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Director & State Health Officer

State of California—Health and Human Services Agency
California Department of Public Health



EDMUND G. BROWN JR.
Governor

May 25, 2012

AFL 12-28

TO: All Facilities

SUBJECT: Curlin Intravenous (IV) Administration Sets: Recall Due to Possible Health Risk

The California Department of Public Health is advising all facilities to take the following actions based on an urgent message from the Food and Drug Administration (FDA):

Immediately discontinue use of Curlin IV Sets with the following REF (catalog) and lot numbers, which were sold and distributed between December 2011 and May 2012:

REF Codes (found in the top right hand corner of the administration set packaging):

340-4114	340-4126	340-4128-V	340-4130-V	340-4137	340-4165	340-4173
340-4115	340-4128	340-4130	340-4133	340-4144	340-4166	340-4176

Lot Numbers (found in the lower right hand corner of the administration set packaging):

CF1127990	CF1132291	CF1200291	CF1201890	CF1204092	CF1206092
CF1127991	CF1133490	CF1200292	CF1201891	CF1204093	CF1206890
CF1127992	CF1133491	CF1200293	CF1201892	CF1204690	CF1206891
CF1129990	CF1134390	CF1200294	CF1201893	CF1204691	CF1206893
CF1130190	CF1134391	CF1200490	CF1202590	CF1204692	CF1207590
CF1130690	CF1134392	CF1200491	CF1202591	CF1205490	CF1207591
CF1130691	CF1134393	CF1200492	CF1202592	CF1205491	CF1207592
CF1130692	CF1134990	CF1200493	CF1203390	CF1205492	CF1207593
CF1130693	CF1135490	CF1200494	CF1203391	CF1205493	CF1208090
CF1131190	CF1135491	CF1201190	CF1203392	CF1205990	CF1208091
CF1131191	CF1135492	CF1201191	CF1204090	CF1206090	CF1208092
CF1132290	CF1200290	CF1201192	CF1204091	CF1206091	CF1209091

The FDA advises that Moog Medical Devices Group (MMDG) has voluntarily issued a recall for these lots of Curlin IV Administration Sets, which have the potential to cause serious injury or death due to blood loss, under-delivery of prescribed medication/fluid, or a potential delay in therapy. The recall was initiated as a result of a customer-discovered

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reverse pump segment. To date, customer complaints have identified three (3) out of 544,900 suspect sets manufactured for the United States. Despite the potential for reverse flow when using an affected set, MMDG has not received any reports of injury or death as a result of this issue. MMDG has identified and corrected the root cause by immediately initiating a supplier corrective action request and implementing additional preventative measures.

MMDG is working with the FDA to coordinate recall activities. Direct customers and distributors will be notified of the process for obtaining replacement administration sets by MMDG. For additional questions, contact Moog Customer Advocacy at (800) 970-2337.

Healthcare professionals and patients are encouraged to report any adverse events or side effects related to the use of these products to the FDA's MedWatch Adverse Event Reporting Program either online, by regular mail or by fax.

Online: <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>

Regular mail: MedWatch
5600 Fishers Lane
Rockville, MD 20852-9787

Fax: 1-800-FDA-0178

For mail or fax reporting, please use FDA form 3500, available at:
<http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/UCM082725.pdf> or by request by calling 1-800-332-1088.

Thank you for your prompt attention to this matter.

Sincerely,

Original Signed By Debby Rogers

Debby Rogers, RN, MS, FAEN
Deputy Director
Center for Health Care Quality