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OCTOBER 20, 2006

## URGENT – VACCINE SHIPMENT RECOVERY NOTICE

ATTN: Dear Doctor, Health Care Professional

**Fluvirin® (Influenza Virus Vaccine)**

**NDC # 66521-109-10**

Lot Number	Expiration Date
71209	Jun 30 2007
71210	Jun 30 2007

We recently became aware of some instances where Fluvirin® shipped under the CDC contract was received from our distributor, Cardinal Health Care, in either a frozen state and/or below the required storage temperature. This letter is a follow up to an October 18th telephone notification in which we asked you to quarantine Fluvirin® influenza vaccine because of a possibility that it may have been frozen during shipment. Novartis Vaccines & Diagnostics Limited is conducting a shipment recovery of the shipment made under the CDC contract containing the above listed shipments of Fluvirin® Influenza Vaccine, which is in 5 mL multidose vials bearing the Chiron Vaccines label. These shipments were distributed by our distributor, Cardinal Health Care, and may have been subjected to freezing temperatures, which is contrary to storage instructions stated on vial, carton and case labeling (2°C-8°C). The shipments were distributed between 11<sup>th</sup> and 17<sup>th</sup> October, 2006. The administration of Fluvirin® that may have been frozen does not pose a risk to patient safety, however, it is our normal policy to advise healthcare professionals to advise patients to be re-immunized if they suspect that their vaccine has been frozen and therefore we are taking this precautionary action.

Patients who were immunized with Fluvirin® from the above mentioned shipments should be re-immunized with another dose of influenza vaccine. Administration of a potentially frozen dose of vaccine is reportable as an adverse event (medication error) under our internal procedures, regardless of whether any adverse effects have been experienced. Therefore, if any of your patients have received a dose from the above-mentioned affected shipment, please contact our Vaccine Information Service to document this administration.

Registered Company:  
Novartis Vaccines and  
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Registered Company  
Address:  
Florey House  
Robert Robinson Avenue  
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Registered in England:  
3970089

VAT Number:  
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Vaccine Information Service

Tel: 1-800-244-7668  
Fax: 510-923-3435  
e-mail: [drug\\_info@chiron.com](mailto:drug_info@chiron.com)

We ask that you examine your inventory of Fluvirin® Vaccine received under the CDC contract and confirm that the lots that are subject to this recovery action are quarantined. Replacement vaccine will be shipped to you as soon as possible, and you will receive further instructions regarding the return of the recalled lots that you may have on hand. This action is being taken with the knowledge of the Food and Drug Administration

To facilitate the return of your quarantined stock will you please fax the following information to our Customer Services Team on fax number 510 923 3434:

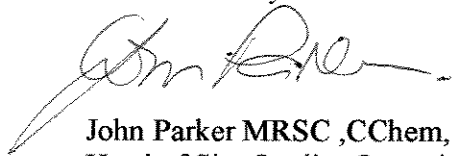
- The number of vials and lot number
- Name of contact person including Telephone Number and Fax Number

A return goods authorization shall then be issued with instructions on how the quarantined stock is to be returned.

It is important to note that this recovery affects only the shipment made by Cardinal Health Care under the CDC contract. It does not affect shipments of Fluvirin ®Vaccine that are received from other distributors.

We appreciate your immediate attention and cooperation, and sincerely regret any inconvenience. If you have any questions, please contact Leslie Trunnell our Customer Services Manager on 510 923 5159

Yours sincerely



John Parker MRSC ,CChem,  
Head of Site Quality Operations Novartis Vaccine & Diagnostics (UK)