Genentech
A Member of the Roche Group

November 2018

Dear Healthcare Provider:

Genentech, a member of the Roche Group, has been informed that a Novartis-branded counterfeit product, labeled LUCENTIS® (ranibizumab injection), 10 mg/mL vial, was seized at a United States border. The purchase was made via an online website offering products that are illegal for sale in the United States. Upon chemical analyses by Novartis, it was confirmed that the counterfeit product did not contain ranibizumab, the active ingredient in LUCENTIS. The counterfeit product originated from outside the United States.

We are working with the U.S. Food and Drug Administration (FDA) to aid their evaluations, determine the source of the counterfeit drug, and prevent its distribution in the United States, including its territories. We are also working with Novartis Pharmaceuticals on this matter.

Patient safety is Roche's and Genentech's primary concern. We continuously assess and enhance our product security strategies to ensure that patients receive safe and effective therapies. Genentech distributes LUCENTIS in the United States through our approved network of authorized distributors. Novartis distributes LUCENTIS outside of the United States only.

The following is true for all authentic Genentech LUCENTIS FDA-approved for use in the United States:

- All cartons, pre-filled syringes, and vials approved for use in the United States have "GENENTECH," "Genentech, Inc." or "Genentech, Inc., a member of the Roche Group" printed on the labels and cartons.
- The date of manufacture is not printed on the carton or vial.
- Serialization text and barcode is white on black (both serialized and non-serialized product may be in the market at the same time).
- All text on the vial labels, cartons, and package inserts is in English.

If you have any product in your possession that you suspect may be illegitimate or a counterfeit drug, or if you suspect a patient may have received illegitimate or a counterfeit drug, you should immediately contact the FDA's Office of Criminal Investigations (OCI) at 1-800-551-3989 (http://www.fda.gov/OCI) or Genentech's Product Complaint Hotline at: 1-800-334-0290.

If you are aware of a patient experiencing any adverse effects that you think may be related to LUCENTIS or to the use of an illegitimate or a counterfeit drug, please immediately call Genentech's Drug Safety Department at 1-888-835-2555, or MedWatch, the FDA Safety Information and Adverse Event Reporting Program at 1-800-FDA-1088.

Healthcare providers in the United States and its territories purchasing LUCENTIS should purchase only Genentech's LUCENTIS product approved for use in the United States. Healthcare providers who purchase and administer medicines that they have obtained from unauthorized distributors may be purchasing illegitimate product and may be putting patients at risk. Please see the following page for information on Genentech's authorized distributors and additional information on this topic.

Sincerely,

Martha Greene

Martha Greene,
Director, Channel Operations
Genentech USA, Inc.

For additional information, please see the following:

Resources:

Genentech LUCENTIS is available for sale to Physicians' Offices and Federally qualified Health Centers exclusively through these authorized distributors*:

Distributor	Phone	Fax	Web Orders
Besse Medical	800-543-2111	800-543-8695	www.besse.com
CuraScript SD	877-599-7748	800-862-6208	www.curascriptsd.com
McKesson Specialty Health	855-477-9800 (Non-Oncology Customers)	N/A	mscs.mckesson.com
Metro Medical (A Cardinal Health Specialty Solutions Company)	800-768-2002	615-256-4194	http://www.metromedicalorder.com

*Note: Authorized distributors may change. This list is current as of October 2018.

The current list of Genentech's authorized distributors for LUCENTIS can also be accessed at: https://www.genentech-access.com/hcp/brands/lucentis/learn-about-our-services/product-distribution.html

Phone Numbers:

- **Genentech Customer Service:** 1-800-551-2231
- **Genentech Medical Information Department:** 1-800-821-8590
- **Genentech Product Complaint Hotline:** 1-800-334-0290
- **Genentech Drug Safety Department:** 1-888-835-2555
- **FDA Office of Criminal Investigations:** 1-800-551-3989 (http://www.fda.gov/OCI)
- **MedWatch, the FDA Safety Information and Adverse Event Reporting Program:** 1-800-FDA-1088; or by facsimile at 1-800-FDA-0178; online at http://www.fda.gov/medwatch; or by mail, using the MedWatch form FDA 3500, to the FDA Medical Products Reporting Program, 5600 Fishers Lane, Rockville, MD 20852-9787

Authentic LUCENTIS packaging in the United States:

LUCENTIS Prefilled Syringe

LUCENTIS Vials