the anticipated benefits, if any, to the subjects, and the importance of the knowledge that may reasonably be expected to result; and (4) does the research present a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children?

All written comments concerning this matter should be submitted to Ms. Kelley Booher, Division of Policy, Planning, and Special Projects, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, The Tower Building, Rockville, MD 20852, telephone number (301) 402–5942 (not a toll-free number). Comments also may be sent via facsimile at (301) 402–2071 or by e-mail to: *407panel01@osophs.dhhs.gov.*

Materials available for review on the OHRP web page (available at: *http://ohrp.osophs.dhhs.gov/panels/407–01pnl/pindex.htm*) include: relevant sections of the grant application; sample consent, parental permission and assent documents; the Rhode Island Hospital IRB's deliberations on the protocol; an explanation of Rhode Island Hospital's Pediatric Risk Categories; and OHRP's January 13, 2003, letter to the principal investigator, Dr. Mary Carskadon, explaining why review pursuant to 46.407 is restricted to Study 2. A paper copy of the information referenced here is available upon request.

Dated: April 7, 2003.

Richard H. Carmona,

Surgeon General and Acting Assistant, Secretary for Health.

[FR Doc. 03–9051 Filed 4–11–03; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day–03–58]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 498–1210.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Send comments to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project: Importation and Shipping of Etiologic Agents (42 CFR 71.54 and part 72) OMB Control No. 0920–0199—Extension—Office of the Director (OD), Centers for Disease Control and Prevention (CDC).

The importation of etiological agents, hosts, and vectors of human disease are regulated by 42 CFR 71.54 and requires that the importation of such materials must be accompanied by a permit issued by the CDC. Interstate shipment of etiologic agents are regulated by 42 CFR part 72. This regulation establishes minimal packaging requirements for all viable micro-organisms, illustrates the appropriate shipping label, and provides reporting instructions regarding damaged packages and failure to receive a shipment. This request is for the information collection requirements contained in 42 CFR 71.54, 72.3(e), 72.3(f), and 72.4 which relate to the importation and interstate shipment of etiologic agents. Respondents include laboratory facilities such as those operated by government agencies, universities, research institutions, and commercial entities. The only cost to respondents is their time to complete the application for permit to import form and report problems with shipment of etiologic agents.

CFR section	Number of respondents	Number of responses per respondent	Avg. burden per response (in hrs.)	Total burden hours
72.54 Application Permit	2,000	1	20/60	666
72.3(e) Damaged Package	50	1	6/60	5
72.3(f) Shipping Requirement	200	10	12/60	400
72.4 Failure to Receive	20	1	12/60	4
Total	2,270			1,075

Dated: April 7, 2003.

Thomas Bartenfeld,

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

[FR Doc. 03–9018 Filed 4–11–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day–03–59]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 498–1210.

Comments are invited on: (a) Whether the proposed collection of information

is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Send comments to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project: Possession, Use, and Transfer of Select Agents and Toxins (OMB Control No. 0920–0576)—Extension—Office of the Director (OD), Centers for Disease Control and Prevention (CDC).

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188) specifies that the Secretary of Health and Human Services shall provide for the establishment and enforcement of standards and procedures governing the possession, use, and transfer of select biological agents and toxins. The Act specifies that facilities that possess, use, and transfer select agents register with the Secretary. The Secretary has designated CDC as the agency responsible for collecting this information.

CDC is requesting continued OMB approval to collect this information through the use of five separate forms. These forms are: (1) Application for Registration; (2) Facility Notification Form; (3) Request for Exemption; (4) Transfer of Select Agent form; and (5) Clinical and Diagnostic Laboratory Reporting Form.

The Application for Registration will be used by facilities to register with CDC. The Application for Registration requests facility information, a list of select agents in use, possession, or for transfer by the facility, characterization of the select agent, and laboratory information. Estimated average time to complete this form is 3 hours, 45 minutes for an entity with one principal investigator working with one select agent. CDC estimates that entities will need an additional 45 minutes for each additional investigator or select agent. This is an increase of 1 hour, 45 minutes over the previous form due to new reporting requirements for security and identification of those individuals the entity has designated to have a legitimate need to handle or use such agents.

Facilities may amend their registration if any changes occur in the information submitted to the Secretary. To apply for an amendment to a certificate of registration, an entity must obtain the relevant portion of the application package and submit the information requested in the package to CDC. Estimated time to amend a registration package is 60 minutes.

The Facility Notification Form must be completed by facilities whenever there is release of a select agent or theft or loss of a select agent. This is a new form. Estimated average time to complete this form is 60 minutes.

The Request for Exemption form will be used by facilities that are using select agents in investigational new drug testing or in cases of public health emergency. This is a new form. Estimated average time to complete this form is 70 minutes.

The Transfer of Select Agent Form will be used by facilities requesting transfer of a select agent to their facilities and by the facility transferring the agent. This is a modification of an existing form approved under OMB Control No. 0920–0199. Estimated average time to complete this form is 1 hour, 45 minutes. This is an increase of 75 minutes due to procedural changes.

The Clinical and Diagnostic Laboratory Exemption Report will be used by clinical and diagnostic laboratories to notify the Secretary that select agents identified as the result of diagnosis or proficiency testing have been properly disposed of. This is a new form. Estimated average time to complete this form is 60 minutes.

In addition to the standardized forms, this regulation also outlines situations in which an entity must notify or make a request of the Secretary in writing and CDC is requesting OMB approval to collect this information. The regulation states that an entity must notify the Secretary in writing at least five business days before destroying all select agent or toxin covered by a certificate of registration. The estimated time to gather the information and submit this notification is 30 minutes.

An entity may also apply to the Secretary for an expedited review of an individual by the Attorney General. To apply for this expedited review, an entity must submit a request in writing to the Secretary establishing the need for such action. The estimated time to gather the information and submit this request is 30 minutes. Entities should be aware that CDC is not developing standardized forms to use in these situations. Rather, the entity should provide the information as requested in the appropriate section of the regulation.

As part of the safety requirements of this regulation, the Responsible Official is required to conduct regular inspections (at least annually) of the laboratory where select agents and toxins are stored. The results of these inspections must be documented. CDC estimates that, on the average, such documentation will take 1 hour.

Also, as part of the safety requirements of this regulation, the entity is required to record the identity of the individual trained, the date of training, and the means used to verify that the employee understood the training. Estimated time for this documentation is 2 hours per principal investigator.

An entity or an individual may request administrative review of a decision denying or revoking either a certification of registration or approval based on a security risk assessment. This request must be in writing within 30 calendar days after the adverse decision. This request should include a statement of the factual basis for the review. CDC estimates the time to prepare and submit such a request is 4 hours.

Finally, an entity must implement a system to ensure that certain records and databases are accurate and that the authenticity of records may be verified. The time to implement such a system is estimated to average 4 hours.

The cost to respondents is their time to complete the forms and comply with the reporting and recordkeeping components of the Act plus a one-time purchase of a file cabinet (estimated cost $400) to maintain records.

CFR reference	Data collection	Number of respondents	Responses per respondent	Avg burden per response (in hrs.)	Total annual burden (in hrs.)
73.7(b)	Registration application	1,000	1	3.75	6,262
73.7(e)	Amendment to registration application	1,000	2	1	2,000
73.17 (a)(e).	Notification form	10	1	1	10

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.

[FR Doc. 03–9019 Filed 4–11–03; 8:45 am]

BILLING CODE 4163–18–P

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).