CANGENE

**URGENT: DRUG RECALL NOTIFICATION**

May 29, 2012
Liz Feldman
**ASD HEALTHCARE**
3101 Gaylord Parkway
Frisco, TX 75034

**Attn:** Liz Feldman

**Please be advised that Cangene Corporation is issuing a voluntary DRUG RECALL of the following finished product lots associated with one bulk lot of the following product:**

***Product Name/Description:***
Hepatitis B Immune Globulin (Human) (HepaGam B) (> 312 IU/mL)

***Finished Product Lot Numbers:***
***11006960***
***11006961***
***11107359***
***11107360***
***11007148***
***11007151***

***Product NDC:***
1 mL vial (> 312 IU/mL) 53270-0052-1 Cangene BioPharma
5 mL vial (> 312 IU/mL) 53270-0051-1 Cangene BioPharma

***Reason for the Recall:***
There have been post-marketing and literature reports of serious thrombotic adverse events associated with the administration of intravenous and subcutaneous immune globulin products (IVIG, SCIG) in a wide range of patient populations. Recently, coagulation factors, including activated factor XI, have been identified in IVIG batches associated with thrombotic events. Measurable levels of procoagulant (factor XIa) activity have been detected in HepaGam B®.

Safe levels of FXIa in immune globulin products are not known. These lots of HepaGam B have been found to contain dose levels of FXIa below, but approaching those administered in immune globulin product lots implicated in thromboembolic events. Therefore, Cangene has made the decision to Voluntarily Recall HepaGam B product lots made from bulk batch 11006907.

***Classification:*** Cangene has categorized this as a Class II Recall. Class II is appropriate for situations in which use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote.


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***Depth of Recall:*** This recall is to the hospital/pharmacy level.

***Quantities distributed to your Facility:***

| Customer Name | Part Code | Quantity | Lot Number |
|---|---|---|---|
| ASD HEALTHCARE | 400112 | 100 | 11006960 |
| | 400112 | 10 | 11107359 |
| | 400113 | 310 | 11007148 |

***Date range recalled product was distributed:*** This product was shipped to you between the following date ranges: March 14, 2011 – December 20, 2011.

***Recall Execution Plan:***

- Immediately examine your inventory
- Immediately cease sale and/or distribution of the affected lots.
- Quarantine all current inventory.
- Initiate Subrecall as per Subrecall Execution Plan (below)
- Reconcile all product (in house inventory and returned inventory from customers) and return to Cangene via Expedited courier (Collect).
- Complete and return the enclosed response form as soon as possible (Appendix 1).

**Subrecall Execution Plan:**

- ***Depth of Subrecall:*** This Subrecall is to the hospital and pharmacy level
- **This Subrecall must be carried out to your customers that may have received any of the lots under recall. Your assistance is appreciated and necessary to prevent patient harm.**
    - If you have further distributed this product, please identify your customers and notify them at once of this product recall. To assist in the Subrecall an enclosed letter has been provided to facilitate notification of your customers (Appendix 2).
- Provide listing of all customers that have received or may have received the product under recall including:
    - Customer Name/address
    - Date Notification sent
    - Method of Notification
    - Quantity Shipped
    - Status of recalled product at customer level (quarantined, held for return, consumed)
- Reconcile all product (returned inventory from customers) and return to Cangene via Expedited courier (Collect).
- Customer to complete and return the enclosed response form as soon as possible (Appendix 1).

Should you have any questions regarding this **DRUG RECALL**, please contact:

Pam Bobbette
Director, Quality
Office: 1 (204) 275-4647
Mobile: 1 (204) 795-9554
Email: pbobbette@cangene.com



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Should you have any questions regarding the **return of product**, please call:

**Phone Number:** 1-877-HepaGam (1-877-437-2426)

We would appreciate your immediate attention regarding this matter.

This recall is being made with the knowledge of the FDA.

Sincerely,

Pam Bobbette
Director, Quality
Cangene Corporation
Phone: 1 (204) 275-4647
Email: pbobbette@cangene.com

*Enclosure(s):*

| | |
|---|---|
| *Appendix 1* | *Response form for Recall* |
| *Appendix 2* | *Letter example for Subrecall* |
| *Appendix 3* | *Response Form for Subrecall* |



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**Appendix 1**

**Please complete response form and return to Cangene as soon as possible**

| **Recall Response Form** | | | | |
|---|---|---|---|---|
| Please complete table and check off appropriate boxes. | | | | |
| √ below | | | | |
| | Read and understand the recall instructions provided in the May 29, 2012 letter. | | | |
| | Examined Inventory | | | |
| | Removed product from sale/distribution | | | |
| | Quarantined inventory | | | |
| | Quantity of quarantined inventory | | Units<br>Vials | |
| | Indicated status of recalled product | | | |
| | Held for return under quarantine | Quantity | Date | Method for product return |
| | Consumed | Quantity | Date | |
| | Initiated Subrecall as instructed | | | |
| | Identified and notified customers that were shipped or may have been shipped this product. | | | |
| | Attached a listing of all customers that have been notified, that includes:<br>Customer Name/address<br>Date Notification sent<br>Method of Notification<br>Quantity Shipped<br>Status of recalled product (quarantined, held for return, consumed) | | | |
| | Have there been any adverse events associated with the recalled product?<br><br>Yes or No<br><br>If yes, please explain: | | | |

| **Recall Response Form Completed by:** | |
|---|---|
| Signature: | |
| Name (print): | |
| Title (print): | |
| Date: | |
| Contact Information: | Company Name: |
| | Phone/Email: |
| | Company Address: |

FAX/EMAIL COMPLETED RESPONSE FORM TO:

Pam Bobbette
Director, Quality
Office: 1 (204) 275-4647
Mobile: 1 (204) 795-9554
Fax: 1 (204) 275-4284
Email: pbobbette@cangene.com



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**Appendix 2- Subrecall**
**Enclosed letter that you should use in notifying your customers**

**URGENT: DRUG RECALL NOTIFICATION**

<Date>
<Contact Name or Dept>
Customer Name
Customer Address

Attention: <Name>

**Please be advised that Cangene Corporation is issuing a voluntary DRUG RECALL of the following finished product lots associated with one bulk lot of the following product:**

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Hepatitis B Immune Globulin (Human) (HepaGam B) (> 312 IU/mL)

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***Product NDC:***
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***Reason for the Recall:***
There have been post-marketing and literature reports of serious thrombotic adverse events associated with the administration of intravenous and subcutaneous immune globulin products (IVIG, SCIG) in a wide range of patient populations. Recently, coagulation factors, including activated factor XI, have been identified in IVIG batches associated with thrombotic events. Measurable levels of procoagulant (factor XIa) activity have been detected in HepaGam B®.

Safe levels of FXIa in immune globulin products are not known. These lots of HepaGam B have been found to contain dose levels of FXIa below, but approaching those administered in immune globulin product lots implicated in thromboembolic events. Therefore, Cangene has made the decision to Voluntarily Recall HepaGam B product lots made from bulk batch 11006907.


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***Classification:*** Cangene has categorized this as a Class II Recall. Class II is appropriate for situations in which use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote.

***Depth of Recall:*** This recall is to the hospital/pharmacy level.

***Distributor/Wholesaler records indicate the following quantities were distributed to your Facility:***

| Lot # | Date shipped | Quantity shipped |
|---|---|---|
| | | |

***Date range recalled product was distributed:*** This product was shipped to you between the following date ranges: <date>.

***Recall Execution Plan:***

- Immediately examine your inventory
- Immediately cease sale and/or distribution of the affected lots.
- Quarantine all current inventory
- Reconcile all product and return to Distributor/Cangene via Expedited courier (Collect).

Should you have any questions regarding this **DRUG RECALL**, please contact:

Pam Bobbette
Director, Quality
Office: 1 (204) 275-4647
Mobile: 1 (204) 795-9554
Email: pbobbette@cangene.com

Should you have any questions regarding the **return of product**, please call:

**Phone Number:** 1-877-HepaGam (1-877-437-2426)

Please complete and return the enclosed response form as soon as possible (Appendix 3).
**Your assistance is appreciated and necessary to prevent patient harm.**

We would appreciate your immediate attention regarding this matter.

This recall is being made with the knowledge of the FDA.

Sincerely,

<Distributor/Wholesaler/Consignee Name>
<Distributor/Wholesaler/Consignee Address>
<City/state/Zip>
<Phone: >
<Email: >



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**Appendix 3-Response Form for Subrecall**
**Please complete response form and return to <Distributor Name> as soon as possible**

| Recall Response Form | | | | |
|---|---|---|---|---|
| Please complete table and check off appropriate boxes. | | | | |
| √ below | | | | |
| | Read and understand the recall instructions provided in the <date> letter. | | | |
| | Examined Inventory | | | |
| | Removed product from sale/distribution | | | |
| | Quarantined inventory | | | |
| | Quantity of quarantined inventory | | Units<br>Vials | |
| | Indicated status of recalled product | | | |
| | Held for return under quarantine | Quantity | Date | Method for product return |
| | Consumed | Quantity | Date | |
| | Reconcile all product and return to <Distributor Name> | | | |
| | Have there been any adverse events associated with the recalled product?<br><br>Yes or No<br><br>If yes, please explain: | | | |

| Recall Response Form Completed by: | |
|---|---|
| Signature: | |
| Name (print): | |
| Title (print): | |
| Date: | |
| Contact Information: | Company Name: |
| | Phone/Email: |
| | Company Address: |

FAX/EMAIL COMPLETED RESPONSE FORM TO:

<Distributor/Wholesaler/Consignee Name>
<Distributor/Wholesaler/Consignee Address>
<City/state/Zip>
<Phone: >
<Email: >



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