Indiana State Department of Health
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Governor

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State Health Commissioner

DATE: October 18, 2010

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

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

SUBJECT: FDA News Release Over-the-Counter Chelation Products

SUGGESTED ACTION: **FDA Advisory; FDA warned eight companies that their over-the-counter (OTC) chelation products are unapproved drugs and devices and that it is a violation of federal law to make unproven claims about these products; Information provided in case of consumer inquiry.**

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FDA PRESS RELEASE

For Immediate Release: Oct. 14, 2010
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Consumer Inquiries: 888-INFO-FDA

FDA issues warnings to marketers of unapproved 'chelation' products

The U.S. Food and Drug Administration today warned eight companies that their over-the-counter (OTC) chelation products are unapproved drugs and devices and that it is a violation of federal law to make unproven claims about these products. There are no FDA-approved OTC chelation products.

The companies that received the warning letters claim that their products treat a range of diseases by removing toxic metals from the body. Some also claim to treat autism spectrum disorder, cardiovascular diseases, Parkinson's disease, Alzheimer's disease, macular degeneration, and other serious conditions. Some companies that received the warning letters also claim their products will detect the presence of heavy metals to justify the need for chelation therapy.

The drug products involved have not been evaluated by the FDA for treatment of these diseases, and violate the Federal Food, Drug, and Cosmetic Act (FFDCA). Despite the claims of the companies that received warning letters, the effectiveness in treating any of the diseases listed is unsubstantiated. Depending on the condition, when relying on unproven OTC chelation products to treat serious conditions, patients may delay seeking effective medical care.

In addition, there are serious safety issues associated with chelation products, which can alter the levels of certain substances in the blood. Even when used under medical supervision, these products can cause serious harm, including dehydration, kidney failure, and death.

"These products are dangerously misleading because they are targeted to patients with serious conditions and limited treatment options," said Deborah Autor, director of the Office of Compliance in the FDA's Center for Drug Evaluation and Research. "The FDA must take a firm stand against companies who prey on the vulnerability of patients seeking hope and relief."

The agency advises consumers to avoid non-prescription products offered for chelation or detoxification. The only FDA-approved chelating agents are available by prescription only and are approved for use in specific indications such as lead poisoning and iron overload. Procedures involving these agents carry significant risks and should be performed only under medical supervision.

The FDA has noted an increase in "chelation therapy" products marketed on the Internet that claim to cleanse the body of toxic chemicals and heavy metals. Although some of the products are marketed as dietary supplements, they are unapproved drugs because they claim to treat, mitigate, prevent, or diagnose disease. The products come in various dosage forms, including transmucosal sprays, suppositories, capsules, liquid drops, and clay baths.

Some of the companies also sell unapproved screening tests that claim to detect the presence of heavy metals in urine to justify the need for chelation therapy.

"FDA will seek enforcement action against companies that promote therapeutic benefits of products not yet evaluated by the agency for safety and effectiveness," said Dara A. Corrigan, associate commissioner for Regulatory Affairs.

Under the FFDCA, companies that market products that claim to prevent, diagnose, treat or cure diseases must file an application with the FDA and provide data that demonstrate their products' safety and effectiveness.

The companies must take prompt action to correct the legal violations cited in the warnings letters or face possible legal action, including seizure and injunction. The FDA issued warning letters to the following companies:

- 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 Nutraceutics/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)

For more information: Questions & Answers about Unapproved Chelation Products