International Headquarters
One Enterprise
Aliso Viejo, CA 92656
949.461.6000
www.valeant.com

December 6, 2007

RE: Product Recall – Infergen® (Interferon alfacon-1) 9 mcg and 15 mcg Lots with Over-Stickered Extended Expiration Dates

Dear Valued Customer:

This notice is to inform you that Valeant Pharmaceuticals is voluntarily recalling specific lots of Infergen® (Interferon alfacon-1) 9 mcg (NDC 64116-0039-06) and Infergen® 15 mcg (NDC 64116-0031-06) drug product from the market.

Based on additional stability data, the cartons of some lots of Infergen® were previously over-stickered with an extended expiration date that added an additional 12 months of shelf-life to the product. The vial labels of the product in these lots, however, were not over-stickered with the extended expiration date and reflect the original expiration date. Although the true stability of the product is accurately reflected on the outer carton of the product, the discrepancy between carton and vial label expiration dates has raised the possibility of patient confusion. In response to this concern and based on discussions with the FDA, Valeant Pharmaceuticals has initiated the recall of the affected lots.

Provided in the table below is a list of the over-stickered lots and corresponding expiration dates. ***Please note that you may have lots in your inventory which have the same seven digits without the letter "A" at the end of the lot number sequence. These lots without the letter "A" are not affected and are not included in this recall.***

INFERGEN 15 MCG (NDC 64116-0031-06)

Product Description	Lot Number	Original Expiration Date	Extended Expiration Date
INFERGEN 15 MCG	P057613 A	11/30/2007	11/30/2008
INFERGEN 15 MCG	P057614 A	11/30/2007	11/30/2008
INFERGEN 15 MCG	P057615 A	11/30/2007	11/30/2008
INFERGEN 15 MCG	P057617 A	02/28/2008	02/28/2009
INFERGEN 15 MCG	P057618 A	11/30/2007	11/30/2008
INFERGEN 15 MCG	P057619 A	12/30/2007	12/30/2008
INFERGEN 15 MCG	P057620 A	11/30/2007	11/30/2008
INFERGEN 15 MCG	P063699 A	12/30/2007	12/30/2008
INFERGEN 15 MCG	P065733 A	02/28/2008	02/28/2009
INFERGEN 15 MCG	P065734 A	02/29/2008	02/29/2009
INFERGEN 15 MCG	P065737 A	03/30/2008	03/30/2009
INFERGEN 15 MCG	P065739 A	03/30/2008	03/30/2009
INFERGEN 15 MCG	P066895 A	03/30/2008	03/30/2009
INFERGEN 15 MCG	P068076 A	03/30/2008	03/30/2009
INFERGEN 15 MCG	P069885 A	03/30/2008	03/30/2009
INFERGEN 15 MCG	P071927 A	11/30/2007	11/30/2008
INFERGEN 15 MCG	P073211 A	12/31/2007	12/31/2008
INFERGEN 15 MCG	P073966 A	03/30/2008	03/30/2009
INFERGEN 15 MCG	P077786 A	04/30/2008	04/30/2009
INFERGEN 15 MCG	P077787 A	04/30/2008	04/30/2009

INFERGEN 9 MCG (NDC 64116-0039-06)

Product Description	Lot Number	Original Expiration Date	Extended Expiration Date
INFERGEN 9 MCG	P057622A	11/30/2007	11/30/2008
INFERGEN 9 MCG	P062263A	10/31/2007	10/31/2008
INFERGEN 9 MCG	P063704A	02/28/2008	02/28/2009

The recall of these specific lots of Infergen® is limited to **wholesalers and retailers.** Product returned from wholesalers will be replaced with product from an unaffected lot. Retail pharmacies should immediately replenish Infergen stock through wholesalers. As Valeant is in the process of trying to rectify this situation, we seek your assistance to reassure patients that the affected product is stable and safe for use until the date reflected on the outer carton. **It is important to note that the replacement product you receive immediately to fill patient demand will have 3 – 4 months remaining shelf-life. This is the best dating currently available and Valeant will ship longer dated product as soon as it is produced.** Please examine your stock immediately to determine if you have product with the above referenced NDCs from the affected lots and complete the attached recall form which provides return instructions. Additionally, please return all expired Infergen® lots not listed as part of the recall through your normal returns process.

This recall is being conducted with the knowledge of the Food and Drug Administration. We appreciate your immediate attention and sincerely regret any inconvenience caused by this action. If you have any questions, please contact our Customer Service team at (800) 556-1937.

Sincerely,

Valeant Pharmaceuticals North America

Asha P. Soto
Vice President, Supply Chain Operations

Enclosure

VALEANT
Pharmaceuticals International

INFERGEN RECALL FORM

Company Name	
Street Address	
City, State, Zip	
Contact Name /Tel No.	
Date	

Please check the appropriate box:

☐ **We do not have Infergen in inventory.**
☐ **We have Infergen in inventory. Fill in quantity by Lot below.**

Product Description	NDC	Lot Number	Expiration Date	Quantity of 6 vial pack cartons returned
INFERGEN 15 MCG	64116-0031-06	P057613 A	11/30/2008	
INFERGEN 15 MCG	64116-0031-06	P057614 A	11/30/2008	
INFERGEN 15 MCG	64116-0031-06	P057615 A	11/30/2008	
INFERGEN 15 MCG	64116-0031-06	P057617 A	02/28/2009	
INFERGEN 15 MCG	64116-0031-06	P057618 A	11/30/2008	
INFERGEN 15 MCG	64116-0031-06	P057619 A	12/30/2008	
INFERGEN 15 MCG	64116-0031-06	P057620 A	11/30/2008	
INFERGEN 15 MCG	64116-0031-06	P063699 A	12/30/2008	
INFERGEN 15 MCG	64116-0031-06	P065733 A	02/28/2009	
INFERGEN 15 MCG	64116-0031-06	P065734 A	02/29/2009	
INFERGEN 15 MCG	64116-0031-06	P065737 A	03/30/2009	
INFERGEN 15 MCG	64116-0031-06	P065739 A	03/30/2009	
INFERGEN 15 MCG	64116-0031-06	P066895 A	03/30/2009	
INFERGEN 15 MCG	64116-0031-06	P068076 A	03/30/2009	
INFERGEN 15 MCG	64116-0031-06	P069885 A	03/30/2009	
INFERGEN 15 MCG	64116-0031-06	P071927 A	11/30/2008	
INFERGEN 15 MCG	64116-0031-06	P073211 A	12/31/2008	
INFERGEN 15 MCG	64116-0031-06	P073966 A	03/30/2009	
INFERGEN 15 MCG	64116-0031-06	P077786 A	04/30/2009	
INFERGEN 15 MCG	64116-0031-06	P077787 A	04/30/2009	

Product Description	NDC	Lot Number	Expiration Date	Quantity of 6 vial pack cartons returned
INFERGEN 9 MCG	64116-0039-06	P057622A	11/30/2008	
INFERGEN 9 MCG	64116-0039-06	P062263A	10/31/2008	
INFERGEN 9 MCG	64116-0039-06	P063704A	02/28/2009	

Please return product immediately with completed form to:

Capital Returns, Inc.
Attn: Infergen Recall
6101 North 64th Street
Milwaukee, WI 53218

IMPORTANT: Fax all completed forms to (949) 461-6626. If you have any questions regarding this recall, please contact Valeant Customer Service at (800) 556-1937.

For complete prescribing information, please visit www.infergen.com or contact Valeant Customer Service at (800) 556-1937.

INFERGEN® (Interferon alfacon-1) is indicated for the treatment of chronic HCV infection in patients 18 years of age or older with compensated liver disease who have anti-HCV serum antibodies and/or the presence of HCV RNA. Other causes of hepatitis, such as viral hepatitis B or autoimmune hepatitis, should be ruled out prior to initiation of therapy with INFERGEN. The most commonly reported adverse events during initial and subsequent treatment were headache, fatigue, fever, myalgia, rigors, body pain, arthralgia, and nausea.

IMPORTANT SAFETY INFORMATION:

Alpha interferons, including Interferon alfacon-1, cause or aggravate fatal or life-threatening neuropsychiatric, autoimmune, ischemic, and infectious disorders.

Patients should be monitored closely with periodic clinical and laboratory evaluations. Patients with persistently severe or worsening symptoms of these conditions should be withdrawn from therapy. In many but not all cases, these disorders resolve after stopping Interferon alfacon-1 therapy.

See: **CONTRAINDICATIONS, WARNINGS, PRECAUTIONS and ADVERSE REACTIONS in the Full Prescribing Information.**

INFERGEN is contraindicated in patients with known hypersensitivity to alpha interferons or to any component of the product, in patients with decompensated hepatic disease and autoimmune hepatitis. Development of or exacerbation of autoimmune disorders (e.g. autoimmune thrombocytopenia, idiopathic thrombocytopenic purpura, psoriasis, rheumatoid arthritis) have been reported in patients receiving alpha interferon therapies, including INFERGEN.

Treatment with INFERGEN should be administered under the guidance of a qualified physician, and may lead to moderate-to-severe adverse experiences requiring dose reduction, temporary dose cessation, or discontinuation of further therapy.

Severe psychiatric adverse events may manifest in patients receiving therapy with alpha interferons, including INFERGEN. Depression, suicidal ideation, suicide attempt, and suicide may occur. Other prominent psychiatric adverse events may also occur, including psychosis, aggressive behavior, nervousness, anxiety, emotional lability, abnormal thinking, agitation, apathy and relapse of drug addiction. INFERGEN should be used with extreme caution in patients who report a history of depression. Physicians should monitor all patients for evidence of depression and other psychiatric symptoms. In severe cases, therapy should be stopped immediately and psychiatric intervention instituted.

Bone Marrow Toxicity: Alpha interferons suppress bone marrow function and may result in severe cytopenias including very rare events of aplastic anemia. It is advised that complete blood counts be obtained pretreatment and monitored routinely during therapy. Alpha interferon therapy should be discontinued in patients who develop severe decreases in neutrophil ($<0.5 \times 10^9$/L) or platelet counts ($<50 \times 10^9$/L).

Hypertension, tachycardia, palpitation, and tachyarrhythmias have been reported in patients treated with INFERGEN. INFERGEN should be administered with caution to patients with preexisting cardiac disease. Supraventricular arrhythmias, chest pain, and myocardial infarction have been associated with alpha interferon therapies.

Pneumonia and interstitial pneumonitis, some resulting in respiratory failure and/or patient deaths, have been induced or aggravated by alpha interferon therapy, including INFERGEN. Patients who develop persistent or unexplained pulmonary infiltrates or pulmonary function impairment should discontinue treatment with INFERGEN.

Chronic hepatitis C patients with cirrhosis may be at risk of hepatic decompensation when treated with alpha interferons, including INFERGEN. During treatment, patients' clinical status and hepatic function should be closely monitored, and INFERGEN treatment should be immediately discontinued if symptoms of hepatic

decompensation, such as jaundice, ascites, coagulopathy, or decreased serum albumin, are observed.

Ophthalmologic Disorders: Decrease or loss of vision, retinopathy including macular edema, retinal artery or vein thrombosis, retinal hemorrhages and cotton wool spots; optic neuritis, and papilledema are induced or aggravated by treatment with INFERGEN or other alpha interferons. All patients should receive an eye examination at baseline. Patients with preexisting ophthalmologic disorders (e.g., diabetic or hypertensive retinopathy) should receive periodic ophthalmologic exams during interferon alpha treatment. INFERGEN therapy should be discontinued in patients who develop new or worsening ophthalmologic disorders.

Ischemic and hemorrhagic cerebrovascular events including hemorrhagic stroke have been observed in patients being treated with INFERGEN. In addition, transient ischemic attack has been reported in young patients being treated with INFERGEN without other reported risk factors.

INFERGEN should be discontinued immediately and appropriate medical treatment instituted if hypersensitivity reactions occur. INFERGEN should be administered with caution to patients with a history of endocrine disorders and should be discontinued immediately in patients who develop signs and symptoms of colitis. In addition, INFERGEN should be suspended in patients with signs and symptoms suggestive of pancreatitis and discontinued in patients diagnosed with pancreatitis.

The most common adverse events reported for INFERGEN during clinical studies were headache (82%), fatigue (69%), fever (61%), myalgia (58%), rigors (57%), body pain (54%), arthralgia (51%), nausea (40%), insomnia (39%), pharyngitis (34%), nervousness (31%), infection upper respiratory (31%), diarrhea (29%), depression (26%), anorexia (24%), injection site erythema (23%), granulocytopenia (23%), dizziness (22%), cough (22%), dyspepsia (21%), thrombocytopenia (19%), anxiety (19%), sinusitis (17%), influenza-like symptoms (15%) and leucopenia (15%).