ATTACHMENT B

ENHANCED COMPLIANCE MEASURES AND CERTIFICATIONS

After the conduct described in the Information had ceased and prior to entering into the Deferred Prosecution Agreement (the "Agreement"), Genzyme Corporation ("Genzyme") was acquired by the Sanofi Group. Following the acquisition, Genzyme became affiliated with Sanofi US Services Inc. and Sanofi-Aventis U.S. LLC (collectively, "Sanofi US") and Sanofi US subsequently became responsible for the sale, marketing, and promotion of Seprafilm® in the United States. Sanofi US, together with its affiliated company, Genzyme (collectively "Sanofi"), both agree to the provisions set forth in this Attachment to the Agreement ("Attachment").

I. Compliance and Ethics Program

Sanofi US has in place and will maintain a compliance program ("Sanofi NA Compliance Program"), which applies to the United States business operations of Sanofi US and Genzyme. The purpose of the Sanofi NA Compliance Program is to: (a) prevent, detect, and correct violations of law and company policy and procedures; (b) assure the establishment of compliance-related policies and procedures for business operations; (c) assure development of training and other programs designed to educate employees regarding applicable policies, procedures and standards; (d) conduct auditing and monitoring of the effectiveness of applicable policies, procedures and standards; (e) implement a mechanism for internal reporting of questionable or

inappropriate activities to enable timely investigation and resolution; and (f) assure appropriate corrective action is taken to prevent recurrence of misconduct.

The Sanofi NA Compliance Program includes a Compliance Committee, which meets at least quarterly, and a Sanofi NA Compliance Officer (the "Compliance Officer"). The mission of the Compliance Committee includes ensuring the implementation and effectiveness of all components of the Sanofi NA Compliance Program. The Compliance Officer reports to the Global Compliance Officer of the parent company of Sanofi and is responsible for overseeing the administration and implementation of the Sanofi NA Compliance Program. The Compliance Officer also reports at least quarterly on the Sanofi NA Compliance Program operations to, among others, the Compliance Committee. The Compliance Officer has direct access to senior executives vested with the authority to direct and implement compliance-related changes in the organization as necessary. The Compliance Officer has the authority to exercise independent judgment in assessing compliance-related matters. The Compliance Officer has authority to seek advice from independent legal counsel or other outside experts when appropriate. The Compliance Officer is authorized to report issues of any kind directly to officers and directors of Sanofi.

Sanofi US does and will continue to maintain policies and procedures designed to prevent, detect, and correct violations of federal healthcare program requirements and the Federal Food, Drug, and Cosmetic Act ("FDCA") regarding the sale, marketing, and promotion of prescription pharmaceutical products and medical devices, including policies and procedures on the following subjects.

A. Sales Compensation and Incentives

Sanofi US will establish and will maintain policies and procedures that shall (1) be designed to ensure that financial incentives do not inappropriately motivate Seprafilm® sales representatives or their managers to engage in improper promotion, sales, and marketing of Seprafilm®; and (2) include mechanisms, where appropriate, that are designed to exclude from incentive compensation sales that may indicate promotion of an indication that is not within the Food and Drug Administration ("FDA")-approved labeling for Seprafilm® and that would constitute misbranding pursuant to FDA requirements ("Off-Label Promotion").

B. Off-Label Promotion and Unsolicited Medical Information Requests

Sanofi US has in place and will maintain policies that require US Seprafilm® sales representatives to discuss only those product uses that are consistent with the indications on the FDA-approved package labeling and to: (1) forward requests for information about non-FDA approved uses of Seprafilm® to the Medical Affairs Group via a completed Medical Information Request Form signed by the individual making the request, including the individual's full contact information and the question posed, which confirms that the request was unsolicited; or (2) respond to the request via another mechanism in accordance with Sanofi US policy (e.g., provide the medical information number for the physician to call directly, forward an unsolicited email to Medical Affairs).

C. Prohibition on Sales Representative Support of Off-Label Uses

Sanofi US will maintain existing policies, and implement policies to the extent they do not yet exist, that prohibit Seprafilm® sales representatives from providing technical assistance to healthcare professionals, and being present in the operating theatre, during surgical or other medical procedures in which Seprafilm® would likely be used in a way that is inconsistent with Seprafilm's® labeling. This prohibition does not apply when: (1) the procedure is performed as part of a clinical investigation in accord with an Investigational Device Exemption pursuant to 21 C.F.R. § 812, approved by both the FDA and the appropriate institutional review board; and (2) the clinical investigator has determined that the presence of a Seprafilm® sales representative is necessary for the safe and effective use of the device.

D. Activity Relating to Oncology Procedures

Sanofi US has in place and will maintain policies regarding the sale and marketing of Seprafilm® for use in oncology procedures which include the following provisions:

1. Sales representatives may have discussions with oncology specialists and attend oncology surgeries only according to the following provisions.

2. Sanofi US must:

    a) require sales representatives to limit discussion with healthcare professionals to the Indications for Use statement and data that is included in the FDA-approved labeling or that is consistent with such data;

b) require sales representatives to assure that healthcare professionals are apprised of the malignancies Precaution included in the Seprafilm® label;

c) use sales training materials that do not reference adhesion reduction or clinical outcomes related to the use of Seprafilm® in surgeries in the presence of malignancies; and

d) require sales representatives to respond to any requests for data related to adhesion reduction in the presence of malignancies, the impact of Seprafilm® on oncology outcomes and treatments, or the safety of Seprafilm® in the presence of malignancies in accordance with Section I.B.

3. In connection with the sale and marketing of Seprafilm®, Sanofi US will not:

a) permit sales representatives to distribute reprints that discuss adhesion prevention or clinical outcomes related to the use of Seprafilm® in the presence of malignancies. Any future distribution of reprints containing this data by sales representatives will be conducted in accordance with the FDA's Good Reprint Practices;

b) distribute marketing materials, including brochures, speaker decks and webpages, that refer to studies that discuss adhesion prevention or clinical outcomes related to the use of Seprafilm® in the presence of malignancies;

c) make promotional claims about: (i) adhesion reduction in the presence of malignancies; (ii) the impact of Seprafilm® on oncology outcomes and treatments; or (iii) the safety of Seprafilm® in the presence of malignancies;

d) have a commercial presence at oncology congresses or conventions;

e) invite oncology specialists to serve as speakers or attend speaker programs; or

f) conduct promotional speaker programs about the use of Seprafilm® in the presence of malignancies.

4. Sanofi US will conduct the Seprafilm® sale and marketing activity relating to oncology procedures in compliance with federal healthcare program requirements,

the FDCA, and any future approved modifications to the Seprafilm® label, and will consult with the Government prior to changing the policies set forth in Section D.

II. Notice to Healthcare Providers and Entities

Within forty-five (45) days after the Effective Date of the Agreement, Sanofi US shall send, by first class mail, postage prepaid, a notice containing the language set forth below to all institutional healthcare providers within the United States who are known to have purchased Seprafilm® within the year prior to the Effective Date, along with a request that the notice be conspicuously posted in a place where it will be readily observed by surgeons and operating room staff for a period of at least 30 days. This notice shall be dated and shall be signed by the President, North America Pharmaceutical Operations, Sanofi US (the "President"). The body of the notice shall state the following:

PLEASE PROMINENTLY POST THIS NOTICE IN CONSPICUOUS AREA(S) WHERE IT WILL BE READILY OBSERVABLE BY PHYSICIANS AND SURGICAL STAFF

As you may be aware, in April 2011, Genzyme Corporation ("Genzyme") was acquired by the Sanofi Group. As a result of that acquisition, Genzyme became an affiliate of Sanofi US Services Inc. and Sanofi-Aventis U.S. LLC (collectively, "Sanofi US"). Based on the conduct of some Genzyme employees before the acquisition, Genzyme agreed to enter into civil and criminal settlements with the United States of America in connection with the promotion and use of Genzyme's Seprafilm® adhesion barrier, currently marketed and sold by Sanofi US. This letter provides you with additional information about the settlements, explains our commitments going forward, and tells you how to obtain more information about those commitments.

In general terms, before 2011, certain Genzyme sales representatives unlawfully advocated and assisted healthcare providers in converting Seprafilm® adhesion barrier into a slurry for use in minimally invasive surgeries. Seprafilm®

adhesion barrier is not approved by the U.S. Food and Drug Administration ("FDA") for use in laparoscopic surgery. Manufacturers of Class III medical devices such as Seprafilm® adhesion barrier must first demonstrate to FDA's satisfaction that there is a reasonable assurance of safety and effectiveness before the product can be lawfully marketed in the United States. The slurry—a medical device consisting of a suspension of sodium hyaluronate and carboxymethylcellulose—has not been approved by FDA. In addition, before 2011, a Genzyme promotional brochure was misleading because it represented that Seprafilm® was "proven safe and effective" in radical pelvic surgeries based on a study of 14 patients.

To resolve these matters, Genzyme entered into a Deferred Prosecution Agreement ("DPA") with the U.S. Department of Justice and the U.S. Attorney's Office for the Middle District of Florida, in which the United States agreed to discontinue and defer its criminal prosecution of Genzyme for violating the Federal Food, Drug, & Cosmetic Act, subject to certain conditions, including Genzyme's payment of a monetary penalty of over $32.5 million. In addition, the federal government and several individual states alleged that Genzyme's conduct violated their False Claims Acts. To resolve those allegations, Genzyme entered into a separate civil settlement whereby Genzyme agreed to reimburse federal and state healthcare programs an additional $22.2 million. Copies of and more information about these settlements may be found at the following websites:

http://www.justice.gov/civil/current-and-recent-cases

http://www.genzyme.com/Products/Resources-for-Health-Care-Professionals.aspx

As part of the DPA, we pledged to maintain our existing comprehensive compliance program, to undertake certain actions designed to advance compliance with federal healthcare program and FDA requirements, and to make periodic compliance certifications to the Department of Justice. We also agreed to provide this notice to Seprafilm® adhesion barrier purchasers to inform them of the criminal and civil settlements and to remind them that they are encouraged to report any questionable practices by our employees to Sanofi's North America Compliance Department (1-800-648-1297, NA.Compliance@sanofi.com) or the FDA (1-888-INFO-FDA).

You should direct any medical questions or concerns about our prescription products to Medical Information Services, 1-800-633-1610, option 1, or https://contactus.sanofiaventis.us/medicalinquiry.aspx.

The Compliance Officer (or a designee) shall maintain a log of all calls and messages received by the Sanofi NA Compliance Program in response to the notice. The log shall include a record and summary of each call and message received

(whether anonymous or not), the status of the call or message, and any corrective action taken in response to the call or message.

III. Log, Certification and Board Resolution

There shall be two review periods ("Review Period") during the term of the Agreement. The first Review Period shall commence on the Effective Date, as defined by the Agreement, and shall conclude ten months after the Effective Date. The second Review Period shall commence ten months after the Effective Date of the Agreement, and shall conclude twenty-two months after the Effective Date.

Sanofi US shall provide the Log required in Section II and the following Certification and Board Resolution to the U.S. Department of Justice within sixty (60) calendar days following the end of each Review Period as follows:

Chief, Criminal Division
U.S. Attorney's Office,
Middle District of Florida
400 N. Tampa Street
Tampa, FL 33602

Director, Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044

The Certification shall be sworn to under penalty of perjury and shall set forth that the representations contained therein may be provided to, relied upon and material to the government of the United States, and that a knowing and material false statement could result in criminal or civil liability for the signatory.

A. Sanofi North America Pharmaceuticals Operations President's Certification

The President shall conduct a review of the effectiveness of the Sanofi NA Compliance Program as it relates to the marketing, promotion, and sale of Seprafilm® by Sanofi US during each Review Period. The President may, in his or her discretion, rely on an outside consultant/reviewer to perform the review. Based on the review, the President shall submit to the United States a signed certification stating that, to the best of his or her knowledge based on a reasonable inquiry into the operations of the Sanofi NA Compliance Program, during each Review Period: (1) the Sanofi NA Compliance Program continued to include the policies and procedures set forth in the section of this Attachment entitled Enhanced Compliance Measures & Certifications, and (2) Sanofi US has implemented an effective Sanofi NA Compliance Program to meet federal healthcare program requirements and the FDCA regarding the sale, marketing, and promotion of Seprafilm®. The certification shall summarize the review described above. If the President is unable to certify that Sanofi US has implemented an effective Sanofi NA Compliance Program as described above, he or she shall provide a detailed explanation of why the Sanofi NA Compliance Program was not effective, and the steps Sanofi US is taking to ensure the effectiveness of the Sanofi NA Compliance Program. This detailed explanation will satisfy Part (2) of the certification requirement above.

B. Board of Directors Resolution

The Board of Directors of Sanofi-Aventis U.S. LLC, or a designated Committee thereof (the "Board"), shall conduct a review of the effectiveness of the Sanofi NA

Compliance Program as it relates to the sale, marketing, and promotion, of Seprafilm® during each Review Period. This review shall include, but not be limited to, updates and reports by the Compliance Officer and other personnel regarding compliance matters. The Board shall evaluate the effectiveness of the Sanofi NA Compliance Program, including, among other means, by receiving updates about the activities of the Compliance Officer and Compliance Committee. The Board review shall not require the retention of third party experts. Based on its review, the Board shall submit to the United States a resolution (the "Board Resolution") that summarizes its review and oversight of Sanofi US's compliance with federal healthcare program requirements and FDCA requirements regarding the sale, marketing, and promotion of Seprafilm® and, at a minimum, includes the following language:

> The Board of Directors of Sanofi-Aventis U.S. LLC has made a reasonable inquiry as described in Section III.B of the Attachment to the Deferred Prosecution Agreement with Genzyme Corporation (Attachment B) into the operations of the Sanofi NA Compliance Program for the applicable time period ***[insert time period],*** including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Sanofi US has implemented an effective compliance program, as defined in the United States Sentencing Commission Guidelines Manual, Chapter 8: Sentencing of Organizations (2012), to meet the requirements of federal healthcare programs, the Federal Food, Drug, and Cosmetic Act regarding sales, marketing, and promotion of Seprafilm,® and as set forth in Attachment B to the Deferred Prosecution Agreement.

If the Board is unable to provide any part of this statement, it shall include in the resolution a written explanation of the reasons why it is unable to provide such a statement.

C. Notifications to Government[1]

Sanofi US agrees to provide the Government with its submissions pursuant to Sections III.H (Notification of Government Investigation or Legal Proceedings), III.I. (Reportable Events), and III.J (Notification of Communications with FDA) of the Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Sanofi, that relate to the sale, marketing, and promotion of Seprafilm®. Sanofi US agrees to provide to the Government, at its request, all relevant non-privileged information concerning the allegations and any resulting disciplinary and remedial measures.

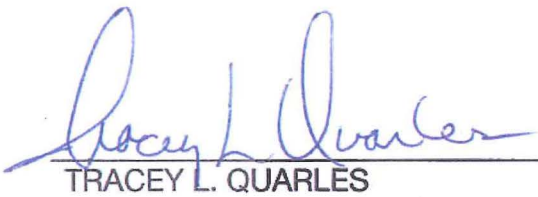
IV. Breach of this Attachment

Sanofi US recognizes that each of the terms in this Attachment constitutes a material term of this Attachment. Sanofi US and the United States agree that failure to comply with the obligations set forth in this Attachment will be considered a breach of the DPA and may subject Genzyme to prosecution in the United States District Court for the Middle District of Florida as set forth in that Agreement.

[1] Consistent with the Department of Justice's Freedom of Information Act ("FOIA") procedures, the government shall make reasonable effort to notify Sanofi US prior to any release by DOJ of information submitted by Sanofi US pursuant to its obligations under this Deferred Prosecution Agreement and identified upon submission by Sanofi US as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Sanofi US shall have the rights set forth under said procedures.

AGREED:

FOR GENZYME CORPORATION:



8/31/15

TRACEY L. QUARLES
Senior Vice President and General Counsel

Genzyme Corporation
500 Kendall Street
Cambridge, MA 02142

Date

KATHY B. WEINMAN
Attorney for Genzyme Corporation

Collora LLP
100 High Street, 20th Floor
Boston, MA 02110

Date

JONATHAN L. DIESENHAUS
Attorney for Genzyme Corporation

Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, DC 20004

Date

AGREED:

FOR GENZYME CORPORATION:

TRACEY L. QUARLES
Senior Vice President and General Counsel

Genzyme Corporation
500 Kendall Street
Cambridge, MA 02142

Date

KATHY B. WEINMAN
Attorney for Genzyme Corporation

Collora LLP
100 High Street, 20th Floor
Boston, MA 02110

August 31, 2015
Date

JONATHAN L. DIESENHAUS
Attorney for Genzyme Corporation

Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, DC 20004

August 31, 2015
Date

R.J. CINQUEGRANA
MELISSA BAYER TEARNEY
Attorneys for Genzyme Corporation

Choate Hall & Stewart LLP
Two International Place
Boston, MA 02110

Date

FOR SANOFI US:

8/26/15

ROBERT DEBERARDINE
Senior Vice President and General Counsel

Sanofi North America
55 Corporate Drive
Bridgewater, NJ 08807

Date

KATHY B. WEINMAN
Attorney for Sanofi US

Collora LLP
100 High Street, 20th Floor
Boston, MA 02110

Date

R.J. CINQUEGRANA
MELISSA BAYER TEARNEY
Attorneys for Genzyme Corporation

Choate Hall & Stewart LLP
Two International Place
Boston, MA 02110

August 31, 2015
Date

FOR SANOFI US:

ROBERT DEBERARDINE
Senior Vice President and General Counsel

Sanofi North America
55 Corporate Drive
Bridgewater, NJ 08807

Date

KATHY B. WEINMAN
Attorney for Sanofi US

Collora LLP
100 High Street, 20th Floor
Boston, MA 02110

August 31, 2015
Date

August 31, 2015

JONATHAN L. DIESENHAUS
Attorney for Sanofi US

Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, DC 20004

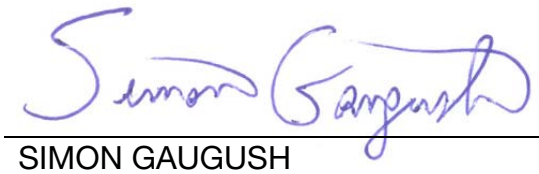
Melissa B Tray August 31, 2015

R.J. CINQUEGRANA
MELISSA BAYER TEARNEY
Attorneys for Sanofi US

Choate Hall & Stewart LLP
Two International Place
Boston, MA 02110

FOR THE UNITED STATES ATTORNEY'S OFFICE
FOR THE MIDDLE DISTRICT OF FLORIDA:

A. LEE BENTLEY III
United States Attorney



August 31, 2015

SIMON GAUGUSH
Assistant United States Attorney
Chief, Major Crimes Section

Date

U.S. Attorney's Office for the
Middle District of Florida
400 N. Tampa Street, #3200
Tampa, FL 33602

FOR THE UNITED STATES DEPARTMENT OF JUSTICE,
CONSUMER PROTECTION BRANCH:

MICHAEL S. BLUME
Director

August 31, 2015

ROSS S. GOLDSTEIN
Trial Attorney

Date

U.S. Department of Justice
Consumer Protection Branch
P.O. Box 386
Washington, DC 20044