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February 21, 2001

Bernard A. Schwetz, D.V.M., Ph.D.
Acting Principal Deputy Commissioner
Dockets Management Branch
U.S. Food and Drug Administration, Room 1061
5630 Fishers Lane
Rockville, MD 20852

RE: Petition for "Truth in Labeling" on Premarin Prescriptions

Dear Acting Commissioner Schwetz,

On behalf of the 10,813 citizens who have signed our enclosed petition, we respectfully request that the U.S. Food and Drug Administration change its labeling guidelines to require full and clear disclosure of the source of the drug Premarin on all information inserts, repackaged bottles, boxes and other containers issued by pharmacies for Premarin prescriptions.

As you know, Premarin is a hormone replacement drug made with estrogens derived from the urine of pregnant mares. However, this information is essentially hidden from women taking the drug.

A recent nationwide survey of women ages 40 and over conducted by Zogby International found that most women aren't aware of the source of Premarin and that most doctors aren't discussing other options for hormone replacement therapy with their patients. It is therefore critical that Premarin labeling clearly indicate that this drug is made with estrogens derived from the urine of pregnant mares. The same survey also found that most women would prefer to take a plant-based or synthetic alternative to Premarin once they know how it is produced. *(A copy of the survey results and a news release on the survey are enclosed for your information.)*

Information inserts included with Premarin prescriptions and other like-sounding HRTs made by Wyeth-Ayerst such as Prempro have a one-line reference to the source material as being derived from pregnant mares' urine. However, this information is incorporated in the fine print intended for physicians in the information. It is not included in the "Information for the Patient" section. *(See enclosed insert for example.)* In addition, once Premarin and Prempro are repackaged in a bottle, box or other container, there is no labeling on any of these packages to let women know that they are taking a drug derived from horse urine.

01P-0083

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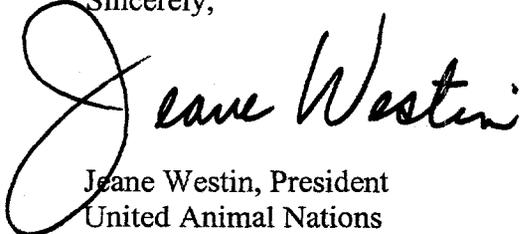
UNITED ANIMAL NATIONS/Page Two

We believe that women have a right to make an informed choice about their hormone replacement therapy. Tens of thousands of pregnant mares are exploited and thousands of foals are slaughtered annually to produce Premarin. At the very least, women who take these drugs should know that they are made with estrogens derived from the urine of pregnant mares. This should be clearly disclosed in "Information for the Patient" section on all inserts as well as on ALL Premarin packaging.

To date, nearly 11,000 women across the United States have signed onto our "truth in labeling" petition, believing that your agency must take a leading role in ensuring that American women are able to make an informed choice about their hormone replacement therapy. If the medical community isn't going to tell women where Premarin comes from, the government should require that this information be clearly labeled on all prescriptions.

We thank you for your attention to this matter, and we look forward to your response.

Sincerely,

A handwritten signature in black ink that reads "Jeane Westin". The signature is written in a cursive style with a large, looping initial "J".

Jeane Westin, President
United Animal Nations



February 23, 2001

Bernard A. Schwetz, DVM, Ph.D.
Acting Principal Deputy Commissioner
Dockets Management Branch
U.S. Food and Drug Administration, Room 1061
5630 Fishers Lane
Rockville, MD 20852

RE: No Requirement for Environmental Impact Statement for "Truth in Labeling" Petition for Premarin Prescriptions

Dear Acting Commissioner Schwetz,

The following letter is to state our position that no environmental impact statement is required for our "Truth in Labeling" Petition for Premarin Prescriptions submitted on February 23.

This petition involves changing the requirements for labeling on Premarin prescriptions and does not involve the approval of food or color additives, drugs, biological products, animal drugs or medical devices.

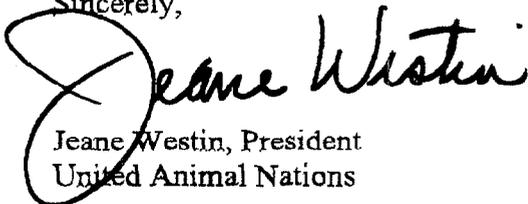
The petition was signed by 10,813 citizens and was submitted by United Animal Nations, under my signature, Jeane Westin, president of United Animal Nations.

My contact information is as follows:

Jeane Westin, President
United Animal Nations
P.O. Box 188890
Sacramento, CA 95818
Tel: (916) 429-2457

Thank you for your attention to this matter.

Sincerely,



Jeane Westin, President
United Animal Nations



February 23, 2001

Bernard A. Schwetz, DVM, Ph.D.
Acting Principal Deputy Commissioner
Dockets Management Branch
U.S. Food and Drug Administration, Room 1061
5630 Fishers Lane
Rockville, MD 20852

RE: Certification for Petition on "Truth in Labeling" for Premarin Prescriptions

Dear Acting Commissioner Schwetz,

The following letter is to certify that our petition submitted on February 21, titled "Truth in Labeling" for Premarin prescriptions, includes all information relevant to our petition to the best of our knowledge.

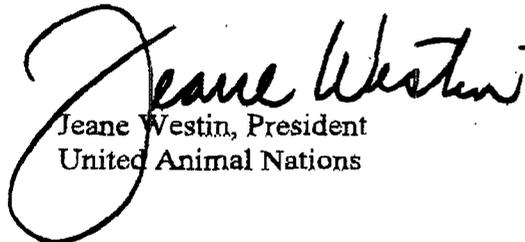
The petition was signed by 10,813 citizens and was submitted by United Animal Nations, under my signature, Jeane Westin, president of United Animal Nations.

My contact information is as follows:

Jeane Westin, President
United Animal Nations
P.O. Box 188890
Sacramento, CA 95818
Tel: (916) 429-2457

Thank you for your attention to this matter.

Sincerely,


Jeane Westin, President
United Animal Nations



UNITED ANIMAL NATIONS

800 440-EARS or 916 429-2457 FAX 916 429-2456 • 5892A S. Land Park Dr., Sacramento, CA 95822
Website: www.uan.org E-mail: info@uan.org

NEWS RELEASE

FOR IMMEDIATE RELEASE

For more information, contact:
Pam Runquist, UAN, (916) 429-2457.

National Survey Shows Doctors Keep Women in Dark About Premarin *Women Prefer Cruelty-Free Alternatives When Told Pregnant Mares and Foals Suffer to Produce Popular Hormone Replacement Drug*

SACRAMENTO, CA (February 6) - A new survey of nearly 500 women age 40 and over shows that medical professionals aren't telling most American women that Premarin -- the most commonly prescribed hormone replacement drug in the United States -- is made with estrogens derived from the urine of pregnant mares.

The survey, conducted by Zogby International, also reveals that most women would prefer to take an alternative to Premarin once they know that tens of thousands of pregnant mares suffer every year to produce this drug. The number of women who object to Premarin increases even more once they know that the majority of baby foals born to these mares are discarded for slaughter as an annual "byproduct" of Premarin production.

"This survey shows just how critical our education effort is on the Premarin issue," said Jeane Westin, president of United Animal Nations (UAN), a nationwide animal advocacy and rescue group based in Sacramento, California, which commissioned the survey. "More and more prescriptions are being written for Premarin and no one is telling women where this drug comes from." Manufactured by Wyeth-Ayerst, Premarin is taken by an estimated 9 million American women and those numbers are predicted to escalate as millions of baby boomers reach menopause during the next decade.

"Evidence clearly indicates that Premarin users face increased risk of breast cancer," says Neal D. Barnard, M.D., president of the Physicians Committee for Responsible Medicine. "In fact, there's no reason to take Premarin. Diet and other lifestyle choices are much healthier and more powerful over the long run. However, women looking for a hormone replacement therapy product will find many effective alternatives to Premarin."

The survey, which was conducted via telephone by Zogby International, asked women ages 40 and over if they were aware that Premarin and other like-sounding hormone replacement therapies such as PremPro and Premphase (which are used to treat menopausal symptoms) are derived from the urine of pregnant horses. About half of the respondents (231 women of the 487 respondents or 47 percent) said they were not aware of the source of Premarin while only 31 percent (less than a third of the respondents) said they were very aware of where Premarin comes from.

When asked if their doctor or other medical professional had told them that there were various alternatives available to Premarin, by more than two to one respondents said

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UNITED ANIMAL NATIONS/Page Two

they hadn't been told about cruelty-free plant-based and synthetic options. (Sixty three percent of respondents, or 309 women, said they hadn't been told that options were available while only 30 percent or 147 respondents said their doctors had shared this information with them.)

When respondents were told that tens of thousands of pregnant mares are forced to stand in small stalls, with a urine collection device hooked to them, for as many as six months out of every year to produce Premarin, a majority of respondents (53 percent or 255 women) said they would choose a plant-based or synthetic treatment as opposed to Premarin. That percentage increased to 54 percent (265 women) when respondents were told that the majority of foals born to these mares are sent to slaughter, their meat shipped overseas to Europe and Japan to be eaten.

Animal advocates, including members of United Animal Nations, have been working to spread the message about Premarin for years. However, they are fighting a long-established industry (Wyeth-Ayerst has been producing Premarin in Canada since 1942) and its close connections with the medical and insurance community. (Wyeth-Ayerst is currently facing an anti-trust lawsuit filed by a competitor, Duramed, based on the administrative rebates and fees it offers doctors and insurers who limit their prescriptions to Premarin.)

The industry also has increased its use and abuse of horses in recent years with the opening of a new "pregnant mares' urine" (PMU) plant in Minnesota by Natural Biologics. This company has applied for a permit from the U.S. Food and Drug Administration to produce a generic version of Premarin and is already contracting with more than 40 farmers throughout the midwestern United States to keep pregnant mares hooked to urine collection devices.

"Wyeth-Ayerst is misleading and deceiving women by withholding important information," said Dr. Paula Rothman, a gynecologist specializing in reproductive endocrinology in the Atlanta, Georgia area who offers alternatives to Premarin to her patients. "We need to do a better job educating women about the needless suffering of PMU horses and the many safe, effective and more natural forms of ERT that would end the suffering of the innocent."

For more information about United Animal Nations and its anti-Premarin campaign visit the website at www.uan.org or contact UAN, P.O. Box 188890, Sacramento, CA 95818, Tel: (916) 429-2457.

Premarin Survey

Submitted to:
United Animal Nations

Submitted by:
Zogby International
John Zogby, President and CEO
Regina Bonacci, Vice President and Chief of Staff
John Bruce, Vice President and Systems Administrator
Rebecca Wittman, Vice President and Managing Editor

January 23, 2001



Date: January 23, 2001

To: Pam
United Animal Nations
Fax: 916-429-2456

From: Rebecca Wittman
Fax: 315-624-0210
e-mail: editorial@zogby.com

RE: Zogby America Report

Methodology

This nationwide poll of 487 women age 40 and older was conducted by Zogby International from January 14 through January 22, 2001. All telephone calls were made from Zogby International headquarters in Utica, N.Y. The margin of error is +/-4.5. Margins of error are higher in sub-groups.

Summary

1. Are you taking any of the following hormone therapy replacements?

Premarin	16%
PremPro/PremPhase/PremPac	7
Other	9
Not taking any	63
Not sure	5

About one in six (16%) women 40 or older are using Premarin in hormone therapy replacement. Another one in twelve (7%) are using something similar to Premarin and one in eleven (9%) are using a plant-based or synthetic option. More than three in five (63%) women 40 and older are not using anything.

Women in the West (25%) and Central/Great Lakes region (19%) are more likely than women in the South (14%) or the East (6%) to use Premarin. Women in the South (15%) are the *most likely* to use other options in hormone replacement therapy, while women living in the East (78%) are the *most likely* to use *no* hormone replacement therapy.

The use of Premarin decreases with education with 20% of those with less than a high school education using the drug. Use drops to 15% among women with a college education or better. There is little difference in the percentage using Premarin among women over 50, however, with women between the ages of 50 and 64, nearly one in seven (14%) use an alternative.

In general, use of alternative therapies increases with income level.

2. *Has your doctor or other medical professional told you that there are a number of options available for hormone replacement therapy including those derived from animal sources, plant-based treatments, and synthetic drugs?*

Yes 30% No 63% Not sure 7%

By more than two to one (63% to 30%), respondents said their doctor or other medical professional has not told them that there are options to Premarin available to them. This is generally true across all sub-groups. Among women 50-64, many more are informed of alternative therapies (44%) compared to women aged 40-49 (24%) or those 65 and older (18%).

3. *How aware are you that Premarin and other like-sounding hormone replacement therapies such as PremPro, PremPhase, and PremPac are made with estrogens derived from the urine of pregnant horses?*

Very aware	32%		
Somewhat aware	12	Aware	44%
Not at all aware	47		
Not sure	9		

Slightly more women are *not aware* that Premarin and other like-sounding hormone replacement therapies are derived from the urine of pregnant horses than those who are aware – 47% to 44% – while 9% are not sure.

Women living in the West (55%) are the most aware, while those living in the South are the least aware (36%). Awareness increases with education (less than high school 28% aware; college or better 45% aware) and among the age groups, women 50-64 are much more aware (51%) than younger women (39%) or older women (39%).

There is no clear pattern among income levels, those women whose household incomes are \$75,000 or more a year are the most aware (54% compared to about 40-43% at the other levels).

4 - 5. If you knew that in order to make Premarin and other like-sounding drugs, pregnant horses are confined in narrow stalls day and night hooked up to a machine that collects their urine, how likely would you be to choose a plant-based or synthetic treatment over Premarin? and If you knew that the foals of the horses used to make Premarin and used-up mares are sold to be slaughtered for meat consumption in Europe and Japan, how likely would you be to choose a plant-based or synthetic treatment over Premarin?

Table 1. More Likely vs. Less Likely

If you knew. . .	More likely			Less likely			No difference	Not sure
	Overall	Much	More	Overall	Much	Less		
used-up mares are sold to be slaughtered for meat consumption in Europe and Japan	54	43	11	10	5	5	21	15
that pregnant horses are confined in narrow stalls hooked up to a machine that collects their urine	53	41	12	10	6	4	22	15

When given the facts about how Premarin is made and what the consequences to the horses are, women are more than five times as likely to say they would prefer plant-based or synthetic treatments over animal-derived treatments. And they are more than twice as likely to prefer alternative treatments than to say it makes no difference to them.

More than half (54% and 53% respectively) say they are more likely to prefer alternative treatment when they learn that mares and their foals are sent for slaughter when the industry is done with them and that pregnant horses are confined in narrow stalls and hooked up to machines to collect their urine. Just one in ten say that knowledge makes them less likely to prefer alternatives and just over one in five say it makes no difference in their decision.

Women in the West seemed to be more bothered by confinement methods than with the slaughter of the horses for food as 53% are more likely to seek alternatives when they learn about confining the horses while 44% are more likely to look for options when they learn about horses being shipped to slaughter after they are used.

The opposite is true in the East – 44% are more likely to look to an alternative source because of confinement methods, while 54% would do so because of slaughtering the animals for food. Women in the South are most open to arguments about confinement – 60% are more likely to prefer alternatives to Premarin – and women in the Great Lakes/Central region are most open to

arguments about slaughtering the mares and foals for food – 60% are more likely to use alternatives.

Younger women are more likely to be swayed by both arguments than older women, and all age groups are slightly more likely to seek a change when confronted with the knowledge that the animals are sent to slaughter when the industry is done with them.

A majority of women in all income groups would be more likely to prefer a plant-based or synthetic alternative to Premarin when given the facts about the confinement and slaughter of horses.

Zogby America 1/22/01 - Women 40+

29. Are you taking any of the following hormone therapy replacements?

	Total		Region								2000Presidential											
			East		South		CentGrLk		West		Gore		Bush		Buchanan		Nader		SmElse		NV/NS	
	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%
Premarin	80	16.4	6	6.2	17	14.0	31	18.7	26	25.2	38	16.7	27	14.8			1	12.5	2	40.0	5	18.5
Premarin-OtherName	34	7.0	5	5.2	5	4.1	14	8.4	10	9.7	21	9.3	10	5.5			1	12.5			2	7.4
Other	42	8.6	5	5.2	18	14.9	13	7.8	6	5.8	14	6.2	21	11.5	1	100.0	1	12.5			3	11.1
None	308	63.2	76	78.4	75	62.0	100	60.2	57	55.3	144	63.4	117	63.9			5	62.5	2	40.0	16	59.3
NS	23	4.7	5	5.2	6	5.0	8	4.8	4	3.9	10	4.4	8	4.4					1	20.0	1	3.7
Total	487	100.0	97	100.0	121	100.0	166	100.0	103	100.0	227	100.0	183	100.0	1	100.0	8	100.0	5	100.0	27	100.0

	AgeGroup						Gender		Education							
	30-49		50-64		65+		Female		<HS		HSGrad		SomeCol		Col+	
	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%
Premarin	6	4.3	41	20.9	33	22.0	80	16.4	5	20.0	20	18.5	25	16.3	29	14.6
Premarin-OtherName	5	3.5	21	10.7	8	5.3	34	7.0	1	4.0	2	1.9	10	6.5	21	10.6
Other	9	6.4	28	14.3	5	3.3	42	8.6	3	12.0	5	4.6	17	11.1	17	8.5
None	114	80.9	95	48.5	99	66.0	308	63.2	15	60.0	78	72.2	92	60.1	123	61.8
NS	7	5.0	11	5.6	5	3.3	23	4.7	1	4.0	3	2.8	9	5.9	9	4.5
Total	141	100.0	196	100.0	150	100.0	487	100.0	25	100.0	108	100.0	153	100.0	199	100.0

Zogby America 1/22/01 - Women 40+

29. Are you taking any of the following hormone therapy replacements?

	Total		Race										Religion									
	f	%	White		Hispanic		African American		Asian		Other		Catholic		Protestant		Jewish		Muslim		Other	
			f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%
Premarin	80	16.4	71	16.6	1	14.3	4	13.3			3	15.8	15	12.9	44	17.5	4	30.8	1	50.0	15	14.7
Premarin-OtherName	34	7.0	32	7.5							2	10.5	7	6.0	16	6.4	1	7.7			10	9.8
Other	42	8.6	38	8.9	1	14.3	1	3.3			2	10.5	9	7.8	25	10.0	1	7.7			7	6.9
None	308	63.2	268	62.8	5	71.4	23	76.7	1	50.0	10	52.6	82	70.7	151	60.2	6	46.2	1	50.0	67	65.7
NS	23	4.7	18	4.2			2	6.7	1	50.0	2	10.5	3	2.6	15	6.0	1	7.7			3	2.9
Total	487	100.0	427	100.0	7	100.0	30	100.0	2	100.0	19	100.0	116	100.0	251	100.0	13	100.0	2	100.0	102	100.0

	Ideology															
	Prog/VeryLib		Liberal		Moderate		Conservative		Very cons		Libertarian		NS			
	f	%	f	%	f	%	f	%	f	%	f	%	f	%		
Premarin	4	21.1	20	19.0	23	14.0	19	14.1	8	26.7				5	18.5	
Premarin-OtherName	2	10.5	8	7.6	13	7.9	7	5.2			1	100.0		2	7.4	
Other	1	5.3	5	4.8	12	7.3	17	12.6	4	13.3				3	11.1	
None	11	57.9	68	64.8	105	64.0	88	65.2	17	56.7				16	59.3	
NS	1	5.3	4	3.8	11	6.7	4	3.0	1	3.3				1	3.7	
Total	19	100.0	105	100.0	164	100.0	135	100.0	30	100.0	1	100.0		27	100.0	

Zogby America 1/22/01 - Women 40+

29. Are you taking any of the following hormone therapy replacements?

	~~ Total ~~		~~~~ BornAgain ~~~~~				----- Income -----											
	f	%	Yes		No/NS		< \$15,000		\$15-24,999		\$25-34,999		\$35-49,999		\$50-74,999		\$75,000+	
			f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%
Premarin	80	16.4	23	17.3	21	17.9	10	21.3	7	14.9	10	15.6	6	8.8	13	16.7	11	12.2
Premarin-OtherName	34	7.0	9	6.8	7	6.0	2	4.3	2	4.3	4	6.3	5	7.4	10	12.8	9	10.0
Other	42	8.6	14	10.5	11	9.4	1	2.1	3	6.4	9	14.1	7	10.3	8	10.3	9	10.0
None	308	63.2	79	59.4	71	60.7	33	70.2	35	74.5	39	60.9	49	72.1	44	56.4	56	62.2
NS	23	4.7	8	6.0	7	6.0	1	2.1			2	3.1	1	1.5	3	3.8	5	5.6
Total	487	100.0	133	100.0	117	100.0	47	100.0	47	100.0	64	100.0	68	100.0	78	100.0	90	100.0

	~~ Outside ~~				----- Party -----								----- Union -----			
	Yes		No/NS		Democrat		Republican		Independent		NS		Yes		No/NS	
	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%
Premarin	28	12.2	51	20.0	35	16.5	20	13.4	18	20.0	2	14.3	13	14.3	66	16.8
Premarin-OtherName	22	9.6	12	4.7	15	7.1	11	7.4	8	8.9			8	8.8	26	6.6
Other	22	9.6	20	7.8	13	6.1	18	12.1	9	10.0	1	7.1	8	8.8	34	8.6
None	145	63.0	163	63.9	139	65.6	93	62.4	52	57.8	9	64.3	57	62.6	251	63.7
NS	13	5.7	9	3.5	10	4.7	7	4.7	3	3.3	2	14.3	5	5.5	17	4.3
Total	230	100.0	255	100.0	212	100.0	149	100.0	90	100.0	14	100.0	91	100.0	394	100.0

Zogby America 1/22/01 - Women 40+

30. Has your doctor or other medical professional told you that there are a number of options available for hormone replacement therapy including those derived from animal sources, plant-based treatments, and synthetic drugs?

	Total		Region								2000 Presidential											
	f	%	East		South		CentGrLk		West		Gore		Bush		Buchanan		Nader		SmIElse		NV/NS	
			f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%
Yes	147	30.2	27	27.8	32	26.4	60	36.1	28	27.2	77	33.9	58	31.7	1	100.0			2	40.0	4	14.8
No	309	63.4	63	64.9	81	66.9	94	56.6	71	68.9	139	61.2	111	60.7			8	100.0	2	40.0	23	85.2
NS	31	6.4	7	7.2	8	6.6	12	7.2	4	3.9	11	4.8	14	7.7					1	20.0		
Total	487	100.0	97	100.0	121	100.0	166	100.0	103	100.0	227	100.0	183	100.0	1	100.0	8	100.0	5	100.0	27	100.0

	AgeGroup						Gender		Education							
	30-49		50-64		65+		Female		<HS		HSGrad		SomeCol		Col+	
	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%
Yes	34	24.1	86	43.9	27	18.0	147	30.2	5	20.0	31	28.7	44	28.8	66	33.2
No	99	70.2	96	49.0	114	76.0	309	63.4	19	76.0	71	65.7	97	63.4	122	61.3
NS	8	5.7	14	7.1	9	6.0	31	6.4	1	4.0	6	5.6	12	7.8	11	5.5
Total	141	100.0	196	100.0	150	100.0	487	100.0	25	100.0	108	100.0	153	100.0	199	100.0

Zogby America 1/22/01 - Women 40+

30. Has your doctor or other medical professional told you that there are a number of options available for hormone replacement therapy including those derived from animal sources, plant-based treatments, and synthetic drugs?

	Total		Race										Religion									
			White		Hisp		AfrAmer		Asian		Other		Catholic		Protestant		Jewish		Muslim		Other	
	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%
Yes	147	30.2	129	30.2	3	42.9	9	30.0			4	21.1	31	26.7	86	34.3	4	30.8	1	50.0	24	23.5
No	309	63.4	273	63.9	3	42.9	19	63.3	1	50.0	13	68.4	75	64.7	150	59.8	8	61.5	1	50.0	74	72.5
NS	31	6.4	25	5.9	1	14.3	2	6.7	1	50.0	2	10.5	10	8.6	15	6.0	1	7.7			4	3.9
Total	487	100.0	427	100.0	7	100.0	30	100.0	2	100.0	19	100.0	116	100.0	251	100.0	13	100.0	2	100.0	102	100.0

	Ideology													
	Prog/VeryLib		Liberal		Moderate		Conservative		Very cons		Libertarian		NS	
	f	%	f	%	f	%	f	%	f	%	f	%	f	%
Yes	7	36.8	30	28.6	57	34.8	35	25.9	13	43.3	1	100.0	2	7.4
No	10	52.6	72	68.6	95	57.9	90	66.7	17	56.7			23	85.2
NS	2	10.5	3	2.9	12	7.3	10	7.4					2	7.4
Total	19	100.0	105	100.0	164	100.0	135	100.0	30	100.0	1	100.0	27	100.0

Zogby America 1/22/01 - Women 40+

30. Has your doctor or other medical professional told you that there are a number of options available for hormone replacement therapy including those derived from animal sources, plant-based treatments, and synthetic drugs?

	-- Total --		----- Born Again -----				----- Income -----											
			Yes		No/NS		< \$15,000		\$15-24,999		\$25-34,999		\$35-49,999		\$50-74,999		\$75,000+	
	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%
Yes	147	30.2	44	33.1	42	35.9	14	29.8	11	23.4	17	26.6	16	23.5	31	39.7	31	34.4
No	309	63.4	82	61.7	67	57.3	30	63.8	35	74.5	43	67.2	47	69.1	45	57.7	53	58.9
NS	31	6.4	7	5.3	8	6.8	3	6.4	1	2.1	4	6.3	5	7.4	2	2.6	6	6.7
Total	487	100.0	133	100.0	117	100.0	47	100.0	47	100.0	64	100.0	68	100.0	78	100.0	90	100.0

	-- Outside --				----- Party -----								----- Union -----			
	Yes		No/NS		Democrat		Republican		Independent		NS		Yes		No/NS	
	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%
Yes	76	33.0	70	27.5	71	33.5	44	29.5	27	30.0	1	7.1	30	33.0	116	29.4
No	137	59.6	172	67.5	133	62.7	94	63.1	56	62.2	9	64.3	58	63.7	251	63.7
NS	17	7.4	13	5.1	8	3.8	11	7.4	7	7.8	4	28.6	3	3.3	27	6.9
Total	230	100.0	255	100.0	212	100.0	149	100.0	90	100.0	14	100.0	91	100.0	394	100.0

Zogby America 1/22/01 - Women 40+

31. How aware are you that Premarin and other like-sounding hormone replacement therapies such as PremPro, PremPhase, and PremPac are made with estrogens derived from the urine of pregnant horses?

	Total		Region								2000 Presidential											
			East		South		CentGrLk		West		Gore		Bush		Buchanan		Nader		SmIElse		NV/NS	
	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%
VAware	154	31.6	24	24.7	34	28.1	53	31.9	43	41.7	78	34.4	57	31.1	1	100.0	3	37.5	1	20.0	9	33.3
SAware	59	12.1	11	11.3	10	8.3	24	14.5	14	13.6	24	10.6	24	13.1					2	40.0	3	11.1
→ NAware	231	47.4	49	50.5	68	56.2	76	45.8	38	36.9	112	49.3	82	44.8			4	50.0	1	20.0	14	51.9
NS	43	8.8	13	13.4	9	7.4	13	7.8	8	7.8	13	5.7	20	10.9			1	12.5	1	20.0	1	3.7
Total	487	100.0	97	100.0	121	100.0	166	100.0	103	100.0	227	100.0	183	100.0	1	100.0	8	100.0	5	100.0	27	100.0

	AgeGroup						Gender		Education							
	30-49		50-64		65+		Female		<HS		HSGrad		SomeCol		Col+	
	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%
VAware	39	27.7	81	41.3	34	22.7	154	31.6	4	16.0	28	25.9	51	33.3	70	35.2
SAware	16	11.3	18	9.2	25	16.7	59	12.1	3	12.0	13	12.0	23	15.0	20	10.1
NAware	76	53.9	83	42.3	72	48.0	231	47.4	14	56.0	57	52.8	65	42.5	95	47.7
NS	10	7.1	14	7.1	19	12.7	43	8.8	4	16.0	10	9.3	14	9.2	14	7.0
Total	141	100.0	196	100.0	150	100.0	487	100.0	25	100.0	108	100.0	153	100.0	199	100.0

31. How aware are you that Premarin and other like-sounding hormone replacement therapies such as PremPro, PremPhase, and PremPac are made with estrogens derived from the urine of pregnant horses?

	Total		Race										Religion									
			White		Hispanic		African Amer		Asian		Other		Catholic		Protestant		Jewish		Muslim		Other	
	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%
VAware	154	31.6	141	33.0	3	42.9	3	10.0			6	31.6	39	33.6	73	29.1	5	38.5	1	50.0	35	34.3
SAware	59	12.1	51	11.9	1	14.3	4	13.3			3	15.8	10	8.6	27	10.8	3	23.1			19	18.6
NAware	231	47.4	201	47.1	3	42.9	18	60.0	1	50.0	7	36.8	61	52.6	123	49.0	4	30.8	1	50.0	41	40.2
NS	43	8.8	34	8.0			5	16.7	1	50.0	3	15.8	6	5.2	28	11.2	1	7.7			7	6.9
Total	487	100.0	427	100.0	7	100.0	30	100.0	2	100.0	19	100.0	116	100.0	251	100.0	13	100.0	2	100.0	102	100.0

	Ideology														
	Prog/VeryLib		Liberal		Moderate		Conservative		Very cons		Libertarian		NS		
	f	%	f	%	f	%	f	%	f	%	f	%	f	%	
VAware	8	42.1	38	36.2	48	29.3	40	29.6	11	36.7				8	29.6
SAware	3	15.8	14	13.3	22	13.4	14	10.4	5	16.7				1	3.7
NAware	6	31.6	48	45.7	79	48.2	68	50.4	12	40.0	1	100.0		14	51.9
NS	2	10.5	5	4.8	15	9.1	13	9.6	2	6.7				4	14.8
Total	19	100.0	105	100.0	164	100.0	135	100.0	30	100.0	1	100.0		27	100.0

Zogby America 1/22/01 - Women 40+

31. How aware are you that Premarin and other like-sounding hormone replacement therapies such as PremPro, PremPhase, and PremPac are made with estrogens derived from the urine of pregnant horses?

	-- Total --		----- BornAgain -----				----- Income -----											
			Yes		No/NS		< \$15,000		\$15-24,999		\$25-34,999		\$35-49,999		\$50-74,999		\$75,000+	
	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%
VAware	154	31.6	34	25.6	39	33.3	15	31.9	11	23.4	20	31.3	17	25.0	26	33.3	40	44.4
SAware	59	12.1	18	13.5	9	7.7	5	10.6	9	19.1	7	10.9	10	14.7	8	10.3	9	10.0
NAware	231	47.4	63	47.4	59	50.4	20	42.6	23	48.9	33	51.6	38	55.9	42	53.8	36	40.0
NS	43	8.8	18	13.5	10	8.5	7	14.9	4	8.5	4	6.3	3	4.4	2	2.6	5	5.6
Total	487	100.0	133	100.0	117	100.0	47	100.0	47	100.0	64	100.0	68	100.0	78	100.0	90	100.0

	-- Outside --				----- Party -----								----- Union -----			
	Yes		No/NS		Democrat		Republican		Independent		NS		Yes		No/NS	
	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%
VAware	79	34.3	74	29.0	70	33.0	50	33.6	29	32.2	1	7.1	29	31.9	124	31.5
SAware	26	11.3	33	12.9	20	9.4	21	14.1	12	13.3	1	7.1	14	15.4	45	11.4
NAware	106	46.1	125	49.0	109	51.4	63	42.3	41	45.6	8	57.1	43	47.3	188	47.7
NS	19	8.3	23	9.0	13	6.1	15	10.1	8	8.9	4	28.6	5	5.5	37	9.4
Total	230	100.0	255	100.0	212	100.0	149	100.0	90	100.0	14	100.0	91	100.0	394	100.0

Zogby America 1/22/01 - Women 40+

32. If you knew that in order to make Premarin and other like-sounding drugs, pregnant horses are confined in narrow stalls day and night hooked up to a machine that collects their urine, how likely would you be to choose a plant-based or synthetic treatment over Premarin?

	Total		Region								2000 Presidential											
			East		South		CentGrLk		West		Gore		Bush		Buchanan		Nader		SmIElse		NV/NS	
	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%
MMoreLkly	197	40.5	34	35.1	58	47.9	63	38.0	42	40.8	103	45.4	68	37.2			3	37.5	1	20.0	6	22.2
MLkly	58	11.9	9	9.3	15	12.4	21	12.7	13	12.6	25	11.0	22	12.0			1	12.5	2	40.0	6	22.2
LLkly	21	4.3	7	7.2	3	2.5	9	5.4	2	1.9	10	4.4	8	4.4							3	11.1
MLessLkly	28	5.7	5	5.2	3	2.5	13	7.8	7	6.8	12	5.3	10	5.5							2	7.4
NoDiff	109	22.4	24	24.7	22	18.2	37	22.3	26	25.2	49	21.6	45	24.6	1	100.0	1	12.5	1	20.0	4	14.8
NS	74	15.2	18	18.6	20	16.5	23	13.9	13	12.6	28	12.3	30	16.4			3	37.5	1	20.0	6	22.2
Total	487	100.0	97	100.0	121	100.0	166	100.0	103	100.0	227	100.0	183	100.0	1	100.0	8	100.0	5	100.0	27	100.0

	AgeGroup						Gender		Education							
	30-49		50-64		65+		Female		<HS		HSGrad		SomeCol		Col+	
	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%
MMoreLkly	64	45.4	89	45.4	44	29.3	197	40.5	8	32.0	48	44.4	65	42.5	75	37.7
MLkly	19	13.5	22	11.2	17	11.3	58	11.9	3	12.0	10	9.3	15	9.8	30	15.1
LLkly	6	4.3	4	2.0	11	7.3	21	4.3	2	8.0	2	1.9	11	7.2	6	3.0
MLessLkly	8	5.7	9	4.6	11	7.3	28	5.7	2	8.0	7	6.5	7	4.6	12	6.0
NoDiff	24	17.0	46	23.5	39	26.0	109	22.4	3	12.0	24	22.2	31	20.3	51	25.6
NS	20	14.2	26	13.3	28	18.7	74	15.2	7	28.0	17	15.7	24	15.7	25	12.6
Total	141	100.0	196	100.0	150	100.0	487	100.0	25	100.0	108	100.0	153	100.0	199	100.0

Zogby America 1/22/01 - Women 40+

32. If you knew that in order to make Premarin and other like-sounding drugs, pregnant horses are confined in narrow stalls day and night hooked up to a machine that collects their urine, how likely would you be to choose a plant-based or synthetic treatment over Premarin?

	Total		Race										Religion									
	f	%	White		Hispanic		African American		Asian		Other		Catholic		Protestant		Jewish		Muslim		Other	
			f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%
MMoreLkly	197	40.5	171	40.0	3	42.9	14	46.7	1	50.0	6	31.6	53	45.7	91	36.3	4	30.8	1	50.0	47	46.1
MLkly	58	11.9	54	12.6	1	14.3	2	6.7			1	5.3	9	7.8	32	12.7	2	15.4	1	50.0	14	13.7
LLkly	21	4.3	20	4.7			1	3.3					5	4.3	12	4.8					4	3.9
MLessLkly	28	5.7	24	5.6			2	6.7			2	10.5	8	6.9	12	4.8					8	7.8
NoDiff	109	22.4	99	23.2	2	28.6	4	13.3			4	21.1	29	25.0	62	24.7	4	30.8			14	13.7
NS	74	15.2	59	13.8	1	14.3	7	23.3	1	50.0	6	31.6	12	10.3	42	16.7	3	23.1			15	14.7
Total	487	100.0	427	100.0	7	100.0	30	100.0	2	100.0	19	100.0	116	100.0	251	100.0	13	100.0	2	100.0	102	100.0

	Ideology														NS	
	Prog/VeryLib		Liberal		Moderate		Conservative		Very cons		Libertarian				f	%
	f	%	f	%	f	%	f	%	f	%	f	%				
MMoreLkly	7	36.8	47	44.8	68	41.5	56	41.5	10	33.3					8	29.6
MLkly	4	21.1	16	15.2	20	12.2	10	7.4	5	16.7					2	7.4
LLkly			4	3.8	5	3.0	7	5.2	1	3.3	1	100.0			3	11.1
MLessLkly	2	10.5	3	2.9	9	5.5	11	8.1	1	3.3					2	7.4
NoDiff	3	15.8	24	22.9	37	22.6	30	22.2	9	30.0					4	14.8
NS	3	15.8	11	10.5	25	15.2	21	15.6	4	13.3					8	29.6
Total	19	100.0	105	100.0	164	100.0	135	100.0	30	100.0	1	100.0			27	100.0

Zogby America 1/22/01 - Women 40+

32. If you knew that in order to make Premarin and other like-sounding drugs, pregnant horses are confined in narrow stalls day and night hooked up to a machine that collects their urine, how likely would you be to choose a plant-based or synthetic treatment over Premarin?

	Total		Born Again				Income											
			Yes		No/NS		< \$15,000		\$15-24,999		\$25-34,999		\$35-49,999		\$50-74,999		\$75,000+	
	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%
MMoreLkly	197	40.5	47	35.3	43	36.8	19	40.4	20	42.6	30	46.9	29	42.6	29	37.2	39	43.3
MLkly	58	11.9	23	17.3	9	7.7	3	6.4	6	12.8	6	9.4	10	14.7	14	17.9	11	12.2
LLkly	21	4.3	4	3.0	8	6.8	4	8.5	4	8.5			1	1.5	5	6.4	2	2.2
MLessLkly	28	5.7	5	3.8	7	6.0	3	6.4	3	6.4	6	9.4	4	5.9	1	1.3	4	4.4
NoDiff	109	22.4	27	20.3	35	29.9	6	12.8	10	21.3	11	17.2	18	26.5	20	25.6	27	30.0
NS	74	15.2	27	20.3	15	12.8	12	25.5	4	8.5	11	17.2	6	8.8	9	11.5	7	7.8
Total	487	100.0	133	100.0	117	100.0	47	100.0	47	100.0	64	100.0	68	100.0	78	100.0	90	100.0

	Outside				Party								Union			
	Yes		No/NS		Democrat		Republican		Independent		NS		Yes		No/NS	
	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%
MMoreLkly	102	44.3	94	36.9	86	40.6	61	40.9	34	37.8	6	42.9	46	50.5	150	38.1
MLkly	26	11.3	32	12.5	27	12.7	17	11.4	12	13.3	1	7.1	11	12.1	47	11.9
LLkly	6	2.6	15	5.9	12	5.7	8	5.4	1	1.1			4	4.4	17	4.3
MLessLkly	11	4.8	17	6.7	16	7.5	6	4.0	2	2.2			7	7.7	21	5.3
NoDiff	54	23.5	55	21.6	44	20.8	34	22.8	23	25.6	5	35.7	12	13.2	97	24.6
NS	31	13.5	42	16.5	27	12.7	23	15.4	18	20.0	2	14.3	11	12.1	62	15.7
Total	230	100.0	255	100.0	212	100.0	149	100.0	90	100.0	14	100.0	91	100.0	394	100.0

Zogby America 1/22/01 - Women 40+

33. If you knew that the foals of the horses used to make Premarin and used-up mares are sold to be slaughtered for meat consumption in Europe and Japan,, how likely would you be to choose a plant-based or synthetic treatment over Premarin?

	Total		Region								2000Presidential											
			East		South		CentGrLk		West		Gore		Bush		Buchanan		Nader		SmiElse		NV/NS	
	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%
MMoreLkly	210	43.1	40	41.2	58	47.9	72	43.4	40	38.8	111	48.9	67	36.6			4	50.0	1	20.0	12	44.4
MLkly	55	11.3	12	12.4	10	8.3	28	16.9	5	4.9	23	10.1	23	12.6			1	12.5	1	20.0	5	18.5
LLkly	22	4.5	6	6.2	5	4.1	5	3.0	6	5.8	9	4.0	11	6.0							1	3.7
MLessLkly	24	4.9	6	6.2	4	3.3	10	6.0	4	3.9	10	4.4	9	4.9							4	14.8
NoDiff	102	20.9	17	17.5	26	21.5	27	16.3	32	31.1	40	17.6	47	25.7	1	100.0	2	25.0	2	40.0	2	7.4
NS	74	15.2	16	16.5	18	14.9	24	14.5	16	15.5	34	15.0	26	14.2			1	12.5	1	20.0	3	11.1
Total	487	100.0	97	100.0	121	100.0	166	100.0	103	100.0	227	100.0	183	100.0	1	100.0	8	100.0	5	100.0	27	100.0

	AgeGroup						Gender		Education							
	30-49		50-64		65+		Female		<HS		HSGrad		SomeCol		Col+	
	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%
MMoreLkly	71	50.4	89	45.4	50	33.3	210	43.1	13	52.0	44	40.7	64	41.8	88	44.2
MLkly	17	12.1	25	12.8	13	8.7	55	11.3	2	8.0	14	13.0	16	10.5	23	11.6
LLkly	4	2.8	6	3.1	12	8.0	22	4.5	1	4.0	6	5.6	8	5.2	7	3.5
MLessLkly	10	7.1	6	3.1	8	5.3	24	4.9			4	3.7	9	5.9	11	5.5
NoDiff	20	14.2	48	24.5	34	22.7	102	20.9	1	4.0	21	19.4	35	22.9	45	22.6
NS	19	13.5	22	11.2	33	22.0	74	15.2	8	32.0	19	17.6	21	13.7	25	12.6
Total	141	100.0	196	100.0	150	100.0	487	100.0	25	100.0	108	100.0	153	100.0	199	100.0

Zogby America 1/22/01 - Women 40+

33. If you knew that the foals of the horses used to make Premarin and used-up mares are sold to be slaughtered for meat consumption in Europe and Japan,, how likely would you be to choose a plant-based or synthetic treatment over Premarin?

	Total		Race										Religion									
			White		Hisp		AfrAmer		Asian		Other		Catholic		Protestant		Jewish		Muslim		Other	
	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%
MMoreLkly	210	43.1	181	42.4	2	28.6	16	53.3	1	50.0	8	42.1	51	44.0	102	40.6	3	23.1	1	50.0	52	51.0
MLkly	55	11.3	54	12.6			1	3.3					17	14.7	26	10.4	3	23.1	1	50.0	8	7.8
LLkly	22	4.5	17	4.0	1	14.3	2	6.7			2	10.5	2	1.7	13	5.2	1	7.7			6	5.9
MLessLkly	24	4.9	20	4.7			3	10.0			1	5.3	9	7.8	9	3.6	1	7.7			4	3.9
NoDiff	102	20.9	95	22.2	2	28.6	2	6.7			3	15.8	22	19.0	59	23.5	3	23.1			18	17.6
NS	74	15.2	60	14.1	2	28.6	6	20.0	1	50.0	5	26.3	15	12.9	42	16.7	2	15.4			14	13.7
Total	487	100.0	427	100.0	7	100.0	30	100.0	2	100.0	19	100.0	116	100.0	251	100.0	13	100.0	2	100.0	102	100.0

	Ideology													
	Prog/VeryLib		Liberal		Moderate		Conservative		Very cons		Libertarian		NS	
	f	%	f	%	f	%	f	%	f	%	f	%	f	%
MMoreLkly	11	57.9	48	45.7	76	46.3	55	40.7	11	36.7			8	29.6
MLkly	2	10.5	13	12.4	19	11.6	13	9.6	4	13.3	1	100.0	2	7.4
LLkly	1	5.3	3	2.9	4	2.4	10	7.4	1	3.3			3	11.1
MLessLkly	2	10.5	8	7.6	4	2.4	7	5.2	2	6.7			1	3.7
NoDiff	1	5.3	17	16.2	37	22.6	28	20.7	9	30.0			8	29.6
NS	2	10.5	16	15.2	24	14.6	22	16.3	3	10.0			5	18.5
Total	19	100.0	105	100.0	164	100.0	135	100.0	30	100.0	1	100.0	27	100.0

Zogby America 1/22/01 - Women 40+

33. If you knew that the foals of the horses used to make Premarin and used-up mares are sold to be slaughtered for meat consumption in Europe and Japan,, how likely would you be to choose a plant-based or synthetic treatment over Premarin?

	-- Total --		----- BornAgain -----				----- Income -----											
			Yes		No/NS		< \$15,000		\$15-24,999		\$25-34,999		\$35-49,999		\$50-74,999		\$75,000+	
	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%
MMoreLkly	210	43.1	50	37.6	51	43.6	21	44.7	19	40.4	37	57.8	30	44.1	35	44.9	40	44.4
MLkly	55	11.3	19	14.3	7	6.0	3	6.4	5	10.6	6	9.4	11	16.2	11	14.1	10	11.1
LLkly	22	4.5	6	4.5	7	6.0	4	8.5	6	12.8	3	4.7	2	2.9	3	3.8		
MLessLkly	24	4.9	2	1.5	7	6.0	3	6.4	3	6.4	2	3.1	1	1.5	2	2.6	4	4.4
NoDiff	102	20.9	32	24.1	27	23.1	6	12.8	8	17.0	8	12.5	17	25.0	18	23.1	26	28.9
NS	74	15.2	24	18.0	18	15.4	10	21.3	6	12.8	8	12.5	7	10.3	9	11.5	10	11.1
Total	487	100.0	133	100.0	117	100.0	47	100.0	47	100.0	64	100.0	68	100.0	78	100.0	90	100.0

	-- Outside --				----- Party -----								----- Union -----			
	Yes		No/NS		Democrat		Republican		Independent		NS		Yes		No/NS	
	f	%	f	%	f	%	f	%	f	%	f	%	f	%	f	%
MMoreLkly	109	47.4	100	39.2	98	46.2	57	38.3	40	44.4	6	42.9	49	53.8	160	40.6
MLkly	26	11.3	29	11.4	26	12.3	21	14.1	6	6.7			12	13.2	43	10.9
LLkly	5	2.2	17	6.7	11	5.2	7	4.7	3	3.3			2	2.2	20	5.1
MLessLkly	10	4.3	14	5.5	12	5.7	7	4.7	4	4.4	1	7.1	7	7.7	17	4.3
NoDiff	49	21.3	53	20.8	35	16.5	37	24.8	22	24.4	4	28.6	13	14.3	89	22.6
NS	31	13.5	42	16.5	30	14.2	20	13.4	15	16.7	3	21.4	8	8.8	65	16.5
Total	230	100.0	255	100.0	212	100.0	149	100.0	90	100.0	14	100.0	91	100.0	394	100.0



Premarin®

(conjugated estrogens tablets, USP)

Caution: Federal law prohibits dispensing without prescription.

1. ESTROGENS HAVE BEEN REPORTED TO INCREASE THE RISK OF ENDOMETRIAL CARCINOMA IN POST-MENOPAUSAL WOMEN.

Close clinical surveillance of all women taking estrogens is important. Adequate diagnostic measures, including endometrial sampling when indicated, should be undertaken to rule out malignancy in all cases of undiagnosed persistent or recurring abnormal vaginal bleeding. There is currently no evidence that "natural" estrogens are more or less hazardous than "synthetic" estrogens at equiestrogenic doses.

2. ESTROGENS SHOULD NOT BE USED DURING PREGNANCY.

Estrogen therapy during pregnancy is associated with an increased risk of congenital defects in the reproductive organs of the male and female fetus, an increased risk of vaginal adenosis, squamous cell dysplasia of the uterine cervix, and vaginal cancer in the female later in life. The 1985 DES Task Force concluded that women who used DES during their pregnancies may subsequently experience an increased risk of breast cancer. However, a causal relationship is still unproven, and the observed level of risk is similar to that for a number of other breast-cancer risk factors.

There is no indication for estrogen therapy during pregnancy. Estrogens are ineffective for the prevention or treatment of threatened or habitual abortion.

DESCRIPTION

Premarin® (conjugated estrogens tablets, USP) for oral administration contains a mixture of estrogens obtained exclusively from natural sources, occurring as the sodium salts of water-soluble estrogen sulfates blended to represent the average composition of material derived from pregnant mares' urine. It contains estrone, equilin, and 17 α -dihydro-equilin, together with smaller amounts of 17 α -estradiol, equilenin, and 17 α -dihydroequilenin as salts of their sulfate esters. Tablets for oral administration are available in 0.3 mg, 0.625 mg, 0.9 mg, 1.25 mg, and 2.5 mg strengths of conjugated estrogens.

Premarin Tablets contain the following inactive ingredients: calcium phosphate tribasic, calcium sulfate, carnauba wax, cellulose, glyceryl monoleate, lactose, magnesium stearate, methylcellulose, pharmaceutical glaze, polyethylene glycol, stearic acid, sucrose, titanium dioxide.

—0.3 mg tablets also contain: D&C Yellow No. 10, FD&C Blue No. 1, FD&C Blue No. 2, FD&C Yellow No. 6; these tablets comply with USP Drug Release Test 1.

—0.625 mg tablets also contain: FD&C Blue No. 2, D&C Red No. 27, FD&C Red No. 40; these tablets comply with USP Drug Release Test 1.

—0.9 mg tablets also contain: D&C Red No. 6, D&C Red No. 7; these tablets comply with USP Drug Release Test 2.

—1.25 mg tablets also contain: black iron oxide, D&C Yellow No. 10, FD&C Yellow No. 6, taic; these tablets comply with USP Drug Release Test 3.

—2.5 mg tablets also contain: FD&C Blue No. 2, D&C Red No. 7, taic; these tablets comply with USP Drug Release Test 3.

CLINICAL PHARMACOLOGY

Estrogens are important in the development and maintenance of the female reproductive system and secondary sex characteristics. They promote growth and development of the vagina, uterus, and fallopian tubes, and enlargement of the breasts. Indirectly, they contribute to the shaping of the skeleton, maintenance of tone and elasticity of urogenital structures, changes in the epiphyses of the long bones that allow for the pubertal growth spurt and its termination, growth of axillary and pubic hair, and pigmentation of the nipples and genitals. Decline of estrogenic activity at the end of the menstrual cycle can bring on menstruation, although the cessation of progesterone secretion is the most important factor in the mature ovulatory cycle. However, in the preovulatory or nonovulatory cycle, estrogen is the primary determinant in the onset of menstruation. Estrogens also affect the release of pituitary gonadotropins.

The pharmacologic effects of conjugated estrogens are similar to those of endogenous estrogens. They are soluble in water and are well absorbed from the gastrointestinal tract.

In responsive tissues (female genital organs, breasts, hypothalamus, pituitary) estrogens enter the cell and are transported into the nucleus. As a result of estrogen action, specific RNA and protein synthesis occurs.

Metabolism and inactivation occur primarily in the liver. Some estrogens are excreted into the bile; however, they are reabsorbed from the intestine and returned to the liver through the portal venous system. Water-soluble estrogen conjugates are strongly acidic and are ionized in body fluids, which favor excretion through the kidneys since tubular reabsorption is minimal.

INDICATIONS AND USAGE

Premarin (conjugated estrogens tablets, USP) is indicated in the treatment of:

1. Moderate to severe vasomotor symptoms associated with the menopause. There is no adequate evidence that estrogens are effective for nervous symptoms or depression which might occur during menopause and they should not be used to treat these conditions.

2. Atrophic vaginitis.

3. Osteoporosis (loss of bone mass). The mainstays of prevention and management of osteoporosis are estrogen and calcium; exercise and nutrition may be important adjuncts.

Estrogen replacement therapy is the most effective single modality for the prevention of osteoporosis in women. Estrogen reduces bone resorption and retards or halts postmenopausal bone loss. Case-controlled studies have shown an approximately 60 percent reduction in hip and wrist fractures in women whose estrogen replacement was begun within a few years of menopause. Studies also suggest that estrogen reduces the rate of vertebral fractures. Even when started as late as 6 years after menopause, estrogen prevents further loss of bone mass but does not restore it to premenopausal levels. The lowest effective dose for prevention and treatment of osteoporosis should be utilized. (See "Dosage and Administration.")

Women are at higher risk than men because they have less bone mass, and for several years following natural or induced menopause, the rate of bone mass decline is accelerated. Early menopause is one of the strongest predictors for the development of osteoporosis. White women are at higher risk than black women, and white men are at higher risk than black men. Women who are underweight also have osteoporosis more often than overweight women. Cigarette smoking may be an additional factor in increasing risk. Calcium deficiency has been implicated in the pathogenesis of this disease. Therefore, when not contraindicated, it is recommended that postmenopausal women receive an elemental calcium intake of 1000 to 1500 mg/day.

Immobilization and prolonged bed rest produce rapid bone loss, while weight-bearing exercise has been shown both to reduce bone loss and to increase bone mass. The optimal type and amount of physical activity that would prevent osteoporosis have not been established.

4. Hypoestrogenism due to hypogonadism, castration, or primary ovarian failure.

5. Breast cancer (for palliation only) in appropriately selected women and men with metastatic disease.

6. Advanced androgen-dependent carcinoma of the prostate (for palliation only).

CONTRAINDICATIONS

Estrogens should not be used in women (or men) with any of the following conditions:

1. Known or suspected pregnancy (see Boxed Warning).

Estrogen may cause fetal harm when administered to a pregnant woman.

2. Known or suspected cancer of the breast except in appropriately selected patients being treated for metastatic disease.

3. Known or suspected estrogen-dependent neoplasia.

4. Undiagnosed abnormal genital bleeding.

5. Active thrombophlebitis or thromboembolic disorders. However, there is insufficient information regarding women who have had previous thromboembolic disease. Premarin Tablets should not be used in patients hypersensitive to their ingredients.

WARNINGS

1. *Induction of malignant neoplasms.* Some studies have suggested a possible increased incidence of breast cancer in those women on estrogen therapy taking higher doses for prolonged periods of time. The majority of studies, however, have not shown an association with the usual doses used for estrogen replacement therapy. Women on this therapy should have regular breast examinations and should be instructed in breast self-examination. The reported endometrial cancer risk among estrogen users was about 4-fold or greater than in nonusers and appears dependent on duration of treatment and on estrogen dose. There is no significant increased risk associated with the use of estrogens for less than one year. The greatest risk appears associated with prolonged use—five years or more. In one study, persistence of risk was demonstrated for 10 years after cessation of estrogen treatment. In another study, a significant decrease in the incidence of endometrial cancer occurred six months after estrogen withdrawal.

Estrogen therapy during pregnancy is associated with an increased risk of fetal congenital reproductive-tract disorders. In females there is an increased risk of vaginal adenosis, squamous cell dysplasia of the cervix, and cancer later in life; in the male, urogenital abnormalities. Although some of these changes are benign, it is not known whether they are precursors of malignancy.

2. *Gallbladder disease.* A study has reported a 2.5-fold increase in the risk of surgically-confirmed gallbladder disease in women receiving postmenopausal estrogens.

3. *Thromboembolic Disorders and Other Vascular Problems.* In some studies, women on estrogen replacement therapy,

given alone or in combination with a progestin, have been reported to have an increased risk of thrombophlebitis, and/or thromboembolic disease. Large doses of estrogen (5 mg conjugated estrogens per day), comparable to those used to treat cancer of the prostate and breast, have been shown in a large prospective clinical trial in men to increase the risk of nonfatal myocardial infarction, pulmonary embolism, and thrombophlebitis. The physician should be aware of the possibility of thrombotic disorders (thrombophlebitis, retinal thrombosis, cerebral embolism, and pulmonary embolism) during estrogen replacement therapy and be alert to their earliest manifestations. Should any of these occur or be suspected, estrogen replacement therapy should be discontinued immediately. Patients who have risk factors for thrombotic disorders should be kept under careful observation.

4. *Elevated blood pressure.* There is no evidence that this may occur with use of estrogens in the menopause. However, blood pressure should be monitored with estrogen use, especially if high doses are used.

5. *Hypercalcemia.* Administration of estrogens may lead to severe hypercalcemia in patients with breast cancer and bone metastases. If this occurs, the drug should be stopped and appropriate measures taken to reduce the serum calcium level.

PRECAUTIONS

A. GENERAL

1. *Addition of a progestin.* Studies of the addition of a progestin for seven or more days of a cycle of estrogen administration have reported a lowered incidence of endometrial hyperplasia. Morphological and biochemical studies of endometrium suggest that 10 to 13 days of progestin are needed to provide maximal maturation of the endometrium and to eliminate any hyperplastic changes. Whether this will provide protection from endometrial carcinoma has not been clearly established. There are possible additional risks which may be associated with the inclusion of progestin in estrogen replacement regimens. The potential risks include adverse effects on carbohydrate and lipid metabolism. The choice of progestin and dosage may be important in minimizing these adverse effects.

2. *Physical examination.* A complete medical and family history should be taken prior to the initiation of any estrogen therapy. The pretreatment and periodic physical examinations should include special reference to blood pressure, breasts, abdomen, and pelvic organs, and should include a Papanicolaou smear. As a general rule, estrogen should not be prescribed for longer than one year without another physical examination being performed.

3. *Familial hyperlipoproteinemia.* Estrogen therapy may be associated with massive elevations of plasma triglycerides leading to pancreatitis and other complications in patients with familial defects of lipoprotein metabolism.

4. *Fluid retention.* Because estrogens may cause some degree of fluid retention, conditions which may be influenced by this factor, such as asthma, epilepsy, migraine, and cardiac or renal dysfunction, require careful observation.

5. *Uterine bleeding and mastodynia.* Certain patients may develop undesirable manifestations of estrogenic stimulation, such as abnormal uterine bleeding and mastodynia.

6. *Uterine fibroids.* Preexisting uterine leiomyomata may increase in size during prolonged high-dose estrogen use.

7. *Impaired liver function.* Estrogens may be poorly metabolized in patients with impaired liver function and should be administered with caution.

8. *Hypercalcemia and renal insufficiency.* Prolonged use of estrogens can alter the metabolism of calcium and phosphorus. Estrogens should be used with caution in patients with metabolic bone disease.

B. INFORMATION FOR THE PATIENT

See text of Patient Package Insert which appears after the "How Supplied" section.

C. LABORATORY TESTS

Clinical response at the smallest dose should generally be the guide to estrogen administration for relief of symptoms for those indications in which symptoms are observable. However, for prevention and treatment of osteoporosis see "Dosage and Administration" section. Tests used to measure adequacy of estrogen replacement therapy include serum estrone and estradiol levels and suppression of serum gonadotrophin levels.

D. DRUG/LABORATORY TEST INTERACTIONS

Some of these drug/laboratory test interactions have been observed only with estrogen-progestin combinations (oral contraceptives):

1. Increased prothrombin and factors VII, VIII, IX and X; decreased antithrombin 3; increased norepinephrine-induced platelet aggregability, decreased fibrinolysis.

2. Increased thyroid-binding globulin (TBG) leading to increased circulating total thyroid hormone, as measured by T4 levels determined either by column or by radioimmunoassay. Free T3 resin uptake is decreased, reflecting the elevated TBG; free T4 concentration is unaltered.

3. Impaired glucose tolerance.

4. Reduced response to meprobamate test.

5. Reduced serum folate concentration.

E. MUTAGENESIS AND CARCINOGENESIS

Long-term continuous administration of natural and synthetic estrogens in certain animal species increases the frequency of carcinomas of the breast, cervix, vagina, and liver.

F. PREGNANCY CATEGORY X

Estrogens should not be used during pregnancy. (See "Contraindications" and Boxed Warning.)

G. NURSING MOTHERS

As a general principle, the administration of any drug to nursing mothers should be done only when clearly necessary since many drugs are excreted in human milk.

ADVERSE REACTIONS

(See "Warnings" regarding induction of neoplasia, adverse effects on the fetus, increased incidence of gallbladder disease.) The following additional adverse reactions have been reported with estrogen therapy.

1. **Genitourinary system.** Changes in vaginal bleeding pattern and abnormal withdrawal bleeding or flow. Breakthrough bleeding, spotting. Increase in size of uterine fibromyomata. Vaginal candidiasis. Change in amount of cervical secretion.
2. **Breasts.** Tenderness, enlargement.
3. **Gastrointestinal.** Nausea, vomiting; abdominal cramps, bloating; cholestatic jaundice, pancreatitis.
4. **Skin.** Chloasma or melasma that may persist when drug is discontinued; erythema multiforme; erythema nodosum; hemorrhagic eruption; loss of scalp hair; hirsutism.
5. **Cardiovascular.** Venous thromboembolism; pulmonary embolism.
6. **Eyes.** Steepening of corneal curvature; intolerance of contact lenses.
7. **CNS.** Headache, migraine, dizziness; mental depression; chorea.
8. **Miscellaneous.** Increase or decrease in weight; reduced carbohydrate tolerance; aggravation of porphyria; edema; changes in libido.

ACUTE OVERDOSAGE

Numerous reports of ingestion of large doses of estrogen-containing oral contraceptives by young children indicate that acute serious ill effects do not occur. Overdosage of estrogen may cause nausea and vomiting.

DOSAGE AND ADMINISTRATION

1. For treatment of moderate to severe vasomotor symptoms and atrophic vaginitis associated with the menopause. The lowest dose that will control symptoms should be chosen, and medication should be discontinued as promptly as possible. Attempts to discontinue or taper medication should be made at 3-month to 6-month intervals.

USUAL DOSAGE RANGES:

Vasomotor symptoms—1.25 mg daily. If the patient has not menstruated within the last two months or more, cyclic administration is started arbitrarily. If the patient is menstruating, cyclic (e.g., three weeks on and one week off) administration is started on day 5 of bleeding.

Atrophic vaginitis—0.3 mg to 1.25 mg or more daily, depending upon the tissue response of the individual patient. Administer cyclically.

2. Hypoestrogenism due to:

a. Female hypogonadism—2.5 mg to 7.5 mg daily, in divided doses for 20 days, followed by a rest period of 10 days' duration. If bleeding does not occur by the end of this period, the same dosage schedule is repeated. The number of courses of estrogen therapy necessary to produce bleeding may vary depending on the responsiveness of the endometrium.

If bleeding occurs before the end of the 10-day period, begin a 20-day estrogen-progestin cyclic regimen with Premarin, 2.5 mg to 7.5 mg daily in divided doses, for 20 days. During the last five days of estrogen therapy, give an oral progestin. If bleeding occurs before this regimen is concluded, therapy is discontinued and may be resumed on the fifth day of bleeding.

b. Female castration or primary ovarian failure—1.25 mg daily, cyclically. Adjust dosage, upward or downward, according to severity of symptoms and response of the patient. For maintenance, adjust dosage to lowest level that will provide effective control.

3. Osteoporosis (loss of bone mass)—0.625 mg daily. Administration should be cyclic (e.g., three weeks on and one week off).

4. Advanced androgen-dependent carcinoma of the prostate, for palliation only—1.25 mg to 2.5 mg three times daily. The effectiveness of therapy can be judged by phosphatase determinations as well as by symptomatic improvement of the patient.

5. Breast cancer (for palliation only) in appropriately selected women and men with metastatic disease. Suggested dosage is 10 mg three times daily for a period of at least three months.

Treated patients with an intact uterus should be monitored closely for signs of endometrial cancer, and appropriate diagnostic measures should be taken to rule out malignancy in the event of persistent or recurring abnormal vaginal bleeding.

HOW SUPPLIED

Premarin® (conjugated estrogens tablets, USP)

— Each oval purple tablet contains 2.5 mg, in bottles of 100 (NDC 0046-0865-81) and 1,000 (NDC 0046-0865-91).

— Each oval yellow tablet contains 1.25 mg, in bottles of 100 (NDC 0046-0866-81); 1,000 (NDC 0046-0866-91); 5,000 (NDC 0046-0866-95); and Unit-Dose packages of 100 (NDC 0046-0866-99).

— Each oval white tablet contains 0.9 mg, in bottles of 100 (NDC 0046-0864-81).

— Each oval maroon tablet contains 0.625 mg, in bottles of 100 (NDC 0046-0867-81); 1,000 (NDC 0046-0867-91); 5,000 (NDC 0046-0867-95); and Unit-Dose packages of 100 (NDC 0046-0867-99).

— Each oval green tablet contains 0.3 mg, in bottles of 100

(NDC 0046-0868-81) and 1,000 (NDC 0046-0868-91).

The appearance of these tablets is a trademark of Wyeth-Ayerst Laboratories.

Store at room temperature (approximately 25° C).

Dispense in a well-closed container as defined in the USP.

INFORMATION FOR THE PATIENT

This leaflet describes when and how to use estrogens and the risks of estrogen treatment.

Estrogen Drugs

Estrogens have several important uses but also some risks. You must decide, with your doctor, whether the risks of estrogens are acceptable in view of their benefits. If you decide to start taking estrogens, check with your doctor to make sure you are using the lowest possible effective dose. The length of treatment with estrogens will depend upon the reason for use. This should also be discussed with your doctor.

Uses of Estrogen

To reduce menopausal symptoms. Estrogens are hormones produced by the ovaries. The decrease in the amount of estrogen that occurs in all women, usually between ages 45 and 55, causes the menopause. Sometimes the ovaries are removed by an operation, causing "surgical menopause." When the amount of estrogen begins to decrease, some women develop very uncomfortable symptoms, such as feelings of warmth in the face, neck, and chest or sudden intense episodes of heat and sweating ("hot flashes"). The use of drugs containing estrogens can help the body adjust to lower estrogen levels.

Most women have none or only mild menopausal symptoms and do not need estrogens. Other women may need estrogens for a few months while their bodies adjust to lower estrogen levels. The majority of women do not need estrogen replacement for longer than six months for these symptoms.

To prevent brittle bones. After age 40, and especially after menopause, some women develop osteoporosis. This is a thinning of the bones that makes them weaker and more likely to break, often leading to fractures of vertebrae, hip, and wrist bones. Taking estrogens after the menopause slows down bone loss and may prevent bones from breaking. Eating foods that are high in calcium (such as milk products) or taking calcium supplements (1000 to 1500 milligrams per day) and certain types of exercise may also help prevent osteoporosis.

Since estrogen use is associated with some risk, its use in the prevention of osteoporosis should be confined to women who appear to be susceptible to this condition. The following characteristics are often present in women who are likely to develop osteoporosis: white race, thinness, and cigarette smoking.

Women who had their menopause by the surgical removal of their ovaries at a relatively young age are good candidates for estrogen replacement therapy to prevent osteoporosis.

To treat certain types of abnormal uterine bleeding due to hormonal imbalance.

To treat atrophic vaginitis (itching, burning, dryness in or around the vagina).

To treat certain cancers.

When Estrogens Should Not Be Used

Estrogens should not be used:

During pregnancy. Although the possibility is fairly small, there is a greater risk of having a child born with a birth defect if you take estrogens during pregnancy. A male child may have an increased risk of developing abnormalities of the urinary system and sex organs. A female child may have an increased risk of developing cancer of the vagina or cervix in her teens or twenties. Estrogen is not effective in preventing miscarriage (abortion).

If you have had any heart or circulation problems. Estrogen therapy should be used only after consultation with your physician and only in recommended doses. Patients with a tendency for abnormal blood clotting should avoid estrogen use (see below).

If you have had cancer. Since estrogens increase the risk of certain cancers, you should not take estrogens if you have ever had cancer of the breast or uterus. In certain situations, your doctor may choose to use estrogen in the treatment of breast cancer.

When they are ineffective. Sometimes women experience nervous symptoms or depression during menopause. There is no evidence that estrogens are effective for such symptoms. You may have heard that taking estrogens for long periods (years) after menopause will keep your skin soft and supple and keep you feeling young. There is no evidence that this is so and such long-term treatment may carry serious risks.

Dangers of Estrogens

Cancer of the uterus. The risk of cancer of the uterus increases the longer estrogens are used and when larger doses are taken. One study showed that when estrogens are discontinued, this increased risk of cancer seems to fall off quickly. In another study, the persistence of risk was demonstrated for 10 years after stopping estrogen treatment. Because of this risk, it is important to take the lowest dose of estrogen that will control your symptoms and to take it only as long as you need it. There is a higher risk of cancer of the uterus if you are overweight, diabetic, or have high blood pressure.

If you have had your uterus removed (total hysterectomy), there is no danger of developing cancer of the uterus.

Cancer of the breast. The majority of studies have shown no association with the usual doses used for estrogen replacement therapy and breast cancer. Some studies have suggest-

ed a possible increased incidence of breast cancer in those women taking estrogens for prolonged periods of time and especially if higher doses are used.

Regular breast examinations by a health professional and self-examination are recommended for women receiving estrogen therapy, as they are for all women.

Gallbladder disease. Women who use estrogens after menopause are more likely to develop gallbladder disease needing surgery than women who do not use estrogens.

Inflammation of the pancreas. Women with high triglyceride levels may have an increased risk of developing inflammation of the pancreas.

Abnormal blood clotting. Taking estrogens may increase the risk of blood clots. These clots can cause a stroke, heart attack or pulmonary embolus, any of which may be fatal.

Side Effects

In addition to the risks listed above, the following side effects have been reported with estrogen use:

- Nausea and vomiting.
- Breast tenderness or enlargement.
- Enlargement of benign tumors of the uterus.
- Retention of excess fluid. This may make some conditions worsen, such as asthma, epilepsy, migraine, heart disease, or kidney disease.
- A spotty darkening of the skin, particularly on the face.

Reducing Risk of Estrogen Use

If you decide to take estrogens, you can reduce your risks by carefully monitoring your treatment.

See your doctor regularly. While you are taking estrogens, it is important that you visit your doctor at least once a year for a physical examination. If members of your family have had breast cancer or if you have ever had breast nodules or an abnormal mammogram (breast X ray), you may need to have more frequent breast examinations.

Reevaluate your need for estrogens. You and your doctor should reevaluate your need for estrogens at least every six months.

Be alert for signs of trouble. Report these or any other unusual side effects to your doctor immediately:

- Abnormal bleeding from the vagina.
- Pains in the calves or chest, a sudden shortness of breath or coughing blood (indicating possible clots in the legs, heart, or lungs).
- Severe headache, dizziness, faintness, or changes in vision, indicating possible clots in the brain or eye.
- Breast lumps.
- Yellowing of the skin.
- Pain, swelling, or tenderness in the abdomen.

Other Information

Some physicians may choose to prescribe another hormonal drug to be used in association with estrogen treatment.

These drugs, progestins, have been reported to lower the frequency of occurrence of a possible precancerous condition of the uterine lining. Whether this will provide protection from uterine cancer has not been clearly established. There are possible additional risks that may be associated with the inclusion of a progestin in estrogen treatment. The possible risks include unfavorable effects on blood fats and sugars. The choice of progestin and its dosage may be important in minimizing these effects.

Your doctor has prescribed this drug for you and you alone. Do not give the drug to anyone else.

If you will be taking calcium supplements as part of the treatment to help prevent osteoporosis, check with your doctor about the amounts recommended.

Keep this and all drugs out of the reach of children. In case of overdose, call your doctor, hospital, or poison control center immediately.

This leaflet provides the most important information about estrogens. If you want to read more, ask your doctor or pharmacist to let you read the professional labeling.

How Supplied

Premarin® (conjugated estrogens tablets, USP)—tablets for oral administration.

Each oval purple tablet contains 2.5 mg.

Each oval yellow tablet contains 1.25 mg.

Each oval white tablet contains 0.9 mg.

Each oval maroon tablet contains 0.625 mg.

Each oval green tablet contains 0.3 mg.

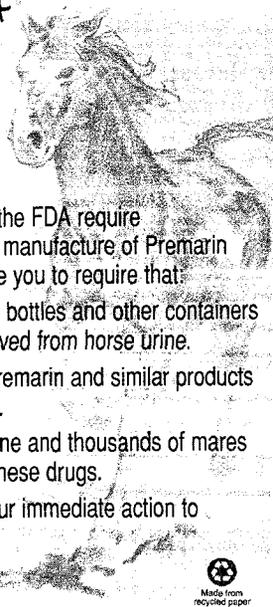
The appearance of these tablets is a trademark of Wyeth-Ayerst Laboratories.



Wyeth-Ayerst Laboratories Inc.
A Wyeth-Ayerst Company
Philadelphia, PA 19101
CI 5084-1 Issued May 4, 1998 Printed in USA



UAN, please rush my signed protest to the FDA immediately!



To: Commissioner Jane E. Henney, M.D.
Food and Drug Administration

Dear Commissioner Henney:

As an American taxpayer and an animal lover, I am writing to request that the FDA require pharmaceutical companies to disclose the source of estrogens used in the manufacture of Premarin and other non-synthetic hormone replacement therapies. Specifically, I urge you to require that:

- All packaging for Premarin and similar products, including repackaged bottles and other containers issued by pharmacies, be clearly labeled as containing estrogens derived from horse urine.
- At the very least, all physicians' and patients' information inserts for Premarin and similar products specify that these drugs are derived from the urine of pregnant mares.

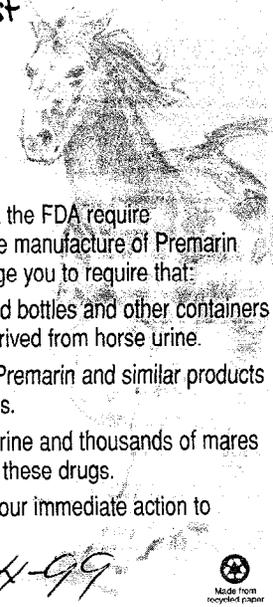
As you know, these estrogens are indeed derived from pregnant mares' urine and thousands of mares are exploited and thousands of foals are slaughtered annually to produce these drugs.

Women should be able to make informed choices. That is why I request your immediate action to require new labeling requirements for (repackaged) Premarin.

Signed: Betty Bauer



UAN, please rush my signed protest to the FDA immediately!



To: Commissioner Jane E. Henney, M.D.
Food and Drug Administration

Dear Commissioner Henney:

As an American taxpayer and an animal lover, I am writing to request that the FDA require pharmaceutical companies to disclose the source of estrogens used in the manufacture of Premarin and other non-synthetic hormone replacement therapies. Specifically, I urge you to require that:

- All packaging for Premarin and similar products, including repackaged bottles and other containers issued by pharmacies, be clearly labeled as containing estrogens derived from horse urine.
- At the very least, all physicians' and patients' information inserts for Premarin and similar products specify that these drugs are derived from the urine of pregnant mares.

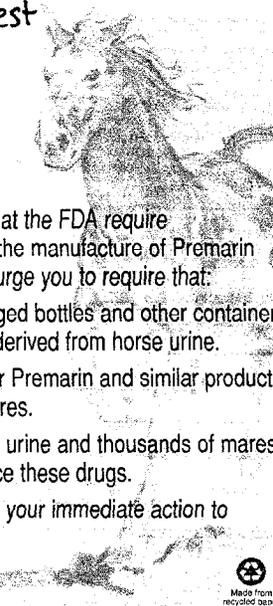
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Signed: Angela H. Charles 9-4-99



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Signed: Mary Lynn Townsend

