Indiana State Department of Health
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Mitchell E. Daniels, Jr.
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

DATE: November 28, 2012

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: Bracco Diagnostics Inc. Recall

SUGGESTED ACTION: **Class I Recall; Nine (9) lots of Isovue® (iopamidol injection) Pre-Filled Power Injector Syringes (Isovue PFS, to be used in combination with Stellant® CT Injection Systems) due to the presence of visible particles in syringes observed at the end of standard stability studies on retained samples; Information is provided in case of consumer inquiry and for healthcare professionals.**

From the information provided by FDA, the recalled products may have been distributed in the State of Indiana. These products were distributed to wholesalers and distributors nationwide.

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Bracco Diagnostics Inc. Issues Voluntary Nationwide Recall of Isovue® (iopamidol injection) Pre-Filled Power Injector Syringes due to Presence of Particulates

Contact:
Consumer:
1-866-201-9133

Media:
Lakshmi Sundar
Bracco Diagnostics Inc.

609.751.7402
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FOR IMMEDIATE RELEASE - November 27, 2012 -Bracco Diagnostics Inc. (BDI) is voluntarily initiating a Class I recall of nine (9) lots of Isovue® (iopamidol injection) Pre-Filled Power Injector Syringes (Isovue PFS, to be used in combination with Stellant® CT Injection Systems) due to the presence of visible particles in syringes observed at the end of standard stability studies on retained samples. BDI has received no reports of adverse events or customer complaints associated with these lots. However, it should be noted that the visible particles in the lots subject to this recall have the potential to cause adverse health consequences.

ISOVUE is indicated for angiography throughout the cardiovascular system, and arterial injection of Isovue (for cerebral angiography) with particulate matter formation could cause stroke.

Isovue PFS is a single use item, administered for diagnostic imaging under medical supervision. The product is packaged in single dose Prefilled Syringe (PFS) presentations of Isovue® - 300 FLS2 and Isovue® - 370 FLS2. The affected Isovue PFS lots include the following:

Isovue® - 370	**NDC**	**Description**	**Lot Number**	**Expiry Date**
Isovue® - 370 FLS2	0270-1316-66	10 X 75 mL Power Injector Syringes, Stellant	9L40746	12/31/2012
Isovue® - 370 FLS2	0270-1316-67	10 X 100 mL Power Injector Syringes, Stellant	0A43705	01/31/2013
Isovue® - 370 FLS2	0270-1316-67	10 X 100 mL Power Injector Syringes, Stellant	0C57509	03/31/2013
Isovue® - 370 FLS2	0270-1316-68	10 X 125 mL Power Injector Syringes, Stellant	9K37791	11/30/2012
Isovue® - 370 FLS2	0270-1316-68	10 X 125 mL Power Injector Syringes, Stellant	0C57521	03/31/2013
Isovue® - 370 FLS2	0270-1316-68	10 X 125 mL Power Injector Syringes, Stellant	0E62913	05/31/2013
Isovue® - 300	**NDC**	**Description**	**Lot Number**	**Expiry Date**
Isovue® - 300 FLS2	0270-1315-67	10 X 100 mL Power Injector Syringes, Stellant	9K34572	11/30/2012
Isovue® - 300 FLS2	0270-1315-67	10 X 100 mL Power Injector Syringes, Stellant	0A43282	01/31/2013
Isovue® - 300 FLS2	0270-1315-67	10 X 100 mL Power Injector Syringes, Stellant	0C56283	03/31/2013

These products were distributed to wholesalers and distributors nationwide. The dates for distribution of the nine (9) affected lots were from January 21, 2010 through May 9, 2012. BDI is notifying wholesalers, distributors and customers by mail and is arranging for return of all recalled product. Hospitals, Emergency Rooms, Clinics, Physician Offices and other healthcare facilities and providers should not use these lots of Isovue PFS and should immediately quarantine product

and contact Stericycle, Bracco's contractor for handling the recall, at 1-866-201-9133 to arrange for return of the product. Call center hours are Monday through Friday 8am-5pm Eastern Standard Time.

Consumers with questions regarding this recall should contact Stericycle. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online: www.fda.gov/medwatch/report.htm [1]
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm[2]. Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

About Bracco Imaging

Bracco Imaging S.p.A., part of the Bracco Group, is one of the world's leading companies in the diagnostic imaging business. Headquartered in Milan, Italy, Bracco Imaging develops, manufactures and markets diagnostic imaging agents and solutions that meet medical needs.

Bracco Imaging offers a product and solution portfolio for all key diagnostic imaging modalities: X-Ray Imaging (including Computed Tomography-CT, Interventional Radiology, and Cardiac Catheterization), Magnetic Resonance Imaging (MRI), Contrast Enhanced Ultrasound (CEUS), Nuclear Medicine through radioactive tracers, and Gastrointestinal Endoscopy. The diagnostic imaging offer is completed by several medical devices and advanced administration systems for contrast imaging products in the fields of radiology.

The Company operates in over 90 markets worldwide, either directly or indirectly, through subsidiaries, joint ventures, licenses and distribution partnership agreements. With an on-going research covering all key modalities, Bracco Imaging has a strong presence in key geographies: North America; Europe and Japan operating through the Joint Venture Bracco-Eisai Co., Ltd. The Company also operates in Brazil, South Korea, and China through the Joint Venture Bracco Sine Pharmaceutical Corp. Ltd.

Operational investments have been made in order to achieve top quality and compliance with a sustainable eco-friendly production. Manufacturing activities are located in Italy, Switzerland, Japan, China and Germany.

Bracco Imaging is an innovative Research and Development (R&D) player with an efficient process oriented approach and a track record of innovation in the diagnostic imaging industry.