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Dated: November 4, 1998.

Anna Snouffer,

Acting Committee Management Officer, NIH.

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

BILLING CODE 4140-01-M

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.

[FR Doc. 98-30432 Filed 11-12-98; 8:45 am]

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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