with the Enforcement Policy. If you contest the violation or significance of the NCV, you should provide a response within 30 days of the date of this letter with the basis for your denial, to the United States Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with copies to the Regional Administrator, Region I, and the Director, Office of Enforcement, United State Nuclear Regulatory Commission, Washington, DC, 20555-0001.

Current NRC regulations are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, industrial, and academic uses of nuclear material;** then **toolkit index page.** The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **What We Do, Enforcement,** then **Enforcement Policy.** Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

Your cooperation with us is appreciated.

Sincerely,

Original signed by James P. Dwyer

James P. Dwyer, Chief
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc:
Christopher Ulriksen, Radiation Safety Officer
State of New Jersey

Distribution:
D. J. Holody, RI

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SISP Review Complete: DLawyer
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OFFICE	DNMS/RI	N	DNMS/RI	N	DNMS/RI	N		
NAME	Dlawyer/JPD f/		Eullrich/JPD f/		JDwyer/JPD			
DATE	11/30/2005		11/30/2005		12/8/2005			

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Laureate Pharma, Inc.
Princeton, NJ

Docket No. 030-19868
License No. 29-21169-01

During an NRC inspection conducted on November 16, 2005, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> 10 CFR 30.3 requires, in part, that except for persons exempted, no person shall possess or use byproduct material except as authorized by a specific or general license issued pursuant to Title 10 Chapter 1, Code of Federal Regulations.
>
> Contrary to the above, during the period of June 15 through November 16, 2005, Laureate Pharma, Inc. possessed byproduct material that was not exempt from the requirements for a license and was not authorized by their specific license or by a general license. Specifically, the licensee possessed the following sources:

Source (Manufacturer)	Identifier	Activity in microcuries
Ba-133 (Model NES 358)	S358006-025	273
Ba-133 (Model NES 358)	S8107016-06	257

> This is a Severity Level IV violation. (Supplement VI)

Pursuant to the provisions of 10 CFR 2.201, Laureate Pharma, Inc. is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the

specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated This 8th day of December 2005