

September 25, 2001

TO WHOM IT MAY CONCERN-

3650 '01 SEP 27 P12:17

Enclosed is a "Petition to the FDA- Docket Management Branch, or forward to the correct FDA Branch concerned with corrections of public information, in accordance with the Federal Food, Drug and Cosmetic Act laws."

I, as Founder and President of P.E.O.P.L.E., or 'People Erroneously On Prescribed Lethal Estrogen', am petitioning the FDA, on behalf of this organization, and the entire American Public.

PROBLEM- The estrogen and progestin drug information, available to the public, is "Misbranded" due to misleading, incorrect, and withholding most important information, in regards to both, drug benefits, and risks of estrogen and progestin hormone drugs as prescribed to an entire healthy population.

This severe lack of correct and truthful information is evident throughout this hormone drug package labeling, drug inserts, drug leaflet information, the Physician's Desk Reference, and Drug Advertisements. The American Public is requesting the truth.

Our EVIDENCE proves.....VIOLATION of-

1. Federal Food, Drug, and Cosmetic Act Sections 403, 502, 602- Violated.
2. 21 CFR 314- pertaining to scientific data to evaluate 'safety, and SUBSTANTIAL evidence of effectiveness' for which the drug is being offered(505)- Violated.
3. 21 CFR 310.300, 301 and 305; 312 and 314;343,80 and 431.60- with the broad intent of these regulations to promote communication needed to ensure safe and effective drugs, for the purpose of protected health through drugs- Violated.
4. 503(b)(2)- Cautionary statements to be contained in the prescription- Violated.
5. 502(d)- Warning; May be habit forming- Violated..
6. 21 CFR 201- labeling information can be understood by the ordinary individual - Violated.
7. 21 CFR 201.5- Adequate directions for use. Quantity of dose. Duration of administration. Violated.
8. 21 CFR 369- Adequate Warnings for the protection of users. Drug interaction precaution- Violated.
9. Section 502(a)- requires labeling must NOT contain any statement which is false or misleading in any particular. Recommended for use for conditions shown by scientific tests to be effectively treated by the drug- Violated.
10. Section 502(n)- Drug advertising, true and nonmisleading summary of information as to adverse side effects, contraindication and effectiveness of drug- Violated.
11. 21 CFR 202- Regulation define requirements in greater detail. Violated.
12. Section 503- Prohibits drug samples and drug coupons- Violated.

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ACTION- P.E.O.P.L.E. is adamantly requesting that the FDA, review and revise public and physician information to comply, and to **INCLUDE** factual risk and benefit drug information, as understood by the drug industry, and the FDA, according to published documentation of numerous studies, FDA written materials, and Freedom of Information Documentation.

As presently reported the drug labeling facts and information of these specific hormone drugs, is **NOT** consistent with factual documentation, causing enormous violation of several of the **LAWS** in which drugs are marketed and prescribed.

Changes must be made, in agreement, and cooperation with Federal Rules and Regulations, and Laws, assuring truthful drug information becomes available to the public.

Boxed Warnings are also an obligation of the laws, due to the several fatal side effects documented as fact within the Freedom of Information Documentation, but concurrently withheld from public view.

The available evidence of withheld information is severe, and this **ACTION** is calling for correction of drug information as **paramount** importance. We request your immediate attention.

The undersigned certifies that it is knowledge of facts, that this petition includes information on which the petition relies, and that it includes representative data and documentation, to demand this investigation, for the health and welfare of the public.

On behalf of P.E.O.P.L.E., I look forward to your deep concern and your reply.



Gail Elbek
380 N. San Marcos Road Santa Barbara, CA 93111
805-967-6845

9-27-01

Attention: MS. HARRIS:

The Letter of FDA violations
of drug labeling does NOT
affect Environmental Impact.

I look forward to an FDA reply.

Thank you,

Gail Elliott

380 N. San Marcos Rd.

Santa Barbara, CA

93111

805-967-6845



Gail Elbek
380 N San Marcos Rd.
Santa Barbara, CA 93111



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most
Important

Food + Drug Administration
Dockets Management Branch (HFA-305)
Room 1-46 Park Building
12420 Parklawn Drive
Rockville, MD 20857