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William Brighton,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

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DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Between the United States, the State of Michigan, and the Wisconsin Electric Power Company Under the Clean Air Act

Under 28 CFR 50.7, notice is hereby given that on July 10, 2003, a proposed Amended Consent Decree ("Amended Consent Decree") between the United States, Michael A. Cox, Attorney General of the State of Michigan, *ex rel.* Michigan Department of Environmental Quality ("State of Michigan"), and the Wisconsin Electric Power Company ("Wisconsin Electric"), Civil Action No. 03-C-0371, was lodged with the United States District Court for the Eastern District of Wisconsin.

This Amended Consent Decree modifies the Consent Decree that was lodged in the Eastern District of Wisconsin on April 29, 2003, notice of which was provided at 68 FR 26354 (May 15, 2003). Like the original proposed Consent Decree, this proposed Amended Consent Decree would resolve claims asserted by the United States against Wisconsin Electric pursuant to Sections 113(b) and 167 of the Clean Air Act (the "Act"), 42 U.S.C. 7413(b) and 7477, and seeks injunctive relief and the assessment of civil penalties for Wisconsin Electric's violations of:

(a) The Prevention of Significant Deterioration provisions in Part C of Subchapter I of the Act, 42 U.S.C. 7470-92;

(b) The nonattainment New Source Review provisions in Part D of Subchapter I of the Act, 42 U.S.C. 7501-7515;

(c) The federally-enforceable State Implementation Plan developed by the

State of Michigan (the "Michigan SIP"); and

(d) The federally-enforceable State Implementation Plan developed by the State of Wisconsin (the "Wisconsin SIP").

In addition, this Amended Consent Decree would resolve claims asserted by the State of Michigan against Wisconsin Electric pursuant to Section 167 of the Act, 42 U.S.C. 7477, and Section 5530 of Part 55 of Michigan's Natural Resources and Environmental Protection Act ("Part 55 of NREPA"), MCL § 324.5530, for injunctive relief and the assessment of civil fines for alleged violations of:

(a) The Prevention of Significant Deterioration provisions in Part C of Subchapter I of the Act, 42 U.S.C. 7470-92; and

(b) Section 5505 of Part 55 of NREPA, MCL § 324.5505.

The proposed Amended Consent Decree incorporates two types of changes from the original Consent Decree. First, various changes have been made to reflect the addition of the State of Michigan as a Plaintiff-Intervenor. Among these are changes to the Penalty and Fines Section (Section X), in which Wisconsin Electric would be required to pay a fine of \$100,000 to the State of Michigan and a civil penalty of \$3.1 million to the United States, and changes to the Resolution of Claims Section (Section XI), in which a Resolution of Claims parallel to that provided by the United States is provided for claims that may be brought by the State of Michigan. Second, clarifying changes have been made to six paragraphs in which Wisconsin Electric's emissions would be limited to levels that are measured as either a 30-day or 12-month rolling average. (See paragraphs 58, 62, 63, 73, 76, and 77.) Each of these clarifying changes is intended to eliminate any ambiguity as to when the compliance requirement actually commences, given that, in each provision, the emission limit is measured by reference to a historical period (*i.e.*, the last 30 days or 12 months).

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044-7611, and should refer to *United States v. Wisconsin Electric*, D.J. Ref. No. 90-5-2-1-07493.

The Consent Decree may be examined at the Office of the United States

Attorney, Eastern District of Wisconsin, Federal Courthouse, 517 East Wisconsin Ave., Milwaukee, Wisconsin 53202, and at U.S. EPA Region V, 77 West Jackson Blvd., Chicago, IL 60604-3507. During the public comment period, the Consent Decree, may also be examined on the following Department of Justice Web site, <http://www.usdoj.gov/enrd/open.html>. A copy of the Consent Decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044-7611 or by faxing or e-mailing a request to Tonia Fleetwood (tonia.fleetwood@usdoj.gov), fax no. (202) 514-0097, phone confirmation number (202) 514-1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of \$19.25 (25 cents per page reproduction cost) payable to the U.S. Treasury.

W. Benjamin Fisherow,

Deputy Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Callahan's Foods; Denial of Application

On October 28, 2001, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Callahan's Foods (Callahan's) proposing to deny its application, executed on May 13, 1997, for DEA Certificate of Registration as a distributor of list I chemicals. The Order to Show Cause alleged that granting the application of Callahan's would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(h) and 824(a)(4). The Order to Show Cause also notified Callahan's that should no request for a hearing be filed within 30 days, its hearing right would be deemed waived.

According to the DEA investigative file, the Order to Show Cause was sent by certified mail to Callahan's at its proposed registered location in Pulaski, Virginia and was received on November 2, 2001. DEA has not received a request for hearing or any other reply from Callahan's or anyone purporting to represent the company in this matter.

Therefore, the Acting Administrator of DEA, finding that (1) thirty days having passed since the delivery of the Order to Show Cause at the applicant's

proposed registered address, and (2) no request for hearing having been received, concludes that Callahan's has waived its hearing right. See *Aqui Enterprises*, 67 FR 12576 (2002). After considering relevant material from the investigative file in this matter, the Acting Administrator now enters his final order without a hearing pursuant to 21 CFR 1309.53(c) and (d) and 1316.67 (2003). The Acting Administrator finds as follows:

List I chemicals are those that may be used in the manufacture of a controlled substance in violation of the Controlled Substances Act. 21 U.S.C. 802(34); 21 CFR 1310.02(a). Pseudoephedrine and ephedrine are list I chemicals commonly used to illegally manufacture methamphetamine, a Schedule II controlled substance.

Methamphetamine is an extremely potent central nervous system stimulant, and its abuse is a growing problem in the United States.

The Acting Administrator's review of the investigative file reveals that on May 21, 1997, DEA's Chemical Operations Registration section received an application dated May 13, 1997, on behalf of Callahan's. The application was submitted by the company's owner, Tony L. Callahan. The applicant sought DEA registration as a distributor of the list I chemicals, ephedrine, pseudoephedrine, and phenylpropanolamine. Because Callahan's submitted its application for registration on or before July 12, 1997, the firm qualified for temporary exemption from the requirement of registration, pursuant to 21 CFR 1309.10.

For reasons unknown, Callahan's registration application was not received by the DEA Richmond (Virginia) District Office for follow-up investigation until April 4, 1999. Nevertheless, on six separate occasions between April 27, 1999 and June 10, 1999, a DEA Diversion Investigator attempted to reach Tony Callahan by telephone to discuss information necessary for completion of the application process. There is no information in the investigative file demonstrating that DEA personnel were successful in reaching Tony Callahan during that time period. However, on December 3, 1999, and again on May 15, 2000, a DEA Diversion Investigator contacted Tony Callahan, and requested the following information:

- a. A list of the company's officers;
- b. A brief description of the company's main business;
- c. Percentage of the company's business pertaining to list I chemicals;
- d. A list of list I chemical suppliers;

- e. A list of list I chemical customers;
- f. Copies of relevant licenses; and
- g. Description of the company's security as well as a copy of any security contracts.

Callahan's failed to provide the requested information. In response, a DEA Diversion Investigator traveled to Callahan's on January 4, and March 2, 2000, again requesting information necessary to process the company's registration application. On both occasions, the investigator met with Robert Callahan (son of Tony Callahan) and his wife Lisa. Robert and Lisa Callahan were part of the management structure and provided assistance to Tony Callahan in the operation of Callahan's. Despite DEA's repeated requests, the requested information was not provided.

On February 2, 2001, the DEA Richmond office directed a letter to Tony Callahan. The letter recited DEA's repeated attempts to obtain information from Callahan's and again requested information needed to process its pending DEA application. The letter further informed Tony Callahan that pursuant to 21 CFR 1309.35, DEA "may require an applicant to submit documents of written statements of fact" relevant to process a pending application. The letter further stated that "[t]he failure of the applicant to provide such documents or statements within a reasonable time after [such request] shall be deemed a waiver by the applicant of an opportunity to present * * * documents or facts for consideration by DEA in granting the application." The letter concluded that should the company fail to respond to DEA correspondence, such failure would be deemed a withdrawal of Callahan's pending application, pursuant to 21 CFR 1309.36(b). Callahan's was given thirty days to respond to DEA's letter. A similar letter was subsequently sent to Callahan's on April 16, 2001.

On or about March 5, 2001, Tony Callahan telephoned the DEA Richmond office and stated that he had sent the requested documents to DEA. However, DEA records did not show receipt of the requested information. Tony Callahan assured DEA personnel that he would send the documents.

On April 20, 2001, Tony Callahan called the Diversion Group Supervisor of the DEA Richmond Office stating that he wished to continue the registration process and to that end, again informed DEA personnel that he would submit all necessary documents. However, when DEA personnel finally received documents from Tony Callahan on May 3, 2001, the information contained

therein was found to be incomplete with respect to names, addresses, phone numbers, and DEA registration numbers of both suppliers and customers of Callahan's Foods. During the following two months, DEA's repeated attempts to obtain further information from Callahan's, and/or arrange times for on-site inspections of the business were unsuccessful.

Pursuant to 21 U.S.C. 823(h), the Acting Administrator may deny an application for Certificate of Registration if he determines that granting the registration would be inconsistent with the public interest as determined under that section. Section 823(h) requires the following factors be considered in determining the public interest:

- (1) Maintenance of effective controls against diversion of listed chemicals into other than legitimate channels;
- (2) Compliance with applicable Federal, State, and local law;
- (3) Any prior conviction record under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;
- (4) Any past experience in the manufacture and distribution of chemicals; and
- (5) Such other factors as are relevant to and consistent with the public health and safety.

As with the public interest analysis for practitioners and pharmacies pursuant to subsection (f) of section 823, these factors are to be considered in the disjunctive; the Acting Administrator may rely on any one or combination of factors, and may give each factor the weight he deems appropriate in determining whether a registration should be revoked or an application for registration denied. See, e.g. *Energy Outlet*, 64 FR 14269 (1999). See also *Harry J. Schwartz, Jr., M.D.*, 54 FR 16422 (1989).

The Acting Administrator finds factors one, four, and five relevant to Callahan's Foods' pending application.

With respect to factor one, maintenance of effective controls against the diversion of listed chemicals, the Acting Administrator's review of the investigative file reveals that Callahan's Foods failed to provide to DEA information regarding security or any security contracts that the company had entered into. Therefore, the record before the Acting Administrator contains no information as to any security measures employed by Callahan's designed to prevent the diversion of listed chemicals.

Regarding factor four, the applicant's past experience in the distribution of chemicals, DEA's investigation revealed

that Callahan's failed to provide information with respect to its list I chemical suppliers and customers. Similarly, with respect to factor five, other factors relevant to and consistent with the public safety, Callahan's failure to provide information necessary to the processing of its application for DEA registration supports the denial of its pending application. In addition, DEA investigators were unable to perform an on-site inspection of Callahan's to determine whether or not the company could adequately handle listed chemicals and the company provided incomplete information necessary to the processing of its DEA application. See, CHM Wholesale Co., 67 FR 9985 (2002).

In light of the above, and the absence of evidence to the contrary, the Acting Administrator is left with the conclusion that Callahan's cannot be entrusted with the responsibilities of a DEA registration. As a result, the Acting Administrator further concludes that it would be inconsistent with the public interest to grant the application of Callahan's Foods.

Accordingly, the Acting Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 28 CFR 0.100(b) and 0.104, hereby orders that the pending application for DEA Certificate of Registration, previously submitted by Callahan's Foods be, and it hereby is denied. This order is effective August 25, 2003.

Dated: July 3, 2003.

William B. Simpkins,
Acting Administrator.

[FR Doc. 03-18868 Filed 7-23-03; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

G & O Pharmacy of Paducah, Incorporated; Denial of Application

On April 19, 2002, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to G & O Pharmacy¹ (G & O) notifying the applicant of an opportunity to show cause as to why DEA should not deny its pending application for DEA Certificate of Registration as a retail-pharmacy practitioner pursuant to 21 U.S.C. 823(f). As a basis for the denial, the Order to Show Cause alleged that G &

O's registration would be inconsistent with the public interest. The Order to Show Cause also notified G & O 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 G & O at its proposed registered location in Paducah, Kentucky, and was received on April 26, 2002. DEA has not received a request for hearing or any other reply from G & O or anyone purporting to represent the pharmacy in this matter.

Therefore, the Acting Administrator of DEA, finding that (1) thirty days having passed since the attempted delivery of the Order to Show Cause at the applicant's last known address, and (2) no request for hearing having been received, concludes that G & O is deemed to have waived its hearing right. See David W. Linder, 67 FR 12579 (2002). After considering material from the investigative file in this matter, the Acting Administrator now enters his final order without a hearing pursuant to 21 CFR 1301.43(d) and (e) and 1301.46.

The Acting Administrator finds that G & O previously possessed DEA Certificate of Registration AG2999691. On July 23, 1992, an Order to Show Cause was issued proposing to revoke that Certificate of Registration. The Order to Show Cause alleged in substance that (1) in July 1990, an individual had overdosed on Demerol received from the owner-manager pharmacist of G & O Pharmacy, Randall Lockhart, without the benefit of a prescription; (2) accountability audits conducted of G & O Pharmacy by DEA investigators in 1990 revealed shortages of Schedules II and III controlled substances; (3) G & O Pharmacy had filled at least 217 call-in prescriptions not authorized by the physicians whose names appeared on the pharmacy's records; and (4) at least one individual, on multiple occasions, had received controlled substances from Mr. Lockhart without seeing the physician listed on the call-in prescription.

Following prehearing procedures, a hearing was held in Louisville, Kentucky, on March 10 and 11, 1993. After the hearing, both parties submitted proposed findings of fact, conclusions of law and argument. Subsequently, on December 16, 1993, counsel for the Government filed a motion to reopen the proceedings, alleging that Mr. Lockhart transferred ownership of G & O to AML Corporation (AML). The motion also alleged that AML had applied for and received DEA Certificate of Registration BA3838553 to operate G & O and that DEA had not been notified

pursuant to 21 CFR 1301.62 and 1307.14(b) (both sections presently designated as section 1301.52). The motion further alleged that G & O Pharmacy had ceased doing business under its previous ownership or that Mr. Lockhart had transferred ownership to another entity. When G & O failed to respond to the Government's motion, Administrative Law Judge Mary Ellen Bittner (Judge Bittner) issued an order reopening the proceedings in Docket No. 92-78.

On March 11, 1994, an Order to Show Cause was issued to AML d/b/a G & O Pharmacy (containing the same allegations as those raised in the July 23, 1992, Order to Show Cause) alleging that its continued registration was inconsistent with the public interest. The Order to Show Cause further alleged that Mr. Lockhart had improperly transferred ownership of G & O without notifying DEA as required. Following the consolidation of the two cases, a hearing was conducted on November 17, 1994.

After finding that the continuance of a registration would be inconsistent with the public interest, the then-Deputy Administrator of DEA revoked DEA Certificate of Registration BA3838553 previously issued to AML Corporation d/b/a G & O Pharmacy. See, AML Corporation d/b/a G & O Pharmacy, and G & O Pharmacy, 61 FR 8973 (March 6, 1996). The Acting Administrator finds that the findings of fact and conclusions of law, which led to the revocation of AML/G & O's DEA Certificate of Registration, are set forth in great detail in the referenced final order. They will not be repeated in this final order, but are incorporated herein and will be referred to as necessary in rendering a decision in this matter.

G & O has a documented history of non-compliance with DEA laws and regulations. From 1989 to 1991 while registered under DEA registration number AG2999691, the pharmacy dispensed 24 vials of Demerol, a Schedule II controlled substance, to a dentist without a valid prescription. It was later determined that these drugs were dispensed for the dentist's personal use. Accountability audits conducted by DEA investigators of G & O's controlled substances revealed significant shortages of various Schedules II, III, and IV controlled substances and the pharmacy filled numerous prescriptions for controlled substances that were not authorized by physicians whose names appeared on the prescriptions. In addition, Mr. Lockhart improperly transferred ownership of G & O to AML without

¹ On the July 18, 2001 application for DEA registration, Mr. Lockhart listed the business address of the pharmacy as "G & O Pharmacy of Paducah Inc."