ATTACHMENT B

ENHANCED COMPLIANCE MEASURES & CERTIFICATIONS

Baxter Healthcare Corporation ("Baxter") agrees to the provisions set forth in this Attachment, which is incorporated by reference as part of the Deferred Prosecution Agreement (the "Agreement") between the Office of the United States Attorney for the Western District of North Carolina and the United States Department of Justice, Consumer Protection Branch (collectively, "the Government") and Baxter.

Quality Compliance Program

1. Baxter has in place and will maintain a Quality Compliance Program that governs Baxter's North Cove plant. The purpose of the Quality Compliance Program is to (a) prevent, detect, and correct potential violations of the Federal Food, Drug, and Cosmetic Act ("FDCA") and violations of Baxter's quality policies and procedures; (b) assure the establishment of quality compliance-related policies and procedures for business and quality operations; (c) assure development of training and other programs designed to educate employees regarding applicable policies, procedures, and standards; (d) implement a mechanism for deterring and detecting non-compliance issues; and (e) assure appropriate corrective action is taken to prevent recurrence of quality compliance issues.

2. Baxter will maintain, or as necessary, establish, policies and procedures designed to ensure compliance with current Good Manufacturing Practices ("cGMP") at North Cove in the areas of sterility and environmental controls, including, but not limited to:

a. Remediating conditions that may contribute to the development of mold in clean rooms used to manufacture drug products;

b. Performing appropriate environmental monitoring of clean rooms used to manufacture drug products;

c. Inspecting high-efficiency particulate absorption ("HEPA") filters on at least a quarterly basis and replacing any filters with evidence of contamination including mold or other discoloration or characteristics suggestive of mold, and reporting any such findings to quality personnel for appropriate investigation and remediation;

d. Maintaining a log of sterility test results and providing them within twenty-four hours upon request of the Government or the Food and Drug Administration ("FDA");

e. Maintaining a log of monthly environmental monitoring results and providing them within twenty-four hours upon request of the Government or the FDA; and

f. Submitting Field Alert Reports ("FARs") to FDA for every complaint received related to North Cove products and potential particulate matter in solution or mold until FDA deems them no longer necessary and subject to any guidance FDA may issue regarding FARs.

3. Baxter will maintain, or as necessary, establish, policies and procedures designed to ensure effective investigation of quality-related complaints through an enhanced corrective and preventative action ("CAPA") system, including, but not limited to:

a. Training all North Cove personnel that they must report all information that may reflect or impact the quality of North Cove's drug products to quality personnel, who in turn will review and determine whether corrective actions are required;

b. Tracking and trending quality-related complaints related to North Cove to identify issues that may require corrective actions;

c. Training relevant personnel on the CAPA process;

d. Installing a CAPA subject matter expert at North Cove to serve as the single point of accountability for the quality and timeliness of all CAPAs at North Cove;

e. Having a qualification process to ensure North Cove CAPA approvers and investigators are appropriately trained and qualified; and

f. Holding CAPA Review Board meetings at North Cove at regular intervals (at minimum, monthly).

4. Baxter will maintain, or as necessary, establish, policies and procedures designed to ensure appropriate handling of employee concerns at North Cove, including, but not limited to:

a. Publicizing a helpline number at North Cove, including with prominent posters on bulletin boards near employee entrances and exits of the plant;

b. Holding plant-wide, annual town hall meetings at North Cove emphasizing its compliance program and non-retaliation policy;

c. Training North Cove management and supervisors annually on the importance of compliance; and

d. Training North Cove human resources personnel annually on how to conduct effective investigations, including when to refer complaints to quality and/or elevate complaints within the organization.

5. Within 90 days of the Effective Date of the Agreement, Baxter will submit to the Government an implementation report summarizing the status of the implementation of its commitments under the Quality Compliance Program.

Certification and Board Resolution

6. Baxter will provide the following Certification and Board resolution to the Government on an annual basis for the Term of the Agreement. Each one-year period, beginning with the one-year period following the Effective Date of the Agreement, will be referred to as a "Review Period." Baxter will provide the Certifications and Board resolution to the Government within ninety (90) calendar days following the end of each Review Period.

7. On an annual basis, the President of Baxter's Hospital Products business (the "President") will conduct a review of the effectiveness of Baxter's Quality Compliance Program as described in paragraphs 1–4 above during the preceding Review Period. Based on his or her review, the President will submit to the Government a signed certification stating that, to the best of his or her knowledge, during the period [insert time period]: (1) the Quality Compliance Program continued to include the policies and procedures set forth in paragraphs 1–4; and (2) at the time of his or her certification, the President is unaware of any facts demonstrating that the aforementioned measures were ineffective in preventing material violations of cGMP related to North Cove's drug products. The certification by the President will summarize the review described above that he or she conducted to provide the required certification. If the President is unable to provide any part of this certification, he or she will provide a detailed explanation for why he or she is unable to provide such certification. The certification and detailed explanation will be sworn to under the pains and penalties of perjury and will set forth that its representations

may be provided to, relied upon, and material to the government of the United States, and that a knowing false statement could result in criminal or civil liability for the signatory.

8. On an annual basis, the Board of Directors, or a designated Committee thereof (the "Board"), will conduct a review of the effectiveness of Baxter's Quality Compliance Program as described in paragraphs 1–4 above during the preceding Review Period. This review will include, but not be limited to, updates and reports by North Cove's Plant Manager and Director of Quality about the adoption and implementation of policies, procedures, and practices designed to satisfy the compliance measures set forth in paragraphs 1–4 above. The Board review will not require the retention of third-party experts. Based on its review, the Board will submit to the Government a resolution that summarizes its review and oversight as set forth above and, at a minimum, includes the following language:

> The Board of Directors of Baxter Healthcare Corporation has made a reasonable inquiry as described in Paragraph 8 of Attachment B to the Deferred Prosecution Agreement with Baxter into the operations of the Quality Compliance Program for the applicable time period [insert time period], including the performance of North Cove's Plant Manager, Director of Quality Assurance, and other personnel employed by Baxter. The Board has concluded that, to the best of its knowledge, Baxter has implemented and maintained the Quality Compliance Program as set forth in Attachment B to the Deferred Prosecution Agreement, and that, to the best of its knowledge, it is unaware of any facts demonstrating that these measures were ineffective in preventing material violations of cGMP related to North Cove's drug products.

If the Board is unable to provide any part of this statement, it will include a thorough explanation of the reasons why it is unable to provide such a statement.