Viatrexx Bio Incorporated, Newark, Delaware is voluntarily recalling 10 mL sterile injectable vials of products, listed in the table below with lot numbers, to the consumer level. The products were sold exclusively to practitioners for office use. The products were manufactured in a manner that cannot guarantee its sterility.

Administration of a non-sterile product, intended to be sterile, may result in a site-specific or systemic infection, which in turn may cause hospitalization, significant morbidity, or a fatal outcome. To date, Viatrexx has not received any reports of adverse events related to this recall.

The products are used as sterile injectables and packaged in a 10 mL vial. The affected lots are included in the table.

Lot #	Ехр	Product	NDC #
19-S00001	May: 2020	Connectissue	73069-100-41
19-S00002	May: 2020	Muskel-Neural	73069-347-41
19-S00003	May: 2020	Ouch	73069-402-41
19-S00004	May: 2020	it hurts	73069-270-41
19-S00005	May: 2020	Adipose	73069-024-41
19-S00007	May: 2020	Systemic Detox	73069-500-41
19-S00008	May: 2020	Articula	73069-037-41
19-S00010	May: 2020	Neuro 3	73069-373-41
19-S00012	May: 2020	Infla	73069-249-41
19-S00014	May: 2020	Collagen	73069-095-41
19-S00016	May: 2020	Prolo	73069-443-41
19-S00017	May: 2020	Lymph 1	73069-310-41
19-S00018	May: 2020	Mesenchyme	73069-102-41
19-S00019	May: 2020	GI	73069-189-41
19-S00021	May: 2020	Arthros	73069-035-41
19-S00023	May: 2020	Immunexx	73069-244-41
19-S00024	May: 2020	Relief +	73069-450-41
19-S00025	May: 2020	Intra-Cell	73069-250-41
19-S00026	May: 2020	Facial	73069-164-41

These products have a very limited distribution to less than 32 US practitioners. They are only for the 10mL sterile injectable products.

Viatrexx is notifying its customers by email and phone and is arranging for the return and replacement of all recalled products. Practitioners that have any of the 10 mL sterile injectable product which is being recalled should stop using/return to Viatrexx or discard.

Consumers with questions regarding this recall can contact Viatrexx by calling 450-536-1295 or <u>info@viatrexx.com</u>, from Monday to Friday, between 9 am to 3 pm EST (closed between 1 and 2 pm EST). Consumers should contact their physician 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.

Complete and submit the report Online

Regular Mail or Fax: <u>Download form</u> or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

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