

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 4, 1998.

**Anna Snouffer,**

*Acting Committee Management Officer, NIH.*

[FR Doc. 98-30304 Filed 11-12-98; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant of Exclusive License: Long-Acting Testosterone Androgenic Compounds and Pharmaceutical Compositions Thereof**

**AGENCY:** National Institutes of Health, Public Health Service, DHHS.

**ACTION:** Notice.

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license worldwide to practice the invention embodied in: U.S. Patent 4,948,790, issued August 14, 1990 entitled, "Long-Acting Androgenic Compounds, and Pharmaceutical Compositions Thereof" to N.V. Organon, having a place of business in The Netherlands. The United States of America is an assignee of the patent rights in this invention.

**DATES:** Only written comments and/or application for a license which are received by the NIH Office of Technology Transfer on or before January 12, 1999, will be considered.

**ADDRESSES:** Requests for a copy of the patent applications, inquiries, comments and other materials relating to the contemplated license should be directed to: Dennis H. Penn, Pharm.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 496-7056, ext. 211; Facsimile: (301) 402-0220.

**SUPPLEMENTARY INFORMATION:** In an effort to develop an efficacious treatment for human reproductive disorders this invention describes testosterone bucyclate, which provides a means for prolonged androgenic activity when administered intramuscularly as an aqueous crystalline suspension. This compound may have utility as a

therapeutic androgen for patients with androgen deficiency syndromes, male contraception, and as an androgen replacement in other methods of male contraception.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within 60 days from the date of this published Notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

The field of use may be limited to the use of the invention for the development of pharmaceutical compounds to treat human androgen deficiency syndromes and male contraception.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: November 5, 1998.

**Jack Spiegel,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration**

**Mandatory Guidelines for Federal Workplace Drug Testing Programs**

**AGENCY:** Substance Abuse and Mental Health Services Administration, HHS.

**ACTION:** Revisions to the Mandatory Guidelines.

**SUMMARY:** On September 30, 1997, the Department of Health and Human Services (HHS) published a notice in the **Federal Register**, 62 FR 51118, revising the testing cutoff levels for opiates that were in Mandatory Guidelines for Federal Workplace Drug Testing Programs, 59 FR 29916 (June 9, 1994). The **Federal Register** notice indicated that May 1, 1998, was the effective date for implementing the new opiate testing cutoff levels. Subsequent to the publication of that notice, it became clear that not all manufacturers of immunoassay test kits would be able to

provide a sufficient supply of the modified opiate reagents by that date, that it would take more time for the certified drug testing laboratories to validate the new immunoassay test kits and confirmatory test procedures for opiates, and that it would take more time to verify the performance of each laboratory using external performance testing samples. For these reasons, on February 4, 1998, the Division of Workplace Programs sent a letter to all Federal agencies, HHS certified and applicant drug testing laboratories, and immunoassay test kit manufacturers informing them that the effective date would be delayed 4 to 6 months beyond the May 1, 1998, effective date published in the September 30, 1997, **Federal Register** notice. This notice establishes a new effective date.

**EFFECTIVE DATE:** December 1, 1998.

**FOR FURTHER INFORMATION CONTACT:** Dr. Donna M. Bush, Drug Testing Team Leader, Division of Workplace Programs, 5600 Fishers Lane, Rockwall II, Suite 815, Rockville, Maryland 20857, tel. (301) 443-6014.

**SUPPLEMENTARY INFORMATION:** The Division of Workplace Programs is satisfied that the manufacturers of test kits can provide an adequate supply of the modified opiate test kits to the certified laboratories by the December 1, 1998, effective date. During June 1998, the certified laboratories received a special set of performance testing samples from the National Laboratory Certification Program (NLCP) contractor to evaluate each laboratory's ability to conduct the initial and confirmatory tests at the revised testing levels for opiates. The results for this set of samples indicate that all the laboratories were able to conduct the initial test using the modified opiate test kits provided by the immunoassay test kit manufacturers. Based on this information, all the manufacturers were contacted and informed that a December 1, 1998, effective date has been selected. There was unanimous agreement among the manufacturers that each would be able to provide a sufficient number of kits to the laboratories before that date. A second set of special performance testing samples will be sent to the laboratories in September 1998 to further ensure that all laboratories are prepared to test specimens for opiates using the revised testing levels.

The September 30, 1997, **Federal Register** notice discusses the background and summary of public comments regarding the changes to the testing cutoff levels of opiates. The Department's responses to those comments and the proposed policy have

not changed. However, to ensure that there is no misunderstanding, the changes to the Mandatory Guidelines for Federal Workplace Drug Testing Programs published on June 9, 1994 (59 FR 29916) are restated in this notice.

**Information Collection Requirements:** There are no new paperwork requirements subject to the Office of management and Budget approval under the Paperwork Reduction Act of 1980.

Dated: September 21, 1998.

**Nelba Chavez,**

*Administrator, Substance Abuse and Mental Health Services Administration.*

Dated: October 31, 1998.

**Donna E. Shalala,**

*Secretary.*

The following amendments are made to the Mandatory Guidelines for Federal Workplace Drug Testing Programs published on June 9, 1994 (59 FR 29916):

**Subpart B**

1. Section 2.4(e)(1), the initial test level for opiate metabolites appearing in the table, is amended by changing the value of "300" to "2,000" and deleting the footnote that had specified a 25 ng/mL testing level if the immunoassay test was specific for free morphine.

2. Section 2.4(f)(1), the confirmatory test level for morphine appearing in the table, is amended by changing the value of "300" to "2,000."

3. Section 2.4(f)(1), the confirmatory test level for codeine appearing in the table, is amended by changing the value of "300" to "2,000."

4. Section 2.4(f)(1), the table of confirmatory test levels, is amended by adding a new line under opiates to read as follows:

6-Acetylmorphine<sup>4</sup> 10 ng/mL

5. Section 2.4(f)(1), the table of confirmatory test levels, is amended by adding a new footnote under the table to read as follows:

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**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

[Docket No. FR-4349-N-40]

**Submission for OMB Review; Comment Request**

**AGENCY:** Office of the Assistant Secretary for Administration, HUD.

**ACTION:** Notice.

**SUMMARY:** The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

**DATES:** Comments due date: December 14, 1998.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments must be received within thirty (30) days from the date of this Notice. Comments should refer to the proposal by name and/or OMB approval number and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

**FOR FURTHER INFORMATION CONTACT:** Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 708-1305. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

**SUPPLEMENTARY INFORMATION:** The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35).

The Notice lists the following information: (1) the title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval

number, if applicable, (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

**Authority:** Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: November 4, 1998.

**David S. Cristy,**

*Director, IRM Policy and Management Division.*

**Title of Proposal:** Loan Guarantee Program—Mortgage Credit Analysis and Transmittal for Payment of Loan Guarantee Fee.

**Office:** Public and Indian Housing.

**OMB Approval Number:** 2577-0200.

**Description of the Need for the Information and its Proposed Use:** The forms will be used by lenders to determine the borrowers' credit worthiness and to forward specific loan data to Treasury. The lender must analyze the borrower's ability to repay the mortgage debt. Once the borrower is approved, a fee of 1 percent is submitted to HUD. This is a one-time fee and can be included in the mortgage amount.

**Form Number:** HUD-53036 and HUD-53038.

**Respondents:** Business or Other-For-Profit.

**Frequency of Submission:** On Occasion.

**Reporting burden:**

	Number of respondents	×	Frequency of response	×	Hours per response	=	Burden hours
53036 .....	500		1		.10		50
53038 .....	500		1		.083		42

<sup>4</sup>Test for 6-AM when the morphine concentration exceeds 2,000 ng/mL.