

pharmaceutical manufacturing operations and, without required notification to DEA, discontinued business within the meaning of 21 CFR 1301.52(a).

Even assuming *arguendo*, that ALRA had a current DEA registration, it could not manufacture the controlled substances for which it seeks a permanent quota unless and until the FDA found the company was in compliance with CGMP. Moreover, as discussed, ALRA's president, who submitted the procurement quota request, is currently incarcerated in federal prison serving a 30 month sentence. Accordingly, ALRA's anticipated requirements for 2002 and its estimated requirements for 2003 do not justify approval of its requested procurement quota. See 21 U.S.C. 826(c) and (d); 21 CFR 1302.12.

Further, despite ample opportunities for corrective action, ALRA has a continuing history of regulatory violations under the Controlled Substances Act continuing from 1987 to the present. Under these circumstances, where the company has failed to conform its conduct to the requirements of federal law over an extensive period, where ALRA as well as its CEO and his wife were convicted of product adulteration felonies, and where the company has ceased manufacturing operations and allowed its DEA registration to lapse, granting a procurement quota under these conditions would be inimical to the public interest.

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 826(c) and (d), 28 CFR 0.100(b) and 0.104 and 21 CFR 1303.37, hereby orders that ALRA Laboratories, Inc.'s Application for Procurement Quota for Controlled Substances be, and it hereby is, denied. This order is effective July 16, 2004.

Dated: May 17, 2004.

**Michele M. Leonhart,**  
Deputy Administrator.

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### Manufacturer of Controlled Substances; Notice of Registration

By Notice dated January 16, 2004, and published in the **Federal Register** on February 11, 2004, (69 FR 6691), American Radiolabeled Chemical, Inc.,

104 ARC Drive, St. Louis, Missouri 63146, made application by letter to the Drug Enforcement Administration for registration as a bulk manufacturer of the basic classes of controlled substances listed below:

| Drug                         | Schedule |
|------------------------------|----------|
| Amphetamine (1100) .....     | II       |
| Methamphetamine (1105) ..... | II       |
| Phenylacetone (8501) .....   | II       |

The firm plans to bulk manufacture small quantities of the listed controlled substances as radiolabeled compounds.

No comments or objections have been received. DEA has considered the factors in Title 21, United States Code, Section 823(a) and determined that the registration of American Radiolabeled Chemical, Inc. to manufacture the listed controlled substances is consistent with the public interest at this time. DEA has investigated American Radiolabeled Chemical, Inc. to ensure that the company's registration is consistent with the public interest. This 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 28 CFR 0.100 and 0.104, the Deputy Assistant Administrator, Office of Diversion Control, hereby orders that the application submitted by the above firm for registration as a bulk manufacturer of the basic class of controlled substance listed is granted.

Dated: May 5, 2004.

**William J. Walker,**

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

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

[Docket No. 03-22]

#### Lewis B. Boone, M.D., Revocation of Registration, Denial of Request for Change of Registered Location

On March 23, 2003, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Lewis B. Boone, M.D. (Respondent) of Russell, Kentucky, notifying him of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration,

BB7108550, as a practitioner pursuant to 21 U.S.C. 824(a)(3) and deny, pursuant to 21 U.S.C. 823(f), any pending applications or requests, including but not limited to, Respondent's request for a modification of his registration to reflect a move to an Ohio location. As a basis for revocation, the Order to Show Cause alleged that Respondent's license to practice medicine in Kentucky had been indefinitely restricted and that his medical license in Ohio had been permanently revoked. As a result, the Order alleged he was not authorized to handle controlled substances in either his current or proposed States of registration.

On April 28, 2003, Respondent, acting *pro se*, timely requested a hearing in this matter. On May 1, 2003, the presiding Administrative Law Judge Mary Ellen Bittner (Judge Bittner) issued the Government, as well as Respondent, an Order for Prehearing Statements.

On May 7, 2003, in lieu of filing a prehearing statement, the Government filed Government's Request for Stay of Proceedings and Motion for Summary Disposition. The Government argued Respondent was without authorization to handle controlled substances in the States of Kentucky and Ohio and, as a result, further proceedings in the matter were not required. Counsel for the Government subsequently filed a copy of the January 18, 2002, Commonwealth of Kentucky, State Board of Medical Licensure's Agreed Order of Indefinite Restriction, specifying Respondent "shall not prescribe, dispense or otherwise professionally utilize controlled substances within the Commonwealth of Kentucky." The Government also filed copies of the State Medical Board of Ohio's August 14, 2002, Entry of Order permanently revoking Respondent's license to practice medicine in Ohio.

On June 11, 2003, Judge Bittner issued a memorandum to the parties seeking clarification of what was encompassed by the term "controlled substances" as used in the Kentucky Agreed Order. Judge Bittner presumed that phrase referred to substances that were controlled pursuant to Kentucky's statutory and regulatory provisions, not the Federal Controlled Substances Act. Judge Bittner invited the parties to file statements (with supporting documents) as to whether there were any substances controlled pursuant to the Federal Controlled Substances Act, but not under Kentucky law. The memorandum reflected a concern that the Agreed Order's use of the State definition of "controlled substances" might not