agricultural tariff rate), as well as significant impediments to trade, such as import bans.

The 48 countries of sub-Saharan Africa covered in this investigation include: Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Democratic Republic of the Congo, Côte d'Ivoire, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gabon, The Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Republic of the Congo, Rwanda, São Tomé and Principe, Senegal, Seychelles, Sierra Leone, Somalia, South Africa, Sudan, Swaziland, Tanzania, Togo, Uganda, Zambia, and Zimbabwe.

The USTR requested that the Commission provide its first report by December 10, 2000, and annually for a period of 4 years thereafter. The second report in the series was delivered to USTR on December 10, 2001; and the third report was delivered on December 10, 2002; the fourth report was delivered to USTR on December 19, 2003. The Commission expects to deliver the fifth report by December 10, 2004.

Written Submissions: The Commission does not plan to hold a public hearing in connection with this fifth report. However, interested persons are invited to submit written statements concerning matters to be addressed in the report. Commercial or financial information that a person desires the Commission to treat as confidential must be submitted in accordance with section 201.6 of the Commission's Rules of Practice and Procedure (19 CFR 201.6). The Commission may include such confidential business information in the report it sends to USTR. All written submissions must conform with the provisions of section 201.8 of the Commission's Rules of Practice and Procedure (19 CFR 201.8). The Commission's Rules do not authorize filing of submissions with the Secretary by facsimile or electronic means, except to the extent permitted by section 201.8 of the Commission's Rules. All written statements, except for confidential business information will be made available for inspection by interested persons in the Office of the Secretary to the Commission. Section 201.8 of the rules require that a signed original (or a copy designated as an original) and fourteen (14) copies of each document be filed. In the event that the confidential treatment of the document is requested, at least four (4) additional copies must be filed, in which the confidential information must be deleted. Section 201.6 of the rules require that the cover of the document and the individual pages clearly be marked as to whether they are the ''confidential'' or ''nonconfidential'' version, and that the confidential business information be clearly identified by means of brackets. To be assured of consideration, written statements relating to the Commission's report should be submitted at the earliest possible date and should be received not later than July 26, 2004. All submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street, SW., Washington DC 20436.

Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

Issued: June 10, 2004.

By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 04–13549 Filed 6–15–04; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

ALRA Laboratories, Inc. Order Denying Procurement Quota

On July 26, 2002, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to ALRA Laboratories, Inc. (ALRA) of Gurnee, Illinois, notifying ALRA of an opportunity to show cause as to why DEA should not revoke ALRA's DEA Certificate of Registration, RA0205193, under 21 U.S.C. 823(a) and (d) and 824(a)(4) and deny any pending applications for renewal or modification of ALRA's manufacturing registration. As a basis for revocation, the Order to Show Cause alleged that ALRA's continued registration was inconsistent with the public interest, citing a long history of regulatory violations dating from 1987 and the 1996 criminal conviction of ALRA's President and Chief Executive Officer, Baldev Ray Bhutani, of seven felony counts of violating the Federal Food, Drug and Cosmetic Act by introducing adulterated pharmaceuticals into commerce. The Order to Show Cause further notified ALRA that should no request for a hearing be filed within 30 days, its hearing right would be deemed waived.

The Order to Show Cause was sent by certified mail to ALRA's registered location at 3850 Clearview Court, Gurnee, Illinois 60031. According to its return receipt, the Order to Show Cause was received at the registered address by Sandra Montana on or around August 5, 2002.

Additionally, on September 27, 2002, pursuant to 21 U.S.C. 826(c) and (d), the Deputy Assistant Administrator, Office of Diversion Control, issued an Order to Deny Procurement Quota on the ground that ALRA's anticipated requirements for the then-current and following years did not justify its request. The Order to Deny Procurement Quota noted that on May 23, 2002, ALRA had submitted a procurement request for, *inter alia*, cocaine, oxycodone and methadone. The denial order recited ALRA's history of regulatory violations set forth in the Order to Show Cause, the June 30, 2002, expiration of its DEA manufacturing registration, Mr. Bhutani's 1996 conviction and following exhaustion of appeals, commencement of his 30 month prison sentence in September 2002. The Order to Deny Procurement Quota further notified ALRA that should no request for a hearing be filed within 30 days, its hearing right would be deemed waived.

The Order to Deny Procurement Quota was sent by certified mail on September 27, 2002, to ALRA's registered address in Illinois and according to its return receipt, was receipted for by Neelam Bhutani on or around October 31, 2002.

DEA has not received a request for hearing or any other reply from ALRA or anyone purporting to represent it in this matter on either the Order to Show Cause or the Order to Deny Procurement Quota. Therefore, the Deputy Administrator, finding that (1) 30 days have passed since the receipt of the Order to Show Cause and Order Denying Procurement Quota, and (2) no request for a hearing having been received, concludes that ALRA is deemed to have waived its hearing right as to both Orders. See *Samuel S. Jackson, D.D.S.*, 67 FR 65145 (2002); *David W. Linder*, 67 FR 12579 (2002). After considering material from the investigative file, the Deputy Administrator now enters her final order without a hearing pursuant to 21 CFR 1303.34(e) and 1303.37.

The Deputy Administrator's review of the investigative file reveals that ALRA has been registered as a manufacturer with DEA since 1995 to handle controlled substances in Schedules II, III, III–N, IV and V under DEA registration number RA0205193. That registration was last renewed on May

31, 2001 and expired on June 30, 2002. There is no evidence in the record that a renewal application has been filed by ALRA for that certificate.

DEA has previously held that ''[i]f a registrant has not submitted a timely renewal application prior to the expiration date, then the registration number expires and there is nothing to revoke.'' Marlou D. Davis, M.D., 69 FR 1307 (2004); Ronald J. Riegel, D.V.M., 63 FR 67132 (1998). Accordingly, while the record contains ample grounds for revocation of ALRA's registration under 21 U.S.C. 824(a)(4) and 823(a) and (d), in light of the expiration of ALRA's manufacturer registration prior to the issuance of the July 26, 2002, Order to Show Cause, revocation proceeding are moot and no further action is required in that regard.

With regard to the procurement quota, the Deputy Administrator finds that ALRA was incorporated as an over-the-counter pharmaceutical manufacturer in 1982. In 1984, ALRA obtained registration as a manufacturer under DEA Certificate of Registration, A0216209. That registration became delinquent and was retired on January 31, 1990. on June 1, 1992, ALRA obtained DEA Certificate of Registration, RA0174273, as a researcher and that registration was retired on January 31, 1996.

ALRA has a long history of regulatory violations. During on-site inspections of its registered location conducted in 1987, 1991 and 1997, DEA investigators noted repeated violations of Controlled Substances Act recordkeeping, reporting and security requirements, including ALRA's failure to maintain adequate records, inadequate security and failure to file appropriate acquisition/distribution reports (ARCOS reports).

On June 20, 1991, DEA issued an Order to Show Cause seeking to deny ALRA's Application for Registration, alleging it had engaged in the unlawful distribution of a controlled substance and unlawful distribution of a controlled substance by use of an expired DEA registration (Certificate of Registration, PA0216209), in violation of 21 U.S.C. 841(a)(1) and 843(a)(2). After an administrative process lasting over four years, on October 4, 1994, the then-Deputy Administrator issued a final decision denying ALRA's application. On May 17, 1995, the U.S. Court of Appeals for the Seventh Circuit issued its decision upholding the final agency action denying registration. *See* 59 FR 50620 (October 4, 1994) and *ALRA* v. *DEA,* 54 F.3d 450 (7th Cir. 1995).

On May 11, 1995, DEA and ALRA entered into a Memorandum of Agreement (MOA) and DEA approved ALRA's Application for Registration as a manufacturer on May 12, 1995, issuing Certificate of Registration RA0205193. Under the terms of the MOA, ALRA promised to surrender that registration within 180 days if ALRA or any of its officers were convicted of an offense in the then-pending matter of *United States* v. *Bhutani and ALRA Labs* (United States District court, Northern District of Illinois, Eastern division, Case No. 93 CR 585).

In February 1996, a jury found the defendants, including Baldev Raj Bhutani, ALRA's president and chief executive officer, his wife, Neelam Bhutani and ALRA, guilty of seven felony counts of violating the Federal Food, Drug and Cosmetic Act. Mr. Bhutani was sentenced to a term of 30 months imprisonment, which was stayed, pending appeal, remained free on bail and continued to serve as the principal officer and CEO of ALRA.

During an on-site inspection of ALRA's registered location conducted in September 1997, DEA investigators found, inter alia, that ALRA had failed to complete a biennial inventory, file ARCOS reports or maintain adequate security for controlled substances. In December 1997 and January 1998, ALRA requested the addition of eight Schedule II controlled substances to its DEA registration and on March 18, 1998, applied for renewal of it DEA manufacturer registration.

In April 1998, ALRA was issued a Letter of Admonition by DEA concerning the violations discovered during the September 1997 inspection. ALRA responded that it would comply with applicable DEA regulations and upgrade its security systems prior to acquisition of any Schedule II controlled substances. On December 28, 1998, after several inspections, the DEA Chicago Field Division verified that ALRA's security mechanisms complied with regulations and closed the case.

On February 9, 1999, because ALRA had failed to conform to current good manufacturing practices (CGMP), the U.S. Food and Drug Administration (FDA) seized all of ALRA's manufacturing lots of potassium chloride extended tablets, erythromycin ethylsuccinate and sulfi soxazole acetyl for oral suspension. In a consent decree filed in U.S. District Court, Northern District of Illinois, *U.S.* v. *ALRA* (Case No. 99 CV 0697), the FDA and ALRA entered into a consent agreement whereby ALRA agreed that the above products had been adulterated with ground metal and contaminated raw materials during the manufacturing process. In the consent decree, ALRA promised it would not begin manufacturing such products until it hired a consultant to assure that its manufacturing process met Federal requirements. ALRA has not yet hired such a consultant.

On May 31, 2001, ALRA's manufacturer registration was renewed and in July 2001, DEA investigators conducted a scheduled, on-site inspection of ALRA's registered location. ALRA had not manufactured any controlled substances for over two years and during that inspection investigators noted ALRA's failure to maintain a complete biennial inventory in December 2000, failure to file quarterly ARCOS reports in a timely manner for almost three years, failure to maintain readily retrievable records and failure to maintain adequate security for controlled substances.

Pursuant to terms of the 1995 MOA where the parties agreed that Mr. Bhutani was to surrender ALRA's certificate if he was convicted of any of the crimes alleged in his then pending criminal case, DEA requested the surrender of ALRA's manufacturer registration on December 31, 2001. However, on January 3, 2002, Mr. Bhutani responded that the MOA had been valid for only three years and asked for another chance. To date he has not surrendered ALRA's certificate of registration.

On May 23, 2002, ALRA submitted the subject Procurement Quota Requests for Year 2002, for the following quantities of Schedule II substances:

a. Cocaine: 128,160 grams
b. Codeine: 61,272 grams
c. Hydrocodone: 15,466 grams
d. Oxycodone: 35,214 grams
e. Morphine: 219,435 grams
f. Hydromorphone: 8,945 grams
g. Oxymorphone: 19,046 grams
h. Meperidine: 36,620 grams
i. Methadone: 82,414 grams
j. Dextropropoxphene: 524,489 grams
k. Thebaine: 83,750 grams
l. Opium granulated: 105,000 grams

However, by June 17, 2002, Mr. Bhutani's criminal judgment had been affirmed on appeal and all challenges to the conviction exhausted. *United States* v. *Bhutani and ALRA Labs,* 266 F.3d 661 (7th Cir. 2001), cert. denied, *Bhutani* v. *U.S.,* 563 U.S. 922 (June 17, 2002). On August 26, 2002, after his bail was revoked, Mr. Bhutani reported to the Federal Correctional Institute in Duluth, Minnesota to commence serving his 30 month sentence.

The FDA has not permitted ALRA to engage in manufacturing operations since 1999 and ALRA has not handled controlled substances for the last three years. It currently has ceased all

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