



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 5

77 WEST JACKSON BOULEVARD

CHICAGO, IL 60604-3590

NOV 05 2010

REPLY TO THE ATTENTION OF:

(AE-17J)

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Margaret R. Giltinan
Chairman and CEO
Gebauer Company
4444 East 153rd Street
Cleveland, Ohio 44128

Dear Ms. Giltinan:

Enclosed is a file stamped Consent Agreement and Final Order (CAFO) which resolves case docket number CAA-05-2011-0005 with Gebauer Company (Gebauer). As indicated by the filing stamp on its first page, we filed the CAFO with the Regional Hearing Clerk on NOV 05 2010.

Pursuant to paragraph 52 of the CAFO, Gebauer must pay the civil penalty within 60 days of the date the CAFO is filed. Your check must display the case docket number, CAA-05-2011-0005, and the billing document number, 2751103A005.

Please direct any questions regarding this case to Karen Peaceman, Associate Regional Counsel at (312) 353-5751.

Sincerely,

A handwritten signature in black ink that reads "William L. MacDowell".

William MacDowell

Chief

Air Enforcement and Compliance Assurance Section (MN/OH)

Enclosure

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

In the Matter of:)

Gebauer Company)
Cleveland, Ohio.)

Respondent.)
_____)

Docket No. CAA-05-2011-0005
Proceeding to Assess a Civil Penalty
Under Section 113(d) of the Clean Air
Act, 42 U.S.C. § 7413(d)

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NOV 05 2010

Consent Agreement and Final Order

Preliminary Statement

REGIONAL HEARING CLERK
U.S. ENVIRONMENTAL
PROTECTION AGENCY

1. This is an administrative action commenced and concluded under Section 113(d) of the Clean Air Act (CAA or the Act), 42 U.S.C. § 7413(d), and Sections 22.1(a)(2), 22.13(b), and 22.18(b)(2) and (3) of the *Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits* (Consolidated Rules), as codified at 40 C.F.R. Part 22.

2. Complainant is the Director of the Air and Radiation Division, U. S. Environmental Protection Agency, Region 5.

3. Respondent is Gebauer Company, a business incorporated in and doing business in the State of Ohio.

4. Where the parties agree to settle one or more causes of action before the filing of a complaint, the administrative action may be commenced and concluded simultaneously by the issuance of a consent agreement and final order (CAFO). 40 C.F.R. § 22.13(b).

5. The parties agree that settling this action without the filing of a complaint or the adjudication of any issue of fact or law is in their interest and in the public interest.

6. Respondent consents to entry of this CAFO and the assessment of the specified civil

penalty, and agrees to comply with the terms of the CAFO.

Jurisdiction and Waiver of Right to Hearing

7. Respondent admits the jurisdictional allegations in this CAFO and neither admits nor denies the factual allegations and denies the violations alleged in the CAFO.

8. Respondent waives its right to request a hearing as provided at 40 C.F.R. § 22.15(c), any right to contest the allegations in this CAFO, and its right to appeal this CAFO.

Statutory and Regulatory Background

Ohio State Implementation Plan

9. On January 15, 1993, EPA promulgated regulations at 40 C.F.R. Part 82 to implement the mandate of Section 610 of the Clean Air Act (CAA). The regulations were amended on November 15, 2001 and became effective on January 14, 2002.

10. Section 610 of the CAA identify nonessential products that release, inter alia, chlorofluorocarbons into the environment, and that prohibit any person from selling, distributing or offering to sell or distribute such products in interstate commerce.

11. The regulations at 40 C.F.R. Part 82, Subpart C, implement the ban on distributing, or offering to sell or distribute, in interstate commerce, nonessential products containing Class I substances and nonessential products containing or manufactured with Class II substances.

12. The term “essential-uses” is defined as those uses of controlled substances designated by the Parties to the Montreal Protocol to be necessary for the health and safety of, or critical for the functioning of, society; and for which there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health. 40 C.F.R. § 82.3.

13. The term “Class I substances” refers to the controlled substances listed in Appendix

A to 40 C.F.R. Part 82, Subpart A.

14. The term “person” means any individual or legal entity, including an individual, corporation, partnership, association, state, municipality, political subdivision of a state, Indian tribe; any agency, department, or instrumentality of the United States; and any officer, agent or employee thereof. 40 C.F.R. § 82.3.

15. The term “product” means an item or category of items manufactured from raw or recycled materials which is used to perform a function or task. 40 C.F.R. § 82.62.

16. The regulations at 40 C.F.R. § 82.64 prohibit, among other things, any person from selling, distributing or offering to sell or distribute, in interstate commerce, any product identified as nonessential in 40 C.F.R. § 82.66.

17. The regulation at 40 C.F.R. § 82.64(c) provides that, effective January 17, 1994, no person may sell, distribute, or offer to sell or distribute, in interstate commerce, any product identified as being nonessential in 40 C.F.R. § 82.66(c) or 40 C.F.R. § 82.66(d), except as permitted under 40 C.F.R. § 82.65(g).

18. The regulation at 40 C.F.R. § 82.66(d) identifies as nonessential, and subject to the prohibition of 40 C.F.R. § 82.64(c), the following products which release a Class I substance (as defined in 40 C.F.R. Part 82, Subpart A, Appendix A): any aerosol product or other pressurized dispenser which contains a chlorofluorocarbon.

19. The term “chlorofluorocarbon” (CFC) is defined at 40 C.F.R. § 82.62 as any substance listed as Class I, group I, or Class I, group III, in 40 C.F.R. Part 82, Subpart A, Appendix A.

20. Dichlorodifluoromethane (a.k.a. “CFC-12”) is listed as a Class I, group I, substance in 40 C.F.R. Part 82, Subpart A, Appendix A, and is therefore a “chlorofluorocarbon.”

21. Dichlorotetrafluoroethane (a.k.a. “CFC-114”) is listed as a Class I group I substance in 40 C.F.R. Part 82, Subpart A, Appendix A, and is therefore a “chlorofluorocarbon.”

22. Trichlorofluoromethane (a.k.a. “CFC-II”) is listed as a Class I group I substance in 40 C.F.R. Part 82, Subpart A, Appendix A, and is therefore a “chlorofluorocarbon.”

23. On January 15, 1993, EPA announced that certain products, including “topical anesthetic and vapocoolant products,” were exempt from the prohibitions of 40 C.F.R. § 82.64. *See* 58 Fed. Reg. 4768 (January 15, 1993).

24. On June 14, 1999, EPA proposed an amendment to the regulations at 40 C.F.R. Part 82, Subpart C, which would eliminate the exemption for “topical anesthetic and vapocoolant products.” *See* 64 Fed. Reg. 31772, at 31778 (June 14, 1999).

25. On November 15, 2001, EPA issued a final rule amending the regulations at 40 C.F.R. Part 82, Subpart C, to eliminate the exemption for “topical anesthetics and vapocoolant products.” The amended regulations became effective on January 14, 2002. *See* 66 Fed. Reg. 57512, at 57515 (November 15, 2001).

26. The Administrator of EPA (the Administrator) may assess a civil penalty of up to \$27,500 per day of violation up to a total of \$220,000 for violations that occurred from January 31, 1997, through March 15, 2004, and may assess a civil penalty of up to \$32,500 per day of violation up to a total of \$270,000 for violations that occurred after March 15, 2004, under Section 113(d)(1) of the Act, 42 U.S.C. § 7413(d)(1), and 40 C.F.R. Part 19.

27. Section 113(d)(1) limits the Administrator’s authority to matters where the first alleged date of violation occurred no more than 12 months prior to initiation of the administrative action, except where the Administrator and the Attorney General of the United States jointly determine that a matter involving a longer period of violation is appropriate for an

administrative penalty action.

28. The Administrator and the Attorney General of the United States, each through their respective delegates, have determined jointly that an administrative penalty action is appropriate for the period of violations alleged in this CAFO.

Factual Allegations and Alleged Violations

29. Gebauer Company owns and operates a facility (the facility) located at 4444 East 153rd Street, in Cleveland, Ohio.

30. Gebauer formerly owned and/or operated a manufacturing facility located at 9410 St. Catherine Avenue, in Cleveland, Ohio.

31. Gebauer manufactures and markets topical skin refrigerants used for controlling pain associated with injections, venipuncture, starting IVs, minor surgical procedures, muscle spasms, sprains and strains.

32. During the most recent five years, Gebauer has manufactured aerosol and/or pressurized dispenser products at its facility at 4444 East 153rd Street.

33. During the most recent five years, Gebauer has sold or distributed, or offered to sell or distribute, in interstate commerce, certain aerosols or pressurized dispensers that contained CFCs.

34. The Ohio Environmental Protection Agency (OEPA) issued a Permit to Install to Gebauer for its Cleveland facility on June 29, 2004 for Emission Units P001 Bowl Filler and Emission Unit P002 British Filler.

35. On November 7, 2008, Inspectors of the Air and Radiation Division of U.S. EPA, Region 5, inspected Gebauer's facility at 4444 East 153rd Street in Cleveland, Ohio, and found

evidence suggesting that Gebauer had manufactured at least two products that contained chlorofluorocarbons (CFCs).

36. On January 13, 2009, EPA issued a CAA Section 114 Information Request to Gebauer.

37. Gebauer submitted its response to the EPA's CAA Section 114 Information Request on January 26, 2009, and submitted an amended response on February 2, 2009.

38. According to Gebauer's responses to the EPA's CAA Section 114 Information Request, Gebauer formerly manufactured and sold a product called Gebauer's Fluori-Methane Topical Anesthetic Skin Refrigerant ("Gebauer's Fluori-Methane"), contained in a pressurized dispenser.

39. According to a Material Safety Data Sheet for Fluori-Methane that Gebauer produced in response to EPA's CAA Section 114 Information Request, Gebauer's Fluori-Methane contained 15% w/w dichlorodifluoromethane, a Class I, group I, controlled substance.

40. According to a Material Safety Data Sheet for Fluori-Methane that Gebauer produced in response to EPA's CAA Section 114 Information Request, Gebauer's Fluori-Methane contained 85% w/w trichlorofluoromethane, a Class I, group I, controlled substance.

41. According to Gebauer's response to EPA's CAA Section 114 Information Request, Gebauer sold or distributed Gebauer's Fluori-Methane in interstate commerce, or offered Gebauer's Fluori-Methane for sale or distribution in interstate commerce, beginning on February 3, 1960.

42. According to Gebauer's response to EPA's CAA Section 114 Information Request, Gebauer ceased production of Gebauer's Fluori-Methane on January 21, 2004, but continued to sell this product until March 2005.

43. According to Gebauer's response to EPA's CAA Section 114 Information Request, Gebauer formerly manufactured and sold a product called Gebauer's Fluro-Ethyl Topical Anesthetic Skin Refrigerant ("Gebauer's Fluro-Ethyl"), an aerosol product.

44. According to a Material Safety Data Sheet for Gebauer's Fluro-Ethyl that Gebauer produced in response to EPA's CAA Section 114 Information Request, Gebauer's Fluro-Ethyl contained 83 wt % and 75 vol % dichlorotetrafluoroethane, a Class I, group I, controlled substance.

45. According to Gebauer's response to EPA's CAA Section 114 Information Request, Gebauer sold or distributed Gebauer's Fluro-Ethyl in interstate commerce, or offered Gebauer's Fluro-Ethyl for sale or distribution in interstate commerce, beginning in 1955, and continued to sell this product until September 8, 2008.

46. According to Gebauer's response to EPA's CAA Section 114 Information Request, Gebauer ceased production of Gebauer's Fluro-Ethyl on February 1, 2008.

47. On September 8, 2008, Respondent initiated a voluntary recall of Fluro-Ethyl with the U.S. Food and Drug Administration and notified its distributors of the recall and advised them to return all affected units to Respondent for credit.

48. As of March 30, 2009, the product Gebauer's Fluro-Ethyl was available for online purchase at the websites of the following distributors:

- a. www.medicalequipment-4sale.com
- b. www.HealDirect.com
- c. www.MedicatedDistrUbution.com
- d. www.EGeneralMedical.com
- e. MedMedics.com
- f. Medworldstore.com

49. As of March 31, 2009, the product Gebauer's Fluro-Ethyl was available for online purchase at the websites of the following distributors:

- a. www.Healthhaven.com
14000 N 94th Street
Suite 1012
Scottsdale, AZ 85260
- b. www.gnrcatalog.com
2140 NE 36th Avenue
Bldg. #300
Ocala, FL 34470-3173

50. On May 8, 2009, EPA issued to Respondent a Findings of Violation (FOV) alleging that Gebauer failed to comply with the ban on nonessential products containing a Class I controlled substance, 40 C.F.R. § 82.64.

Civil Penalty and Other Relief

51. Based on analysis of the factors specified in Section 113(e) of the Act, 42 U.S.C. § 7413(e), the facts of this case, and Gebauer's cooperation in resolving this matter, Complainant has determined that an appropriate civil penalty to settle this action is \$75,804.47.

52. Within 60 days after the effective date of this CAFO, Respondent must pay a \$75,804.47 civil penalty by one of the following options:

- a. Sending via U.S. Postal Service mail a cashier's or certified check payable to the "Treasurer, United States of America," to:

U.S. EPA
Fines and Penalties
Cincinnati Finance Center
P.O. Box 979077
St. Louis, MO 63197-9000

The check must note the case name, docket number of this CAFO, and the billing document number.

b. Sending via a carrier that will not deliver to P.O. Boxes (*e.g.* express carrier) a cashier's or certified check payable to the "Treasurer, United States of America," to:

U.S. Bank
Government Lockbox 979077 U.S. EPA Fines and Penalties
1005 Convention Plaza
Mail Station SL-MO-C2-GL
St. Louis, MO 63101

The check must note the case name, docket number of this CAFO, and the billing document number.

c. Sending via electronic funds transfer payable to the "Treasurer, United States of America," to:

Federal Reserve Bank of New York
ABA No. 021030004
Account No. 68010727
33 Liberty Street
New York, NY 10045
Field Tag 4200 of the Fedwire message should read:
"D68010727 Environmental Protection Agency"

In the comment or description field of the electronic funds transfer, state the case name, the docket number of this CAFO and the billing document number.

53. A transmittal letter stating Respondent's name, complete address, the case docket number, and the billing document number must accompany the payment. Respondent must send a copy of the check and transmittal letter to:

Attn: Regional Hearing Clerk, (E-13J)
U.S. Environmental Protection Agency, Region 5
77 West Jackson Blvd.
Chicago, IL 60604;

Attn: Compliance Tracker, (AE-17J)
Air Enforcement and Compliance Assurance Branch
Air and Radiation Division
U.S. Environmental Protection Agency, Region 5
77 West Jackson Blvd.
Chicago, IL 60604; and

Karen Peaceman, (C-14J)
Office of Regional Counsel
U.S. Environmental Protection Agency, Region 5
77 West Jackson Blvd.
Chicago, IL 60604

54. This civil penalty is not deductible for federal tax purposes.

55. If Respondent does not pay timely the civil penalty, the EPA may bring an action to collect any unpaid portion of the penalty with interest, handling charges, nonpayment penalties and the United States' enforcement expenses for the collection action under Section 113(d)(5) of the Act, 42 U.S.C. § 7413(d)(5). The validity, amount, and appropriateness of the civil penalty are not reviewable in a collection action.

56. Pursuant to 31 C.F.R. § 901.9, Respondent must pay the following on any amount overdue under this CAFO. Interest will accrue on any overdue amount from the date payment was due at a rate established by the Secretary of the Treasury. Respondent must pay a \$15 handling charge each month that any portion of the penalty is more than 30 days past due. In addition, Respondent must pay a quarterly nonpayment penalty each quarter during which the assessed penalty is overdue according to Section 113(d)(5) of the Act, 42 U.S.C. § 7413(d)(5). This nonpayment penalty will be 10 percent of the aggregate amount of the outstanding penalties and nonpayment penalties accrued from the beginning of the quarter.

57. Respondent must make a reasonable effort to contact, in writing, all of its distributors or other customers of Gebauer's Fluori-Methane and Fluro-Ethyl for the past ten (10) years within 30 days of the effective date of this CAFO. This written communication must

include the following language:

“Under EPA regulations, at 40 C.F.R. § 82.64, sales of Gebauer’s Fluori-Methane and Fluro-Ethyl violate the ban on nonessential products containing a Class I controlled substance. Gebauer has ceased production, distribution and sales of these products. Please cease all sales and/or remaining orders and return any remaining product to Gebauer, so it can be disposed of in a proper manner as required under EPA regulations within 30 days of receipt of this letter. Continuing to distribute the above stated products will be considered a violation of law by EPA.”

58. Within 45 days of the effective date of this CAFO, Respondent shall submit to EPA a certification signed by a responsible corporate officer, stating that Gebauer has made the written communication required by Paragraph 57 above. This certification shall be sent to Shilpa Patel, Environmental Engineer, AE-17J, United States Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604-3590. The certification shall be as follows:

I certify under penalty of law that, to the best of my knowledge and belief, the task identified in paragraph 57 of the CAFO has been completed. This certification is based on my inquiry of the person or persons who performed the tasks, or those persons directly responsible for the person or persons who performed the tasks. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.

General Provisions

59. This CAFO resolves only Respondent’s liability for federal civil penalties for the violations alleged in this CAFO.

60. The CAFO does not affect the right of EPA or the United States to pursue appropriate injunctive or other equitable relief or criminal sanctions for any violation of law.

61. This CAFO does not affect Respondent's responsibility to comply with the Act and other applicable federal, state, and local laws. Except as provided in Paragraph 59, above, compliance with this CAFO will not be a defense to any actions subsequently commenced pursuant to federal laws administered by Complainant.

62. Respondent certifies that it is complying fully with 40 C.F.R. Part 82, Subpart C.

63. This CAFO constitutes an "enforcement response" as that term is used in EPA's *Clean Air Act Stationary Source Civil Penalty Policy* to determine Respondent's "full compliance history" under Section 113(e) of the Act, 42 U.S.C. § 7413(e).

64. The terms of this CAFO bind Respondent, its successors, and assigns.

65. Each person signing this consent agreement certifies that he or she has the authority to sign for the party whom he or she represents and to bind that party to its terms.

66. Each party agrees to bear its own costs and attorneys' fees in this action.

67. This CAFO constitutes the entire agreement between the parties.


Gebauer Company, Respondent

10/18/10
Date

Margaret R. Giltman
Margaret R. Giltman
Chairman and CEO
Gebauer Company

United States Environmental Protection Agency, Complainant

11/3/10
Date


Cheryl L. Newton, Director
Air and Radiation Division
U.S. Environmental Protection
Agency, Region 5 (A-18J)

CONSENT AGREEMENT AND FINAL ORDER

In the Matter of:

Gebauer Company

Docket No. CAA-05-2011-0005

Final Order

This Consent Agreement and Final Order, as agreed to by the parties, shall become effective immediately upon filing with the Regional Hearing Clerk. This Final Order concludes this proceeding pursuant to 40 C.F.R. §§ 22.18 and 22.31. IT IS SO ORDERED.

11-3-10

Date



Susan Hedman
Regional Administrator
U.S. Environmental Protection
Agency, Region 5

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PROTECTION AGENCY

CAA-05-2011-0005

CERTIFICATE OF MAILING

I, Loretta Shaffer, certify that I sent a Request to Provide Information Pursuant to the Clean Air Act by Certified Mail, Return Receipt Requested, to:

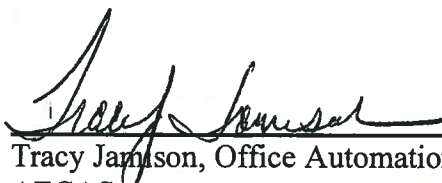
Margaret R. Giltinan
Gebauer Company
4444 East 153rd Street
Cleveland, Ohio 44128

I also certify that I sent a copy of the Request to Provide Information Pursuant to the Clean Air Act by First Class Mail to:

George Baker, Chief of Enforcement
Cleveland Department of Public Health
Division of Air Quality
1925 St. Clair Avenue
Cleveland, Ohio 44114

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on the 5 day of Oct 2010.


Tracy Jamison, Office Automation Assistant
AECAS

Certified Mail Receipt Number: 7009 1680 0000 7670 4021