UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

VOTE SHEET

Date: JAN 14 2002

TO : The Commission
Todd Stevenson, Secretary

FROM : Alan Shakin, Acting General Counsel
Stephen Lemberg, Assistant General Counsel
Patricia M. Pollitzer, Attorney

SUBJECT : Notice of Proposed Rulemaking to Exempt HRT Products from Special Packaging Requirements

The staff recommends that the Commission issue a notice of proposed rulemaking ("NPR") proposing to exempt hormone replacement therapy ("HRT") products from the special packaging requirements of the PPPA. A draft Federal Register notice is attached at Tab B of the briefing package.

Please indicate your vote on the following options.

I. Approve the draft Federal Register notice without change.

_____ _____
Signature Date

II. Approve the draft Federal Register notice with the following changes (please specify):

_____

_____

_____

_____ _____
Signature Date

1

1/14/02

1/14/02

CPSA 6 (b)(1) Cleared

No Mfrs. Private Labels or Products Identified w/in CMEA Excepted by Statute REMOVE

III. Do not approve the draft Federal Register notice.

_____ _____

Signature Date

IV. Take other action (please specify):

_____

_____

_____

_____ _____

Signature Date

U.S. Consumer Product Safety Commission

Proposed Rule to Exempt Hormone Replacement Therapy Products from the Special Packaging Requirements of the Poison Prevention Packaging Act

For Information Contact:
Jacqueline Ferrante, Ph.D.
Directorate for Health Sciences
(301) 504-0477

Initial [illegible] Date 1/14/02

CPSA § 5(a) Cleared
No Labels/Pamphlets or
Products Identified
Except [illegible]

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Executive Summary

The Commission requires child-resistant (CR) or special packaging for oral prescription drugs under the Poison Prevention Packaging Act (PPPA), but exempts some substances with low acute toxicity, including some sex hormones (e.g., estrogens and progestins). These hormones have multiple therapeutic uses including contraception and the treatment of menopausal symptoms. There are four exemptions for sex hormones under the PPPA:

1. Oral contraceptives in mnemonic (memory-aid) packages containing one or more progestogen (or progestin) or estrogen substances.
2. Conjugated estrogens in mnemonic packages.
3. Norethindrone acetate in mnemonic packages.
4. Medroxyprogesterone acetate.

Currently, there are a number of hormone replacement therapy (HRT) products for menopausal women that contain the same or similar sex hormones as those used in oral contraceptives. However, HRT products are not generically exempt from special packaging requirements as are oral contraceptives. HRT products that contain only individually exempted hormones as the active ingredients (i.e., conjugated estrogens, norethindrone, or medroxyprogesterone) are exempt under the PPPA.

HRT refers to the treatment of menopausal symptoms with either estrogen alone or a combination of estrogen and progestin. HRT is effective therapy for immediate menopausal symptoms such as hot flashes and vaginal dryness, but also helps to prevent osteoporosis, a long term effect of menopause.

There is a potentially large market for HRT products since it is estimated that 40 million women will go through menopause in the next 20 years. Since HRT products contain estrogen/progestin combinations with low acute toxicity, similar to oral contraceptives, the staff recommends exempting them from the special packaging requirements of the PPPA. This action will conserve Commission resources by eliminating the need for separate rulemaking to exempt individual HRT products.

United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

JAN 14 2002

MEMORANDUM

To: The Commission
Todd Stevenson, Secretary

Through: Alan Shakin, Acting General Counsel
Through: for Thomas W. Murr, Jr., Acting Executive Director

From: Jacqueline Elder, Acting Assistant Executive Director, Office of Hazard Identification and Reduction
Jacqueline Ferrante, Ph.D., Pharmacologist, Directorate for Health Sciences

Subject: Inclusion of hormone replacement therapy (HRT) as an exempted oral prescription drug under the Poison Prevention Packaging Act (PPPA)

I. Issue

In this document, the staff recommends an exemption for HRT products from the special packaging requirements of the PPPA.

II. Background

A. PPPA Requirements

The U.S. Consumer Product Safety Commission (CPSC) requires special or CR packaging for oral prescription drugs under the PPPA [16 C.F.R. § 1700.14(a)(10)]. However, a number of substances with low acute toxicity are exempt from this requirement including some sex hormones. Sex hormones are primarily used for contraception and for HRT. Currently there are four exemptions for sex hormones under the PPPA:

1. Cyclically administered oral contraceptives in manufacturer's mnemonic or memory-aid dispenser packages (packaging designed for administration of one dosage unit at a time and incorporating features which remind the patient to take the medication at specified intervals) that rely solely upon the activity of one or more *progestogen (typically referred to as progestin) or estrogen substances* [16 C.F.R § 1700.14(a)(10)(iv)].

2. Conjugated estrogens tablets when dispensed in mnemonic packages containing not more than 32.0 mg [16 C.F.R. § 1700.14(a)(10)(xvii)].

3. Norethindrone acetate tablets when dispensed in mnemonic packages containing not more than 50 mg [16 C.F.R. § 1700.14(a)(10)(xviii)].

4. Medroxyprogesterone acetate tablets [16 C.F.R. § 1700.14(a)(10)(xix)].

B. HRT

HRT products contain the same or similar sex hormones as those used in oral contraceptives. However, unlike oral contraceptives, HRT products are not generically exempt from special packaging requirements (See Table 1, Product # 5). HRT products are exempt from special packaging if they only contain hormones that are already exempt (i.e., conjugated estrogens, norethindrone, or medroxy-progesterone) [See Table 1, Product # 4]. HRT products with one exempt component (e.g., medroxyprogesterone) and one non-exempt component (e.g., any estrogen other than conjugated estrogens such as estradiol) would not be exempt.

HRT is used to replace the estrogen and progesterone that normally decline following menopause (the cessation of menstruation). Generally, women experience a range of menopausal symptoms with some reporting minimal discomfort, while others have more severe effects (National Cancer Institute [NCI], 2001). Hot flashes are the most frequent symptom and often begin several years before other menopausal symptoms (NCI, 2001). Additionally, menopause accelerates bone depletion that commonly occurs with aging, leading to osteoporosis (NCI, 2001).

HRT relieves a number of menopausal symptoms (e.g., hot flashes and vaginitis) and helps to prevent osteoporosis. HRT consists of using estrogen alone or various combinations of estrogens and progestins. The latter regimen is similar to that for oral contraceptive products except the goal of therapy is to replace declining hormone levels rather than to prevent pregnancy.

According to the NCI, the average life expectancy for women in the U.S. increased from 51 years in 1900 to 79 years in 1990 because of medical care advances and fewer deaths from childbirth. In the next 20 years, an estimated 40 million women will go through menopause. As a result, the pharmaceutical industry is developing new prescription products specifically designed and marketed for HRT in post-menopausal women. Some of these may not be covered under the existing exemptions for sex hormones because they contain different or more selective estrogens or progestins to minimize side effects.

III. Discussion

A. Oral Contraceptive and HRT Products

Sex hormone products contain various estrogens and progestins. Some are natural hormones (e.g., estradiol) and others are semi-synthetic or synthetic (e.g., norgestimate). Synthetic hormones are usually developed to alter bioavailability (e.g., enhance oral absorption) or to reduce side effects.

Table 1 shows: 1) the similar hormone content of some oral contraceptive and HRT products; and 2) the inconsistency in the existing exemptions for sex hormones, i.e., some currently available HRT products do not require CR packaging because they contain sex hormones already exempt from the PPPA, while one other HRT product is not exempt because it contains estradiol (a natural human estrogen), which is not currently included in the exemptions.

Table 1. A sample of currently marketed estrogen/ progestin products.

Product Type	Estrogen	Progestin	Exempt*
1. oral contraceptive	0.035 mg ethinyl estradiol	250 mg norgestimate	Yes
2. oral contraceptive	0.035 mg ethinyl estradiol	215, 250, or 280 mg norgestimate	Yes
3. HRT	0.625 mg conjugated estrogens	2.5 mg or 5 mg medroxyprogesterone	Yes
4. HRT	0.625 mg conjugated estrogens	5 mg medroxy-progesterone	Yes
5. HRT	1 mg estradiol	0.09 mg norgestimate	No

* Exempt from CR packaging under the PPPA.

The other estrogens shown in Table 1 are ethinyl estradiol (a synthetic estrogen with an ethinyl substitution at the C 17 position) and conjugated estrogens (semi-synthetic sulfate esters of equine estrogens). The wide variation in potency of these estrogens is primarily due to differences in metabolism (Goodman & Gilman, 1996). Estradiol is not absorbed as well orally as ethinyl estradiol and conjugated estrogens because it undergoes extensive metabolism in the liver before it reaches the general circulation.

Conjugated estrogens and ethinyl estradiol have very different oral potencies, usually 0.625 mg of conjugated estrogens is considered equivalent to 0.005 mg to 0.01 mg of ethinyl estradiol. Data from a two week human study suggest that conjugated estrogens are equipotent to estradiol in suppression of follicle stimulating hormone (Maschak et al., 1982). Accounting for the different potencies of available estrogens, the doses used for HRT are substantially less than those used for oral contraception (Goodman & Gilman, 1996). Additionally,

the level of norgestimate in product # 5 is significantly less than that in the two exempt oral contraceptive products. Moreover, if this product was marketed as an oral contraceptive it would be exempt.

B. Acute Toxicity and Poisoning Data

Human toxic doses for estrogens or progestins have not been defined. Exposure summaries in the Poisindex® for estrogens, progestins, and oral contraceptives* state that acute toxicity is unlikely following overdosage. Gastrointestinal effects (e.g., nausea, vomiting, abdominal cramps) may occur after an acute overdose, but typically no treatment is necessary.

There is little information in the medical literature concerning acute overdosage of progestins or estrogens. One case showed that a single dose of 160 mg estradiol valerate (80 tablets/2 mg each), ingested by a 19-year-old woman in a suicide attempt, produced little toxicity (Punnonen and Salmi, Annals of Clinical research 3:134-136, 1983). The woman slept easily during the night of the ingestion and the next evening presented in the emergency clinic in generally good condition with nausea and a headache. A slight increase in serum triglyceride/phospholipid levels was observed with a marked increase in serum cortisol attributed to patient stress. An electroencephalogram (EEG) performed one day after the exposure showed findings typical of subcortical disturbance**, but the EEG was normal a week later.

Poisoning data from the American Association of Poison Control Centers (AAPCC) Toxic Exposure Surveillance System (TESS), corroborate the lack of acute toxicity associated with sex hormones. Table 2 shows acute exposures in children less than five years old to estrogens, progestins, and oral contraceptives from 1993 to 1998. There were no deaths and most of the exposures were non-toxic. There was one major outcome out of 37,645 exposures to oral contraceptives, but no details are readily available relating to this case. It is possible that this oral contraceptive formulation contained iron or that the child was exposed to a second substance or product.

*Acute toxicity is unlikely after an overdose unless the oral contraceptive contains iron (Poisindex®, 2001). Iron-containing drugs with 250 mg or more elemental iron require CR packaging under the PPPA [16 C.F.R. § 1700.14(a)(12)].

**There was no detailed information about the precise type of subcortical disturbance observed, but subcortical refers to regions beneath the cerebral cortex, i.e. the external gray layer of the largest portion of the brain.

Table 2. AAPCC TESS data.* Exposures in children < 5 years old (1993 to 1998).

		OUTCOME					
Substance	Total	None	Minor	Moderate	Major	NF nontoxic	NF minor
Estrogens	12032	3981	174	21	0	4204	3487
Progestins	3247	1012	45	6	0	1195	935
Oral Contraceptives	37645	9132	731	16	1	16590	10543

*AAPCC TESS data consists of toxic exposure reports to participating poison control centers within the U.S.
None – *no effect.*
Minor effect – The patient showed minimal signs & symptoms which resolved rapidly.
Moderate effect – The patient showed symptoms that were more pronounced, prolonged, or of a systemic nature which usually required some form of treatment. Symptoms were not life threatening and the patient recovered with no residual disability.
Major effect – The patient showed some symptoms which were life threatening or resulted in residual disability.
NF nontoxic – Not followed, judged as a nontoxic exposure.
NF minor – Not followed, minimal clinical effects possible.

C. Economic Information

The Directorate for Economic Analysis preliminarily determined that an exemption for HRT products from special packaging requirements will not have a significant impact on the environment or on a substantial number of small businesses (Tab A). The exemption would give manufacturers more packaging options and permit use of slightly cheaper packages which is expected to reduce the final product cost.

IV. Options

A. Propose to exempt HRT products from special packaging requirements.

The Commission may propose rulemaking if it concludes that exempting HRT products will not present a risk of serious personal injury or illness to young children.

B. Decline proposal to exempt HRT products from special packaging requirements.

The Commission may decline a proposal to exempt HRT products from special packaging requirements if the findings cannot be made.

V. Conclusion and Recommendation

Hormone replacement therapy is used to treat the immediate symptoms (e.g., hot flashes) and to prevent the delayed effects (e.g., osteoporosis) of menopause. Some HRT products contain estrogen/progestin combinations similar to those used in oral contraceptives. Currently, several of these HRT products do not require CR packaging because they contain sex hormones already exempt under the PPPA. However, another HRT product requires CR packaging because its hormone content does not fall under a current exemption even though the toxicity profile is the same.

Based on available information, the staff recommends that the Commission propose a rule to exempt HRT products from the special packaging requirements of the PPPA that rely solely upon the activity of one or more progestogen or estrogen substances. A draft Federal Register notice is at Tab B.

VI. References

Goodman & Gilman's, The Pharmacological Basis of Therapeutics, Ninth Edition, 1996.

Maschak et al., Comparison of Pharmacodynamic Properties of Various Estrogen Formulations. AM. J. Obstet. Gynecol. 144:511-518, 1982

National Cancer Institute Website. Cancer Facts: Menopausal Hormone Replacement Therapy, 2001.

Poisindex (R) System: Rumack, B.H., Hess A.J., & Gelman, C.R. (Eds): Micromedex, Inc., Englewood, Colorado (July 2001).

Punnonen and Salmi, Effects of a Massive Single Oral dose of Oestradiol Valerate in a Young Woman. Annals of Clinical research 3:134-136, 1983

TAB A

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: December 20, 2001

TO : Jacqueline Ferrante
Directorate for Health Sciences

THROUGH: Warren Prunella, AED, Directorate for Economic Analysis

FROM : Robert Franklin
Economist
Directorate for Economic Analysis

SUBJECT : Small Business and Environmental Considerations Related to Exempting HRT Products from PPPA Requirements.

The CPSC staff is recommending an exemption from the requirements of the Poison Prevention Packaging Act (PPPA) for hormone replacement therapy (HRT) products. Despite the low acute toxicity of HRT products, they are available only by prescription and so must be in child-resistant packaging unless they are specifically exempted from those requirements. The exemption would apply to HRT products, used for the treatment of menopausal symptoms, that contain one or more progestogen or estrogen substances. The Commission has previously granted exemptions from special packaging requirements for other products that contain the same or similar sex hormones as HRT products, such as oral contraceptives packaged in mnemonic packages. The Commission has also exempted certain specific sex hormones (i.e., conjugated estrogens, norethindrone acetate, and medroxyprogesterone acetate) from some special packaging requirements. Although HRT products that contain these specific hormones are already exempt from the special packaging requirements, the staff believes that a generic exemption for HRT products is justified. The staff believes that these exemptions are justified because, based on the available information, sex hormones have low acute toxicity.

Small Business Considerations

The staff does not know the universe of companies that would be affected by the Commission exempting HRT products. The staff also does not know how many of the companies that would be affected by the exemption are small businesses according to the criteria established by the Small Business Administration. However, the staff does not believe that the exemption would have a significant economic impact on a substantial number of companies. The exemption would increase the packaging options of manufacturers because it would allow them to package the affected HRT products in non-CR packages. The cost to manufacturers of child-resistant packaging is small, usually only a few cents per package, thus any cost savings is likely to be small. However, because the exemption will allow manufacturers to avoid the use of the slightly more expensive CR packages, it is expected to reduce the final cost of the HRT products.

Environmental Considerations

Pursuant to the National Environmental Policy Act, and in accordance with the Council on Environmental Quality regulations and CPSC procedures for environmental review, the staff assessed the possible environmental effects that may be associated with an exemption from CR packaging requirements for HRT products.

The Commission's regulations at 16 CFR Sec. 1021.5 (c) (3) state that rules exempting products from special packaging requirements under the PPPA normally have little or no potential for affecting the human environment. There is no reason to suspect that this exemption would be any different. The staff does not believe that this exemption will have any significant impact on the human environment.

TAB B

DRAFT 12/20/2001

Billing Code 6355-01

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Poison Prevention Packaging Requirements;

Proposed Exemption of Hormone Replacement Therapy Products

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed rule.

SUMMARY: The Commission is proposing to amend its child-resistant packaging requirements to exempt hormone replacement therapy ("HRT") products containing one or more progestogen or estrogen substances. Current exemptions cover some HRT products, but not others. This proposal would uniformly exempt all HRT products that rely solely on the activity of one or more progestogen or estrogen substances from child resistant packaging requirements.

DATES: Comments on the proposal should be submitted no later than _____ [insert date that is 75 days after publication in the **FEDERAL REGISTER**].

ADDRESSES: Comments should be mailed to the Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207, or delivered to the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East-West Highway, Bethesda, Maryland 20814-4408, telephone (301) 504-0800. Comments may also be filed by telefacsimile to (301) 504-0127 or by email to cpsc-os@cpsc.gov. Comments should be captioned

"Proposed HRT exemption."

FOR FURTHER INFORMATION CONTACT: Jacqueline Ferrante, Ph.D., Division of Health Sciences, Directorate for Epidemiology and Health Sciences, Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301) 504-0477 ext. 1199.

SUPPLEMENTARY INFORMATION:

A. Background

The Poison Prevention Packaging Act of 1970 ("PPPA"), 15 U.S.C. 1471-1476, provides the Commission with authority to establish standards for the special packaging of household substances, such as drugs, when child resistant packaging is necessary to protect children from serious personal injury or illness due to the substance and the special packaging is technically feasible, practicable, and appropriate for such substance. Accordingly, the Commission requires that oral prescription drugs be in child resistant ("CR") packaging. 16 CFR 1700.14(a)(10).

The Commission's regulations allow exemptions from this requirement for substances with low acute toxicity. Currently, there are four PPPA exemptions for sex hormones: (1) oral contraceptives in mnemonic packages containing one or more progestogen or estrogen substances; (2) conjugated estrogen tablets in mnemonic packages; (3) norethindrone acetate tablets in mnemonic packaging; and (4) medroxyprogesterone acetate tablets. 16 CFR 1700.14(a)(10)(iv), (xvii), (xviii) and (xix). Some HRT products fall within these exemptions, but because of

the way these exemptions are written, other HRT products currently require CR packaging. The proposed exemption would cover all HRT products that rely solely on the activity of one or more progestogen or estrogen substances.

B. HRT Products

HRT is used to replace the estrogen and progesterone that normally decline following menopause (the cessation of menstruation). Generally, women experience a range of symptoms with some reporting minimal discomfort, while others have more severe effects. Hot flashes are the most frequent symptom and often begin several years before other menopausal symptoms. Additionally, menopause accelerates bone depletion that commonly occurs with aging, leading to osteoporosis.

HRT relieves a number of menopausal symptoms (e.g., hot flashes and vaginitis) and helps to prevent osteoporosis. HRT consists of using estrogen alone or various combinations of estrogens and progestins. The latter regimen is similar to that for oral contraceptive products except the goal of therapy is to replace declining hormone levels rather than to prevent pregnancy.

Because the life expectancy of women in the United States is increasing, it is estimated that 40 million women will go through menopause in the next 20 years. Therefore, the pharmaceutical industry is developing new prescription products specifically designed and marketed for HRT post-menopausal women. Some of these products may not be covered under current PPPA regulations

although their toxicity is as low as those products currently exempt.

Sex hormone products contain various estrogens and progestins. Some are natural hormones (e.g., estradiol) and others are semi-synthetic or synthetic (e.g., norgestimate). Synthetic hormones are usually developed to alter bioavailability (e.g., enhance oral absorption) or to reduce side effects. Since available HRT products contain similar estrogen/progestin combinations, it is reasonable and consistent to exempt them like oral contraceptives.

C. Toxicity Data

Human toxic doses for estrogens or progestins have not been defined. Exposure summaries in the Poisindex® for estrogens, progestins, and oral contraceptives state that acute toxicity is unlikely following overdosage. Gastrointestinal effects (e.g., nausea, vomiting, abdominal cramps) may occur after an acute overdose, but typically no treatment is necessary.

There is little information in the medical literature concerning acute overdosage of progestins or estrogens. One case showed that a single dose of 160 mg estradiol valerate (80 tablets/2 mg each), ingested by a 19-year-old woman in a suicide attempt, produced little toxicity. The woman slept easily during the night of the ingestion and the next evening presented in the emergency clinic in generally good condition with nausea and a headache.

Poisoning data from the American Association of Poison Control Centers ("AAPCC") Toxic Exposure Surveillance System ("TESS"), corroborate the lack of acute toxicity associated with sex hormones. The staff reviewed data showing acute exposures in children less than five years old to estrogens, progestins, and oral contraceptives from 1993 to 1998. There were no deaths and most of the exposures were non-toxic. There was one major outcome out of 37,645 exposures to oral contraceptives, but no details are readily available relating to this case. It is possible that this oral contraceptive formulation contained iron or that the child was exposed to a second substance or product.

D. Impact on Small Business

The Commission's Directorate for Economic Analysis prepared a preliminary assessment of the impact of a rule to exempt HRT products from special packaging requirements. The staff reports that it does not know the universe of companies that would be affected by the proposed exemption or how many companies would be small businesses. However, the exemption is not likely to have a significant impact on a substantial number of companies, regardless of size. The exemption would actually increase the packaging options for manufacturers because it would allow them to package the affected HRT products in non-CR packages. Although the cost to manufacturers of CR packaging is small - usually only a few cents per package - the exemption would allow manufacturers to use slightly cheaper packages and thus reduce the final cost of the HRT products.

Based on this assessment, the Commission preliminarily concludes that the proposed amendment exempting HRT products from special packaging requirements would not have a significant impact on a substantial number of small businesses or other small entities.

E. Environmental Considerations

Pursuant to the National Environmental Policy Act, and in accordance with the Council on Environmental Quality regulations and CPSC procedures for environmental review, the Commission has assessed the possible environmental effects associated with the proposed PPPA amendment.

The Commission's regulations state that rules requiring special packaging for consumer products normally have little or no potential for affecting the human environment. 16 CFR 1021.5(c)(3). Nothing in this proposed rule alters that expectation.(3) Therefore, because the rule would have no adverse effect on the environment, neither an environmental assessment nor an environmental impact statement is required.

I. Executive Orders

According to Executive Order 12988 (February 5, 1996), agencies must state in clear language the preemptive effect, if any, of new regulations.

The PPPA provides that, generally, when a special packaging standard issued under the PPPA is in effect, "no State or political subdivision thereof shall have any authority either to establish or continue in effect, with respect to such household

substance, any standard for special packaging (and any exemption therefrom and requirement related thereto) which is not identical to the [PPPA] standard." 15 U.S.C. 1476(a). A State or local standard may be excepted from this preemptive effect if (1) the State or local standard provides a higher degree of protection from the risk of injury or illness than the PPPA standard; and (2) the State or political subdivision applies to the Commission for an exemption from the PPPA's preemption clause and the Commission grants the exemption through a process specified at 16 CFR Part 1061. 15 U.S.C. 1476(c)(1). In addition, the Federal government, or a State or local government, may establish and continue in effect a non-identical special packaging requirement that provides a higher degree of protection than the PPPA requirement for a household substance for the Federal, State or local government's own use. 15 U.S.C. 1476(b).

Thus, with the exceptions noted above, the proposed rule exempting HRT products from special packaging requirements would preempt non-identical state or local special packaging standards for those products.

The Commission has also evaluated the proposed rule in light of the principles stated in Executive Order 13132 concerning federalism, even though that Order does not apply to independent regulatory agencies such as CPSC. The Commission does not expect that the proposed rule will have any substantial direct effects on the States, the relationship between the national government

and the States, or the distribution of power and responsibilities among various levels of government.

List of Subjects in 16 CFR Part 1700

Consumer protection, Drugs, Infants and children, Packaging and containers, Poison prevention, Toxic substances.

For the reasons given above, the Commission proposes to amend 16 CFR part 1700 as follows:

PART 1700--[AMENDED]

1. The authority citation for part 1700 continues to read as follows:

Authority: Pub. L. 91-601, secs. 1-9, 84 Stat. 1670-74, 15 U.S.C. 1471-76. Secs 1700.1 and 1700.14 also issued under Pub. L. 92-573, sec. 30(a), 88 Stat. 1231. 15 U.S.C. 2079(a).

2.Section 1700.14 is amended by adding new paragraph (a)(10)(xxi) to read as follows (although unchanged, the introductory texts of paragraph (a) and paragraph (10) are included below for context):

§ 1700.14 Substances requiring special packaging.

(a) *Substances.* The Commission has determined that the degree or nature of the hazard to children in the availability of the following substances, by reason of their packaging, is such that special packaging meeting the requirements of § 1700.20(a)

is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substances, and the special packaging herein required is technically feasible, practicable, and appropriate for these substances:

* * * * *

(10) *Prescription Drugs.* Any drug for human use that is in a dosage form intended for oral administration and that is required by Federal law to be dispensed only by or upon an oral or written prescription of a practitioner licensed by law to administer such drug shall be packaged in accordance with the provisions of § 1700.15(a),(b), and (c), except for the following:

* * * * *

(xxi) Hormone Replacement Therapy Products that rely solely upon the activity of one or more progestogen or estrogen substances.

Dated: _____

_____
Todd Stevenson, Secretary
Consumer Product Safety Commission

List of Relevant Documents

1. Briefing memorandum from Jacqueline Ferrante, Ph.D., Directorate for Health Sciences, to the Commission, "Proposed Rule to Exempt HRT Products from the Special Packaging Requirements of the PPPA," _____, 2001.

2. Memorandum from Robert Franklin, Directorate for Economic Analysis, to Jacqueline Ferrante, Ph.D., Project Manager, "Small Business and Environmental Considerations Related to Exempting HRT Products from PPPA Requirements," December _____, 2001.