

CFR reference	Data collection	Number of respondents	Responses per respondent	Avg burden per response (in hrs.)	Total annual burden (in hrs.)
73.6 (c-e)	Request for exemption	17	1	70/60	20
73.14	Transfer of select agent	1,000	5	1.75	8,750
73.6 (a)(2)	Clinical and diagnostic laboratory exemption report.	1,000	4	1	4,000
73.7(i)	Notification of inactivation	6	1	30/60	3
73.8(g)	Request expedited review	6	1	30/60	3
73.10(b) ...	Documentation of self-inspection	1,000	1	1	1,000
73.13(f)	Documentation of training	1,000	1	2	8,700
73.18	Administrative review	14	1	4	56
73.15(d) ...	Ensure secure recordkeeping system	1,000	1	30/60	4,000
Total	1,000	34,804

Dated: April 7, 2003.

Thomas Bartenfeld,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 78N-0377 and 98P-1041; DESI 7661]

Certain Estrogen-Androgen Combination Drugs; Drugs for Human Use; Drug Efficacy Study Implementation; Amendment and Opportunity for Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is amending a previous **Federal Register** notice to reclassify certain estrogen-androgen combination drugs as lacking substantial evidence of effectiveness for the treatment of moderate to severe vasomotor symptoms associated with the menopause in those patients not improved by estrogen alone. The agency is taking this action because for this indication there is not substantial evidence of the contribution of each component to the effectiveness of these combination drugs. FDA is offering an opportunity for a hearing to persons affected by this action.

DATES: Requests for hearings are due on or before May 14, 2003. Data in support of hearing requests are due June 13, 2003.

ADDRESSES: Communications in response to this notice should be identified with the reference number DESI 7661 and directed to the attention of the appropriate office named below. A request for hearing, supporting data,

and other comments should be identified with Docket No. 76N-0377 and submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A request for an opinion on the applicability of this notice to a specific drug product should be directed to the Division of New Drugs and Labeling Compliance (HFD-310), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

David T. Read, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of September 8, 1972 (37 FR 18225), FDA announced its evaluation of the various indications claimed for the following combination drugs that contain an estrogen and an androgen:

1. Halodrin Tablets (NDA 11-267), containing fluoxymesterone and ethinyl estradiol;
2. Tylosterone Injection (NDA 8-099), containing diethylstilbestrol and methyltestosterone;
3. Tylosterone Tablets (NDA 7-661), containing diethylstilbestrol and methyltestosterone;
4. Tace with Androgen Capsules (NDA 10-597), containing chlorotrianisene and methyltestosterone;
5. Deladumone Injection and Deladumone OB Injection (NDA 9-545), containing testosterone enanthate and estradiol valerate.

As announced in that 1972 notice, FDA found these drugs to be safe and effective for the "prevention of postpartum breast engorgement and "for the menopausal syndrome in those

patients not improved by estrogen alone."

In the **Federal Register** of December 17, 1998 (63 FR 69631), FDA withdrew approval of estrogen-containing drugs insofar as they are indicated for postpartum breast engorgement because estrogens have not been shown to be safe for this use. That **Federal Register** notice included, among others, four of the five NDAs listed above. (NDA 11-267 was not included because the drug product covered by that application, Halodrin Tablets, was not labeled for use for postpartum breast engorgement.) Given this December 17, 1998 notice, the following discussion relates only to the second indication found safe and effective in the 1972 notice, i.e., "for the menopausal syndrome in patients not improved by estrogen alone."

In the **Federal Register** of September 29, 1976 (41 FR 43112), the agency announced that the menopausal indication for combination drugs containing an estrogen and an androgen was revised to read as follows:

Moderate to severe vasomotor symptoms associated with the menopause in those patients not improved by estrogen alone. (There is no 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.) 41 FR 43112 at 43113. (emphasis in original)

This action was taken as one part of a large agency undertaking with respect to the labeling (patient-directed as well as physician-directed) for all estrogen-containing drug products. The following documents were also published in the **Federal Register** of September 29, 1976: (1) 41 FR 43110 (DESI 2238; Certain Preparations for Vaginal Use); (2) 41 FR 43114 (DESI 1543; Certain Estrogen-Containing Drugs for Oral or Parenteral Use); (3) 41 FR 43117 (DESI 740, 1543, 2238, and 7661; Physician Labeling and Patient Labeling for Estrogens for General Use); and (4) 41 FR 43108 (a proposed rule that would require certain patient-directed labeling for estrogens for general use).