DEPARTMENT OF JUSTICE
Drug Enforcement Administration

MANUFACTURER OF CONTROLLED SUBSTANCES; NOTICE OF APPLICATION; CAMBRIDGE ISOTOPE LAB

Pursuant to §1301.33(a), Title 21 of the Code of Federal Regulations (CFR), this is notice that on July 01, 2013, Cambridge Isotope Lab, 50 Frontage Road, Andover, Massachusetts 01810, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of Morphine (9300), a basic class of controlled substance listed in schedule II.

The company plans to utilize small quantities of the listed controlled substance in the preparation of analytical standards. 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 written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than October 25, 2013.


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

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE
Drug Enforcement Administration

MANUFACTURER OF CONTROLLED SUBSTANCES; NOTICE OF APPLICATION; NAVINTA, LLC

By Notice dated April 10, 2013, and published in the Federal Register on April 19, 2013, 78 FR 23596, Navinta, LLC., 1499 Lower Ferry Road, Ewing, New Jersey 08618–1414, made application to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pentobarbital (2270)</td>
<td>II</td>
</tr>
<tr>
<td>Remifentanil (9739)</td>
<td>II</td>
</tr>
</tbody>
</table>

The company plans initially to produce API quantities of the listed controlled substances for validation purposes and FDA approval, then to produce commercial size batches for distribution to dosage form manufacturers upon FDA approval.

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 Navinta, LLC., to manufacture the basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Navinta, LLC., 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(a), 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.


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

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DEPARTMENT OF JUSTICE
Drug Enforcement Administration

TIN T. WIN, M.D., DISMISSAL OF PROCEEDING

On February 27, 2013, I, the Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to Tin T. Win, M.D. (hereinafter, Registrant), of Lake Havasu, Arizona. GX 10, at 1. Among various charges, the Order alleged that Registrant issued numerous controlled substance prescriptions after the Arizona Medical Board had prohibited her “from prescribing controlled substances” and thus violated both the Board’s order and federal law. Id. at 1–3 (citing Ariz. Rev. Stat. §32–1401(27)(r); 21 U.S.C. 841). The Order also notified Registrant of her right to either request a hearing on the allegations or submit a written statement of position in lieu of a hearing within thirty (30) days of her receipt of the Order, the procedure for electing either option, and the consequence of failing to elect either option.

On March 6, 2013, the Order was personally served on Registrant by a DEA Special Agent and a Diversion Investigator. See GX 11. On May 20, 2013, the Government filed a Request for Final Agency Action, which sought the revocation of Registrant’s...
registration. Request for Final Agency
Action, at 12. Therein, the Government
represented that neither Registrant, nor
anyone purporting to represent her, had
deposited either a request for a hearing or
a written statement in lieu of a hearing.
*Id.* at 2.

Upon review of the record, the
Government’s evidence showed that
Registrant’s registration was due to
expire on May 31, 2013. See *GX 2.*
However, because the filing of a timely
renewal application would have
prevented the expiration of her
registration (albeit in suspended status),
see 5 U.S.C. 556(e), I took official notice
of her registration record with the
Agency. According to that record,
Registrant did not file either a renewal
application or a new application. The
Agency therefore deemed her
registration as expired and retired her
registration number.

While ordinarily these findings render
a case moot, see *Ronald J. Riegel,* 63 FR
67132, 67133 (1998), simultaneously
with the issuance of the Order to Show
Cause, I immediately suspended
Registrant’s registration. Because the
Immediate Suspension Order also
authorized the Government to seize any
controlled substances in Registrant’s
possession, and thus created the
possibility that a collateral consequence
existed which precludes a finding of
mootness, see *Robert Charles Ley,* 76 FR
20033, 20034 (2011), I directed the
Government to notify my Office as to
whether it had seized any controlled

On July 22, 2013, the Government
notified my Office that it had not seized
any controlled substances pursuant to
the Immediate Suspension Order. Gov.
Response Regarding Mootness, at 2. The
Government further acknowledged that
this “case is now moot.” *Id.*
Accordingly, I will dismiss this
proceeding. *See Ley,* 76 FR at 20034.

Order
Pursuant to the authority vested in me
by 21 U.S.C. 824(a), as well as 28 CFR
0.100(b), I order that the Order to Show
Cause and Immediate Suspension of
Registration issued to Tin T. Win, M.D.,
be, and it hereby is, dismissed. This
Order is effective immediately.

Dated: August 16, 2013.

Michele M. Leonhart,
Administrator.

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