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FDA Enforcement Action
Unapproved Over-the-Counter Chelation Products

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Office of Compliance, CDER, FDA
Silver Spring, MD

Overview

- CDER, Health Fraud and Consumer Outreach Branch
- Health Fraud and Drug Law
- OTC Chelation Drug Products
  - FDA Enforcement Action
  - Representative Products
  - Legal Authority for Action

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Health Fraud and Consumer Outreach Branch

- General Purpose: Identify and address fraudulent and dangerous drugs that pose the threat of a direct or indirect health hazard
- What is a health fraud product:
  - The FDA defines health fraud as the deceptive promotion, advertising, distribution, or sale of a product represented as being effective to prevent, diagnose, treat, cure or lessen an illness or condition, or provide another beneficial effect on health, but that has not been scientifically proven safe and effective for such purposes. (CPG 7150.10)

What is Health Fraud?

- No statutory definition of health fraud in FDCA
- Examples of FDA health fraud:
  - Ineffective or unproven products that consumers may use in place of proven medical treatments
  - A dietary supplement product that contains an undeclared prescription drug ingredient or a product that is not what it is represented to be
  - Counterfeits of approved products
- Some products are distributed by sincere but misguided individuals; others involve promotional schemes by "quick-buck artists" and charlatans.

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Where are Fraud Products Found?

- Internet
  - Firms at undisclosed locations
    - Contact info: PO Boxes, email, anonymous/registered by proxy
    - Often times operated out of residences
  - Fly-by-night companies
    - Easily change names/internet addresses/ locations
  - Minimal cost of running the business
  - Never have to confront victim
- Newspaper and magazine ads, and TV infomercials
- Retail stores

Health Fraud and Consumer Outreach Branch

- Examples of health fraud products:
  - Unapproved drugs with outrageous claims
    - Cancer, HIV, diabetes, autism, H1N1 influenza (Swine Flu)
  - Products tainted with drug ingredients
    - Weight Loss products, Sexual Enhancement products, Bodybuilding products
  - Products that fall outside the policies set forth in the homeopathic CPG
    - Hyland's Teething Tablets
    - Zicam Nasal Spray
  - Traditional Chinese Medicine (TCM) and Ayurvedics making drug claims or adulterated with harmful contaminants
  - Products marketed as Dietary Supplements with disease claims
  - Street Drug Alternatives
  - Cosmetics that are also unapproved new drugs

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Health Fraud and Consumer Outreach Branch

- Investigates websites
- Directs field investigations and coordinate case development
- Drafts Warning Letters and Cyberletters
- Reviews and approves seizure and injunction recommendations
- Educates consumers through outreach including videos, podcasts, radio and TV interviews, pamphlets, and online materials.

Enforcement Strategy

- Risk based assessment
- Highest priority given to products that pose a direct health hazard
- If indirect health hazard, consider the following factors:
  - Disease severity (e.g. cancer, HIV/AIDS)
  - Vulnerability of user group
  - Number of users affected and geographic scope
  - Negative influence on the new drug approval process
  - Economic impact
  - Agency resources

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Outreach Activities

- Live action and animation videos
- FDA Consumer Update articles
- Radio and TV interviews
- Podcasts
- Websites and Q and A's
  - Please visit www.fda.gov/healthfraud
- RSS feed – rapid notification system to quickly warn consumers about fraud products
- Messaging to trade associations

Food Drug and Cosmetic Act (FDCA)

- 1937 – Almost 100 people died from Elixir Sulfanilamide with a lethal solvent, diethylene glycol
- Led to passage of the Federal Food Drug and Cosmetic Act (FDCA) of 1938
- FDCA significantly amended since 1938, but same general statutory framework

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Food Drug and Cosmetic Act (FDCA)

- New Drug Approval Process
  - Premarket review for safety and effectiveness
- OTC Drug Review
  - Monograph system (no premarket review) OR
  - NDA for new ingredients/indications/dosage/ formulations
- Dietary Supplements
  - No premarket review; cannot make disease claims
  - FDA must prove significant or unreasonable risk of injury
- Biologics, Devices, Conventional Foods, Cosmetics, and Veterinary products

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Statutory Violations: Unapproved New Drug

- **FDCA § 301(d); [21 USC §331(d)]** – Introduction or delivery for introduction into interstate commerce of any article in violation of section … 505.
  - FDCA § 505; [21 USC § 355(a)] – No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application … is effective with respect to such drug
  - Definition of "new drug" FDCA § 201(p); [21 USC § 231(p)] – Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling

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Statutory Violations: Misbranding

- **FDCA § 301(a); [21 USC §331(a)]** – The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

  Misbranding – FDCA § 502(a); [21 U.S.C. § 352(a)] – If its labeling is false or misleading in any particular
  - **False** – product is represented as sterile but in fact isn't; label declares X is an ingredient, but X is not in the drug
  - **Misleading** – labeling has the capacity or tendency to deceive – omission, exaggeration, ambiguity

Statutory Violations: Misbranding

- **FDCA § 301(a); [21 USC §331(a)]** – The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

  Misbranding – FDCA § 502(f)(1); [21 U.S.C. § 352(f)(1)] – labeling fails to bear adequate directions for its intended uses
  - The product is offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners
  - Therefore, adequate directions cannot be written so that a layman can use it safely for its intended uses.

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Regulation of Dietary Supplements

- Dietary Supplement Health and Education Act of 1994
  - Dietary supplements are foods with special statutory provisions
  - Definition of "dietary supplement"
    - Intended to supplement the diet and contains one or more of the following ingredients:
      - Vitamins and minerals
      - Herbs or botanicals
      - Amino acids
      - A concentrate, metabolite, constituent, or extract of any of the above
    - Ingested and in tablet, capsule, powder, softgel, and/or liquid form
      - Topical and suppository products cannot be dietary supplements
    - Labeled as "dietary supplement"
    - Not an approved drug, or subject of an Investigational New Drug (IND) application

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Regulation of Dietary Supplements

- Marketing/labeling claims for dietary supplements
  - Affect or maintain the normal structure or function of the body
  - Cannot make disease claims

*****Disease claims make the product a drug*****

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FDA Enforcement of Health Fraud

- Advisory
  - Warning Letter, “Untitled” letter, or Cyberletter
- Administrative
  - Import alerts/refusals, recalls, detention, debarment or disqualification
- Judicial
  - Seizure, injunction, criminal prosecution

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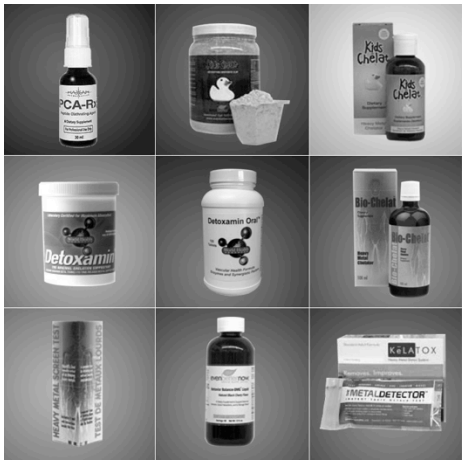

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Over-the-Counter Chelation Products

- FDA became aware of an increase in the number of chelation products marketed on the Internet
- Claim to treat and prevent disease by cleansing the body of heavy metals and toxic chemicals
- Marketed as dietary supplements, however they are unapproved drugs
- In violation of FDCA, products claiming to treat and prevent disease must be approved by FDA or meet the OTC monograph to be legally marketed

Chelation Fraudulent Claims

- “90% Reduction in Cancer Mortality”
- “Alternative to Amputation”
- "UNCLOG arteries and restore cardiovascular function"
- "The more chelation we give people, the less osteoporosis they have ...."
- “For anyone who is serious about avoiding degenerative diseases facing the human race, getting tested for heavy metals is more important than ever before.”

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FDA Initiative Against OTC Chelation Products

- WHEN: October 14, 2010
- WHAT:
  - Warning Letters to 8 Firms
  - FDA Press Release and Consumer Update
- WHY:
  - Over-the-counter products offered for chelation and detoxification
  - Marketed over the Internet as dietary supplements in various dosage forms (e.g., sprays, capsules, suppositories, liquid drops, clay baths)

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Over-the-Counter Chelation Products

- Firms target patients with serious and incurable diseases and/or limited treatment options.
- No evidence that products can treat these conditions:
  - Autism Spectrum Disorders
  - High blood pressure
  - Angina pectoris
  - Prevention of heart attack or stroke, as an alternative to coronary artery bypass surgery,
  - Alzheimer's Disease
  - Parkinson's disease

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Over-the-Counter Chelation Products

- No FDA-approved OTC chelation products
- All FDA-approved chelation products require a prescription because they can be used safely only under the supervision of a healthcare practitioner
- FDA's concerns include:
  - Patients will delay seeking proven and essential medical care while relying on these products
  - Potential for serious side effects such as dehydration, kidney failure, and/or death

FDA Recommendations to Consumers

- Advised consumers to talk with healthcare practitioners about treatment and prevention
- Consider in enrolling in clinical trials monitored by an Institutional Review Board and conducted under an approved Investigational New Drug application
- Report adverse events to MedWatch and the Adverse Event Reporting System
  - http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm

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Over-the-Counter Chelation Products

- 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)

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PC3x

PC3X 2oz (60ml)

Aids in and accelerates the cellular detoxification process. Has four of our most effective detoxifiers in one convenient product.
Averages 4 months' supply.

Our Price	**$99.99**
Retail	$125.00
Code	PC3X
Weight	0.28
7 Reviews	★★★★★

Qty 1 BUY 3 & GET 1 FREE! Save wishlist
ADD

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PC3x

- Disease claims of component drugs
  - Autism, Alzheimer's disease, allergies
  - Removes cardiovascular and cerebral vascular plaque
  - Removes uterine fibroids
  - Herpes, influenza, mad cow disease, cancer

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Bio-Chelat

Bio-Chelat Heavy Metal Chelator
Free UPS Ground Shipping on orders totaling over $150 (USA only).

List Price: ~~$45.00~~
Price: $39.95

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add to cart

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Bio-Chelat

Bio-Chelat™ is guaranteed to remove heavy metal ions from the body without removing essential minerals. It contains EDTA, an amino acid that is so effective at removing unwanted minerals and metals from the body, it has been the standard FDA approved treatment for lead, mercury, aluminum and cadmium poisoning for more than 50 years.

Through the Law of Isotonicity, Bio-Chelat™ can remove (indirectly) mercury from the brain, central nervous system and other organs.

As a preventative measure, Bio-Chelat™ keeps any unbound heavy metal ions from being absorbed (or re-absorbed) by the body, even with continuous exposure, whether it be metal ions from food, amalgams, or the environment. *Bio-Chelat*™ has its greatest value for sub-acute or chronic heavy metal toxicity.

Bio-Chelat

- Additional disease claims
  - Subacute and chronic heavy metal toxicity
  - Autism, behavioral and developmental disorders
  - Neuropathy
  - Pollen allergies

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Kids Chelat

Kids Chelat™ Heavy Metal Chelator for Children

Safely Remove Mercury and Other Toxic Metals

Price: $46.50
2+ $40.00 ea

View Supplement Facts and Order Now >>

Kids Chelat Heavy Metal Chelator is the same formula as Bio-Chelat™ Heavy Metal Chelator, only with added trace minerals. It is manufactured by Dr. Thomas Nissen, who introduced Bio-Chelat™ to North America from Germany. Kids Chelat has some very special and unique properties that set it apart from other chelators on the market.

Kids Chelat™ is a patented chelator that is composed of a very dilute solution of Disodium EDTA (200 mg per 100 ml bottle), mineral salts, and a small amount of an oxidative catalyser. Because of the addition of the *oxidative catalyser,* which loosens the molecular bonds of the heavy metal ions attached to the proteins' sufhydral group, only a tiny amount of EDTA needs to be used for maximum effectiveness.

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Kids Chelat

Thus, there are *no harmful side effects* with *Kids Chelat*™. It does not affect or harm the liver, kidneys or gastro-intestinal tract. Clinical studies in Germany have proven its safety and effectiveness for children.

Now the reason we like to recommend this product is that unlike most chelators, *it is able to chelate metals that are tightly bound to tissues and organs, including the brain.* By creating a high electric-magnetic gradient in the gastrointestinal tract, new heavy metal ions are pulled from the body (brain) into the blood stream and stomach/intestine and excreted (Law of Isotonicity). Therefore, the heavy metal ions are loosened and excreted even if they are very tightly bound to the tissues and organs.

And equally importantly, *Kids Chelat prevents the metals that have been loosened in the chelating process from being re-absorbed.* In an acidic environment (i.e. stomach, intestines etc.), Disodium EDTA forms a high complex bond with mercury and other heavy metals. Because of this, heavy metals coming from food, teeth, bile and so on are chelated and excreted through the bowel and not re-absorbed through the intestinal tract. So you do no need to worry about the metals being re-distributed in your child's body, and doing more damage to the tissues and organs.

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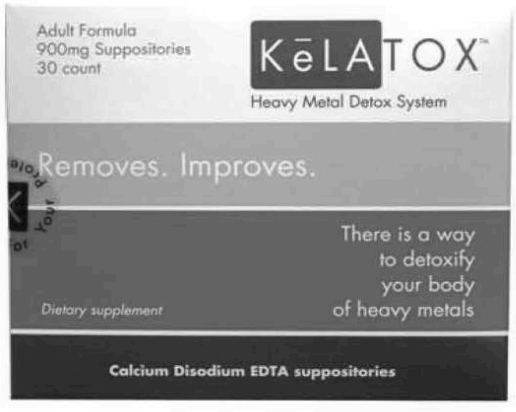
Kelatox



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Kelatox

The Center for Disease Control (CDC) has recommended EDTA chelation therapy for lead poisoning and other toxic heavy metal conditions for decades and is widely accepted as the best form of treatment for such conditions. Harmful heavy metals may cause or help exacerbate conditions as far ranging as decreased circulation, degenerative diseases such as Alzheimer's, diabetes, decreased adrenal gland function and Autism. The human body requires about 70 trace elements/minerals for optimal function such as magnesium, zinc, copper and manganese but there are several heavy metals that are classified as toxic to human physiology and include lead, mercury, aluminum, arsenic, cadmium and nickel. These harmful heavy metals have no place in the human body and may be toxic even at very low levels; therefore the need to remove them is great. For this fact alone Chelation therapy with Kelatox® should be considered as "the first step to any intelligent nutritional or detoxification regimen".

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Kelatox

- Additional disease claims
  - Chronic fatigue and fibromyalgia
  - Depression
  - Parkinson's Disease
  - Macular degeneration
  - Peripheral neuropathy

Outcomes of FDA Enforcement Action

- Two firms immediately voluntarily complied by removing or disabling their websites and ceased selling violative products
- One firm signed a consent decree of permanent injunction
- FDA continues to pursue additional enforcement actions for 5 remaining firms

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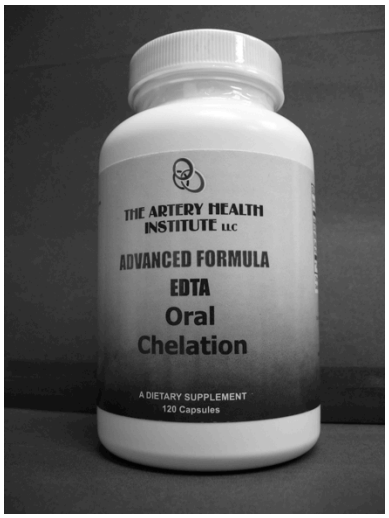
Artery Health Institute Injunction

June 29, 2011

- Inadequate website corrections after WL.
- Signed consent decree of Permanent Injunction:
  - Remove claims
  - Hire independent expert.



Public Outreach

- Media coverage
  - ABC News, Washington Post, Chicago Tribune, Associated Press, Reuters, NPR
- FDA.gov Website pages
  - FDA Warns Marketers of Unapproved "Chelation" Drugs
    - 15,333 visits
  - Unapproved Chelation Products
    - 11,585 visits
  - Press Release, FDA issues warnings to marketers of unapproved "chelation" products
    - 3,509 visits
  - Questions and Answers on Unapproved Chelation Products
    - 8,580 visits

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Summary

- Health Fraud and Consumer Outreach Branch, Office of Compliance, CDER, FDA
  - Compliance and enforcement activities for health fraud drugs such as OTC chelation products
  - 1-301-796-3110, OUDLCMail@fda.hhs.gov
- October 14, 2010 Warning Letters
  - 8 firms, multiple products marketed as dietary supplements, but were unapproved new drugs and misbranded drugs
- MedWatch Reports for adverse events associated with OTC chelation products
  - http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm

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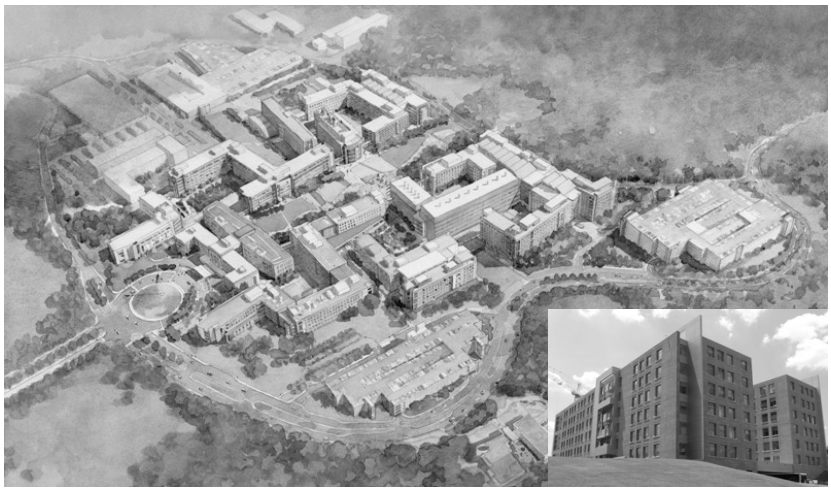
Questions?



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