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.

[FR Doc. 04–13535 Filed 6–15–04; 8:45 am]

BILLING CODE 4410–09–M

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.

[FR Doc. 04–13531 Filed 6–15–04; 8:45 am]

BILLING CODE 4410–09–M

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

include every substance defined as such under Federal law and thus, may not have restricted Respondent's ability to prescribe each and every substance controlled under the Federal scheme. The Government filed a response asserting such a comparison was unnecessary.

On August 29, 2003, Judge Bittner issued her Opinion and Recommended Decision of the Administrative Law Judge (Opinion and Recommended Decision). As part of the recommended ruling, Judge Bittner granted the Government's Motion for Summary Disposition, in part, finding Respondent was not licensed to practice medicine in Ohio, the jurisdiction where he sought to be registered and further finding, to the extent that substances scheduled under the Federal Controlled Substances Act are controlled under Kentucky State law, that he lacked authorization to handle controlled substances in Kentucky. Judge Bittner recommended, to that extent, that Respondent's DEA Certificate of Registration be revoked. She also recommended denial of Respondent's application to modify his DEA registration to reflect an Ohio address.

On September 9, 2003, along with a motion asking Judge Bittner to reconsider her Opinion and Recommended Decision, the Government filed newly obtained documentation showing Respondent's Kentucky medical license had recently been suspended. On September 24, 2003, Judge Bittner issued a Memorandum to the Parties, granting the Government's Motion for Reconsideration and rescinding the Opinion and Recommended Decision, insofar as it applied to the Kentucky registration. While reaffirming her findings and recommendations with regard to Ohio, she advised both parties that, with respect to Kentucky, she was considering the Government's motion as an amended motion for summary disposition, based on the ground that Respondent was not currently authorized to practice medicine in that State. Respondent did not avail himself of the opportunity afforded him to respond to the motion.

On October 22, 2003, Judge Bittner issued a Supplemental Opinion and Recommended Decision of the Administrative Law Judge (Supplemental Opinion and Recommended Decision). In it, Judge Bittner found Respondent's Kentucky medical license had been suspended by that State's June 20, 2003, Emergency Order of Suspension. Further, she concluded that because he is not currently licensed to practice medicine in Kentucky, he is not eligible to hold a DEA registration in that State. Accordingly, Judge Bittner granted the Government's Motion for Summary Disposition, recommending that Respondent's DEA registration be revoked.

No exceptions were filed by either party to the Supplemental Opinion and Recommended Decision or to those sections of Judge Bittner's initial Opinion and Recommended Decision which had not been rescinded. On November 24, 2003, the record of these proceedings was transmitted to the Office of the DEA Deputy Administrator.

The Deputy Administrator has considered the record in its entirety and pursuant to 21 CFR 1316.67, hereby issues her final order based upon findings of fact and conclusions of law as hereinafter set forth. As to the Kentucky registration, the Deputy Administrator adopts in full the Supplemental Opinion and Recommended Decision. Regarding Respondent's application for a change of registered location to Ohio, the Deputy Administrator adopts only those findings of fact and conclusions of law and recommendations in the Opinion and Recommended Decision which are relevant to that issue. The remaining findings of fact, conclusions of law and recommendations in the Opinion and Recommended Decision, pertaining to Respondent's Kentucky registration, were rescinded and the Deputy Administrator takes no action with regard to those findings, conclusions or recommendations.

The Deputy Administrator finds Respondent holds DEA Certificate of Registration, BB7108550, as a practitioner on the Commonwealth of Kentucky. The Deputy Administrator further finds that on June 20, 2003, the Commonwealth of Kentucky, Board of Medical Licensure, issued an Emergency Order of Suspension, indefinitely suspending Respondent's authority to practice as a physician in the Commonwealth of Kentucky. The Deputy Administrator further finds that on August 14, 2002, the Ohio Medical Board permanently revoked Respondent's medical license in that State. There is no evidence in the record indicating that either the suspension or revocation has been stayed or modified or that Respondent's license to practice medicine in either jurisdiction has been reinstated. As a result, he is not authorized to prescribe, dispense, administer, or otherwise handle controlled substances in Kentucky, the place of current DEA registration, or in Ohio, the location of proposed registration.

DEA does not have statutory authority under the Controlled Substances act to issue or maintain a registration if the applicant or registrant is without State authority to handle controlled substances in the State in which he conducts business. *See* 21 U.S.C. 802(21), 823(f) and 824(a)(3). This prerequisite has been consistently upheld. *See* Karen Joe Smiley, M.D., 68 FR 48944 (2003); Dominick A. Ricci, M.D., 58 FR 51104 (1993); Bobby Watts, M.D., 53 FR 11919 (1988). Revocation is also appropriate when a State license has been suspended, but with a possibility of future reactivation. *See* Anne Lazar Thorn, M.D., 62 FR 12,847 (1997).

Here, it is clear that because Respondent is not currently licensed to practice medicine in either jurisdiction, he currently lacks authority to handle controlled substances in Kentucky, the State where he is registered and in Ohio, the State where he seeks to be registered. Therefore, DEA does not have authority to maintain Respondent's DEA Certificate of Registration or grant any pending applications for renewal or modification of that registration, including, but not limited to, Respondent's application to change his registered location to Ohio.

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration, BB7108550, issued to Lewis B. Boone, M.D., be, and it hereby is, revoked. The Deputy Administrator further orders that his application for modification of such registration be, and they hereby are, denied. This order is effective July 16, 2004.

Dated: May 17, 2004.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 04–13533 Filed 6–15–04; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By notice dated October 7, 2003, and published in the **Federal Register** on October 29, 2003, (68 FR 61699), Guilford Pharmaceuticals, Inc., 6611 Tributary Street, Baltimore, Maryland 21224, made application by renewal to the Drug Enforcement Administration