

of Liaison and Policy (ODLR) and must be filed no later than March 7, 2005.

Dated: December 21, 2004.

William J. Walker,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 05-70 Filed 1-3-05; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to Section 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on November 16, 2004, Organichem Corporation, 33 Riverside Avenue, Rensselaer, New York 12144, made application by letter to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of Hydrocodone (9193) and Fentanyl (9180), a basic class of controlled substances in Schedule II.

The company plans to manufacture the listed controlled substances in bulk for distribution to its customers.

Any other such applicant and any person who is presently registered with DEA to manufacture such a substance may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such comments or objections may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: Federal Register Representative, Office of Liaison and Policy (ODLR) and must be filed no later than March 7, 2005.

Dated: December 21, 2004.

William J. Walker,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 05-69 Filed 1-3-05; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to 21 CFR 1301.33(a), Title 21 of the Code of Federal Regulations (CFR), this is notice that on September 2, 2004, Organix Inc., 240 Salem Street, Woburn, Massachusetts 01801, made application by renewal to the Drug

Enforcement Administration (DEA) for registration as a bulk manufacturer of Codeine (9041), a basic class of controlled substance listed in Schedule II.

The company plans to manufacture small quantities of the listed controlled substance for use in drug abuse detection kits.

Any other such applicant and any person who is presently registered with DEA to manufacture such a substance may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such comments or objections may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: DEA **Federal Register** Representative, Office of Liaison and Policy (ODLR) and must be filed no later than March 7, 2005.

Dated: December 21, 2004.

William J. Walker,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated July 21, 2004, and published in the **Federal Register** on August 10, 2004, (69 FR 48525), Syva Company, Dade Behring Inc., Regulatory Affairs Dept. 1-310, 20400 Mariani Avenue, Cupertino, California 95014, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed below, and by letter dated July 6, 2004, to modify its name to Dade Behring, Inc.

Drug	Schedule
Tetrahydrocannabinols (7370) ...	I
Ecgonine (9180)	II
Morphine (9300)	II

The company plans to produce the listed controlled substances in bulk to be used in the manufacture of reagents and drug calibrator/controls for DEA exempt products.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Syva

Company, Dade Behring Inc. to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Syva Company, Dade Behring Inc. to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: December 21, 2004.

William J. Walker,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration

By Notice dated September 16, 2004 and published in the **Federal Register** on September 30, 2004, (69 FR 58548), Tocris Cookson, Inc., 16144 Westwoods Business Park, Ellisville, Missouri 63021-4500, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of Tetrahydrocannabinols (7370), a basic class of controlled substance listed in Schedule I.

The company plans to import small quantities of the listed substance for research purposes.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and 952(a) and determined that the registration of Tocris Cookson, Inc. to import the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971, at this time. DEA has investigated Tocris Cookson, Inc. to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the

company's background and history. Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above named company is granted registration as an importer of the basic class of controlled substance listed.

Dated: December 21, 2004.

William J. Walker,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

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NUCLEAR REGULATORY COMMISSION

[Docket No. 50-312]

Sacramento Municipal Utility District; Rancho Seco Nuclear Generating Station; Partial Exemption from Requirements of 10 CFR 50.719(c); 10 CFR Part 50, Appendix A; 10 CFR Part 50, Appendix B

1.0 Background

Sacramento Municipal Utility District (SMUD) is the licensee and holder of Facility Operating License No. DPR-54 for the Rancho Seco Nuclear Generating Station (Rancho Seco), a permanently shutdown decommissioning nuclear plant. Although permanently shutdown, this facility is still subject to all rules, regulations, and orders of the U.S. Nuclear Regulatory Commission (NRC).

The Sacramento Municipal Utility District (SMUD) shut down Rancho Seco Nuclear Generating Station permanently on June 7, 1989, after approximately 15 years of operation. On August 29, 1989, SMUD formally informed the NRC that the plant was shut down permanently. On May 20, 1991, SMUD submitted the Rancho Seco decommissioning plan and on March 20, 1995, the NRC issued an Order approving the decommissioning plan and authorizing the decommissioning of Rancho Seco.

SMUD began actively decommissioning Rancho Seco in February 1997, and completed the transfer of all of the spent nuclear fuel to the 10 CFR Part 72 licensed Independent Spent Fuel Storage Installation (ISFSI) on August 21, 2002. Accordingly, the only quality-related structures, systems, or components (SSCs) at the Rancho Seco 10 CFR Part 50 licensed site are the radioactive sources used to calibrate the instrumentation used to measure radioactivity in gaseous and liquid effluents.

Plant dismantlement is substantially (approximately 80%) complete and most of the SSCs that were safety-related or important-to-safety have been removed from the plant and shipped for disposal. The pressurizer was shipped to Envirocare for disposal in April 2004, removal of the steam generators is in progress with both steam generators scheduled to be shipped to Envirocare by spring 2005 (one by the end of 2004 and the second in spring 2005), and activities in preparation for the reactor vessel internals segmentation are underway and mobilization of the segmentation contractor is scheduled to begin in early 2005.

On September 2, 2004, SMUD filed a request for NRC approval of a partial exemption from the recordkeeping requirements of 10 CFR 50.71(c); 10 CFR 50, Appendix A; and 10 CFR 50, Appendix B.

2.0 Request/Action

Pursuant to the requirements of 10 CFR 50.71(d)(2) and 10 CFR 50.12, SMUD requested partial exemption to the recordkeeping requirements of 10 CFR 50.71(c); 10 CFR Part 50, Appendix A; CFR Part 50, Appendix B. This exemption request was characterized as "partial" because the exemption would apply only to the disposal of hardcopies of records, prior to termination of the Rancho Seco license, that: (1) Are associated with the operation, design, fabrication, erection, and testing of structures, systems, and components (SSCs) that are no longer quality-related or important to safety or have been removed from the plant for disposal; and (2) require storage in their original hard copy format due to practical and feasibility limitations associated with transferring them to microfilm or microfiche.

Most of these records are for SSCs that have been removed from Rancho Seco and disposed of off-site. Disposal of these records will not adversely impact the ability to meet other NRC regulatory requirements for the retention of records [e.g., 10 CFR 50.54(a), (p), (q), and (bb); 10 CFR 50.59(d); 10 CFR 50.75(g); *etc.*]. These regulatory requirements ensure that records from operation and decommissioning activities are maintained for safe decommissioning, spent nuclear fuel storage, completion and verification of final site survey, and license termination.

3.0 Discussion

NRC licensees are required to maintain their records according to the NRC regulatory recordkeeping requirements. Pursuant to the requirements of 10 CFR 50.12, "Specific

Exemptions," and 10 CFR 50.71(d)(2), SMUD filed a request for a partial exemption from the NRC regulatory recordkeeping requirements contained in 10 CFR 50.71(c), 10 CFR 50, Appendix A, and 10 CFR 50, Appendix B. The NRC recordkeeping requirements at issue in SMUD's request for exemption are as follows.

10 CFR 50.71, "Maintenance of records, making of reports," subpart (c) states: Records that are required by the regulations in this part, by license condition, or by technical specifications, must be retained for the period specified by the appropriate regulation, license condition, or technical specification. If a retention period is not otherwise specified, these records must be retained until the Commission terminates the facility license.

10 CFR 50, Appendix A, "General Design Criteria for Nuclear Power Plants," establishes the necessary design, fabrication, construction, testing, and performance requirements for structures, systems, and components important to safety; that is, structures, systems, and components that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public. Specifically, SMUD requests an exemption from Criterion 1, "Quality standards and records," which states in part:

Appropriate records of the design, fabrication, erection, and testing of structures, systems, and components important to safety shall be maintained by or under the control of the nuclear power unit licensee throughout the life of the unit."

10 CFR 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," establishes quality assurance requirements for the design, construction, and operation of structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. Specifically, SMUD requests an exemption from Criterion XVII, "Quality Assurance Records," which states:

Sufficient records shall be maintained to furnish evidence of activities affecting quality. The records shall include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. The records shall also include closely-related data such as qualifications of personnel, procedures, and equipment. Inspection and test records shall, as a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. Records shall be identifiable and retrievable.