

December 4, 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

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.