SWOG
Leading cancer research. Together.

January 1, 2013

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TO: ALL SWOG MEMBER, CCOP AND AFFILIATE MEDICAL INVESTIGATORS AND CLINICAL RESEARCH ASSOCIATES

FROM: SWOG Operations Office

RE: Carboplatin Injection by Hospira, Inc.

**IRB Review Requirements**

( ) Full board review required. Reason:
- ( ) Initial activation (should your institution choose to participate)
- ( ) Increased risk to patient
- ( ) Complete study redesign
- ( ) Addition of tissue banking requirements
- ( ) Study closure due to new risk information

( √ ) Expedited review allowed

( ) No review required

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**MEMORANDUM**

Hospira, Inc. is further informing the general public about a previously communicated voluntary user-level recall of three lots of carboplatin injection due to visible particulates identified during a routine sample inspection. Findings have identified the particles as carboplatin crystals. If particulate matter from crystallization is injected into a patient, it may potentially become lodged in and obstruct blood vessels, potentially causing local infarction, thromboembolism and vasculitis. Chronically, following sequestration, granulomatous formation in the lungs is possible.

Anyone with an existing inventory should stop use and distribution, quarantine the product immediately, and call Stericycle at 877/650-8362 between the hours of 8am and 5pm EST, Monday through Friday, to arrange for the return of the product.

Read the complete MedWatch Safety Alert, including a link to the Recall Notice at: http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm332358.htm.