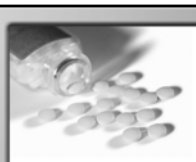
Division of New Drugs and Labeling Compliance

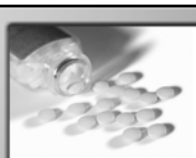
Kathleen Anderson
301-827-8930

Targeted Risk Based Enforcement

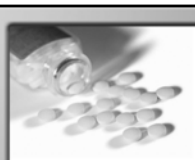
CDER Forum for International Drug Regulatory Authorities



- Internet and Health Fraud Team
- New Drugs and Labeling Team
- Over-the-Counter Drugs Team
- Imports, Exports and PDMA Team
- Compounding Team

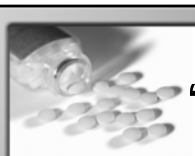


Internet and Health Fraud Team



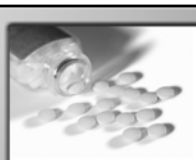
Risk-Based Assessment and Prioritization

- Prioritize unapproved new drugs identified for regulatory action using risk-based assessment
- Develop compliance strategies to address the most significant legal violations.



"Dietary Supplement" Survey

- Products promoted and sold on websites as "dietary supplements" for treating erectile dysfunction and enhancing sexual performance.
- Undercover buy survey: 17 products sold as "dietary supplements" were purchased and analyzed.
- Six of 17 products contained either sildenafil [approved prescription drug active pharmaceutical ingredient (API)] or an analogue of sildenafil or vardenafil, another API.
- Products: Zimaxx, Libidus, Neophase, Nasutra, Vigor-25, Actra-Rx.



"Dietary Supplement" Survey – Continued

- Significant risk to public health.
- Warning letters were issued to the firms who marketed the products. Libidus and 4EVERON were placed on import alert. A press release was issued.
- Investigations are ongoing.

Hydrogen Peroxide Therapy

- 35% (high-strength) hydrogen peroxide marketed over the internet for oral and IV medicinal uses.
- Claims to treat cancer, emphysema, AIDS, and other serious, life-threatening diseases.
- 35% hydrogen peroxide is not approved by FDA for any purpose.
- Direct health hazard: Reports of serious adverse events, including death.
- Warning letters issued to two firms.
- Press Release

New Drugs and Labeling Team

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Marketed Unapproved Drugs Initiative

- lack rigorous scientific review that demonstrates safety and effectiveness
- labeling may be deficient and not meet contemporary standards
- potentially significant public health issue

Marketed Unapproved Drugs – Compliance Policy Guide

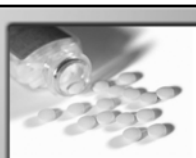
- issued June 2006
- intended to assure that all drugs are safe and effective
- a prioritized, risk-based enforcement approach encouraging companies to independently comply with the approval process
- outlines a risk-based enforcement approach that is flexible, but firm
- prioritization based on potential to harm the public health
- one part of our ongoing drug safety initiative to ensure that patients, consumers, and health-care providers have the most up-to-date drug safety information

Enforcement Priorities

- Drugs with potential safety risks
- Drugs that lack evidence of effectiveness
- Health fraud drugs
- Drugs that present direct challenges to the new drug approval and OTC monograph systems
- Unapproved new drugs that violate the act in other ways (e.g., GMP deficiencies)
- Drugs that are reformulated to evade FDA enforcement action

Initiation Process

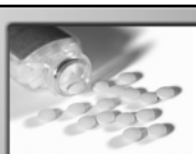
- Ongoing assessment of marketed unapproved drugs for risk potential
- Ad hoc assessments
- Action Process
  - -Federal Register Notice
  - -Administrative Action (Warning Letter)



Accomplishments

Carbinoxamine Action

- DESI reviewed drug, requires approval for marketing
- Two approved carbinoxamine products for various allergic symptoms
- Numerous unapproved products, single ingredient and combinations, marketed without FDA approval
- Unapproved products labeled for treatment of cough and cold symptoms, an indication for which carbinoxamine has not been found safe and effective by FDA
- Safety concerns regarding their use in children under 2 years of age.
- Formulated as drops and syrups specifically labeled for use in children as young as one month of age
- Never studied in very young children, and FDA cannot predict how they will respond
- Children under 2 years of age more susceptible to drug-related adverse events, in part due to the immaturity of their systems



Over-the-Counter Drugs Team

OTC Enforcement Priorities

- Products that present a health hazard
- Products that violate the integrity of the OTC monograph process or the NDA process

Selected OTC Priorities

- Nail Fungus Products
- Topical Hormone Products
- Cough/Cold Combination Products
- Barrier Cream Products

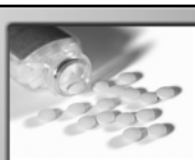
Recent Enforcement Action

- Triaminic Vapor Patch (cough/cold relief)

  To be used on children 2 yrs. to 12 yrs. of age

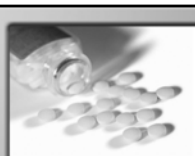
- Ingredients met the final monograph, but patch dosage form did not
- Child could remove patch and ingest drug ingredients
- Class I health hazard – product was recalled

Import-Export Team



Import-Export Team

- Agency focal point for all compliance issues that involve the import and export of drug products in the U.S.
- Enforces the laws and regulations under the Prescription Drug Marketing Act (PDMA) and implementing related regulatory policies.



Import- Export Team

Team Priority: Secure Supply Chain (SSC)

- To facilitate entry review of compliant products under a secure supply chain program.
- Pilot program will be used to evaluate feasibility and benefits of the program.
- Requires manufacturers to provide certain product information from the foreign manufacturing sites to the U.S. distribution centers.

Import- Export Team

SSC

This information includes:

- API source, intermediate manufacturing steps, storage, packaging and labeling processes, methods of transportation from the foreign manufacturing site to the foreign port of loading and into the U.S. port of entry; and methods of transportation from the port of entry to the U.S. consignee.

Import-Export Team

Advantages of a secure supply chain:

- Protects against terrorism, counterfeiting, and diversion activities in imported products.
- FDA can verify and/or audit all data.
- Agency can focus its resources on the review of non-complaint products that can pose a risk to U.S. consumers.

The Compounding Team (TCT)

The Compounding Team Priorities

- Compounding vs Manufacturing
- Copying commercially available drugs
- Risks to public health
- False and misleading internet claims

The Compounding Team Priorities

- Compounding vs Manufacturing
  * Inhalation drugs

The Compounding Team Priorities

- Inhalation Drugs
  - CMS reimbursement
  - Sterility requirement, inappropriate compounding
  - Recent Warning Letters

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