

URGENT: Drug Recall Notice

Manufacturing/Recall Firm:
Genentech USA, Inc
1 DNA Way
South San Francisco, CA 94080-4990

Recall Contact:
GENCO Pharmaceutical Services
6101 North 64th Street
Milwaukee, WI 53218

June 27, 2011

Genentech is conducting a voluntary drug recall of select lots of **CellCept® Oral Suspension (mycophenolate mofetil for oral suspension) 200mg/mL 225mL Bottle (NDC # 0004-0261-29)**. Please see the table below for lot numbers, expiry dates, and manufacturer distribution dates.

PRODUCT:

CellCept® Oral Suspension 200mg/mL 225mL Bottle (NDC # 0004-0261-29)

Lot #	Expiration Date	Genentech Distribution Dates
896992	02/28/2013	03/29/2011 - 04/12/2011
896993	02/28/2013	04/07/2011 - 04/19/2011
904407	02/28/2013	05/12/2011 - 05/13/2011
904408	02/28/2013	06/06/2011 - 06/07/2011
905985	02/28/2013	04/08/2011 - 05/10/2011
905986	02/28/2013	04/13/2011 - 04/27/2011
905987	02/28/2013	05/05/2011 - 05/16/2011

REASON:

Genentech is conducting a voluntary recall of the above-specified lots of CellCept® Oral Suspension 200mg/mL 225mL Bottle from Wholesalers and Pharmacies due to receipt of customer complaints from pharmacists and patients (in the U.S.) that the bottle adapter (also known as the Press in Bottle Adapter (PIBA)) does not fit into the bottle.

Genentech is taking this voluntary action to recall the affected lots of CellCept® Oral Suspension 200mg/mL 225mL Bottle with the knowledge of the Food and Drug Administration (FDA).

A multi-dose immunosuppressant product with an adapter for dispenser that does not fit on the bottle can present risks to patients related to potential interruption of treatment, inappropriate dose administration, and leakage of product outside the bottle.

LEVEL:

This recall is being carried out to the Wholesaler and Pharmacy level for the above-specified lots of CellCept® Oral Suspension 200mg/mL 225mL Bottle.

This recall is being conducted with the knowledge of the United States Food and Drug Administration.

IMPORTANT PHONE NUMBERS:

Medical Inquiries: Please contact Medical Communications at 1-800-821-8590.

Drug Safety/Adverse Events: In the event of any adverse health effects associated with this product recall, contact Genentech Drug Safety/Adverse Events at 1-888-835-2555.

Returns processing questions: Please contact GENCO Pharmaceutical Services at 1-888-840-1137.

Genentech appreciates your immediate attention and cooperation, and sincerely regrets any inconvenience caused by this action.