

FDA Warns Marketers of Unapproved 'Chelation' Drugs



Federal regulators are warning eight companies to stop selling so-called 'chelation' products that claim to treat a range of disorders from autism to Alzheimer's disease.

The Food and Drug Administration (FDA) says the companies have not proven their products are safe and effective in treating autism spectrum disorder, cardiovascular disease, macular degeneration, Parkinson's disease or any other serious illness. Some of the companies also claim their products can detect the presence of heavy metals in the body in an attempt to justify the need for chelation therapy.

FDA compliance expert Deborah Autor says the companies are preying on people made vulnerable because of serious illness.

"These products are dangerously misleading because they are targeted to patients with serious conditions and lim-

ited treatment options," says Autor.

In letters dated Oct. 14, FDA warns the companies that they are facing possible legal action if they continue to make unsubstantiated claims. The firms that received the letters (along with the chelation products they market) are:

- World Health Products, LLC: Detoxamin Oral, Detoxamin Suppositories, and the Metal Detector test kit
- Hormonal Health, LLC and World Health Products, LLC: Kelatox Suppositories, and the METALDETECTOR Instant Toxic Metals Test
- Evenbetternow, LLC: Kids Chelat Heavy Metal Chelator, Bio-Chelat Heavy Metal

Chelator, Behavior Balance DMG Liquid, AlkaLife Alkaline Drops, NutriBiotic Grapefruit Seed Extract, Natur-Leaf, Kids Clear Detoxifying Clay Baths, EBN Detoxifying Bentonite Clay, and the Heavy Metal Screen Test

- Maxam Nutraceuticals/Maxam Laboratories: PCA-Rx, PC3x, AFX, AD-Rx, AN-Rx, Anavone, AV-Rx, BioGuard, BSAID, CF-Rx, CreOcell, Dermatotropin, Endotropin, GTF-Rx, IM-Rx, Keto-Plex, Natural Passion, NG-Rx, NX-Rx, OR-Rx, Oxy-Charge, PN-Rx, Ultra-AV, Ultra Pure Yohimbe, and the Heavy Metal Screening Test
- Cardio Renew, Inc: CardioRenew and CardioRestore
- Artery Health Institute, LLC: Advanced Formula EDTA Oral Chelation
- Longevity Plus: Beyond Chelation Improved, EndoKinase, Viral Defense, Wobenzym-N
- Dr. Rhonda Henry: Cardio Chelate (H-870)

FDA says consumers should avoid non-prescription products offered for chelation or detoxification. FDA-approved chelating agents are available by prescription only and are approved for use in specific indications such as the treatment of lead poisoning and iron overload. The agency says even the prescription medications carry significant risks, and they should only be used with medical supervision.

The products come in a number of forms, including sprays, suppositories, capsules, liquid drops, and clay baths.

Overall, FDA says there's been an increase in the number of nonprescription, chelation products that claim to cleanse the body of toxic chemicals and heavy metals. Although some of the products are marketed on the Internet as dietary supplements, by law they're unapproved drugs and devices because they claim to treat, mitigate, prevent, or diagnose disease. [FDA](#)

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