

HHS NEWS

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Food and Drug Administration
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The Food and Drug Administration today issued a blunt warning to all Americans urging them not to use so-called "chelation therapy" capsules and tablets which have been promoted for home use for the prevention or treatment of cardiovascular diseases.

The warning was coupled with regulatory action by FDA to remove all such chelation products from interstate commerce.

Promoters have been selling these oral chelation tablets and capsules through the mails, over-the-counter and door-to-door with claims that they will reduce arterial plaque and improve circulation.

These products usually consist of vitamins, minerals and amino acids in various mixtures. FDA scientists said these mixtures have no proven benefit for the prevention or treatment of cardiovascular diseases.

True chelation agents are substances that combine with metals and are used to combat poisonings with heavy metals, digitalis overdoses and excess calcium. In this therapy, physicians inject FDA-approved chelating drugs.

But, FDA has neither received nor approved any marketing applications for a nonprescription oral chelation product. Moreover, FDA has not approved clinical trials in humans with any such formulation.

FDA is notifying all known makers and distributors that oral chelation products are unapproved new drugs and their sale must stop. If the companies

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fail to comply within 10 days of letter receipt, FDA warned it will take "legal action to enforce the law."

Anyone concerned about heart or circulatory diseases should obtain reputable medical counsel and a complete diagnostic workup, FDA said. The agency suggested that consumers ask questions about the scientific basis for any unorthodox therapy.

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