



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 4
ATLANTA FEDERAL CENTER
61 FORSYTH STREET
ATLANTA, GEORGIA 30303-8960

OCT 07 2014

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Michael J. Cooke, Esq.
Greenberg Traurig, LLP
625 E Twiggs Street, Suite 100
Tampa, Florida 33602

Re: Medtronic Xomed, Inc.
Consent Agreement and Final Order
Docket Number: EPCRA-04-2014-2041(b)

Dear Mr. Cooke:

Enclosed please find an executed copy of the Consent Agreement and Final Order (CAFO) that resolves the Comprehensive Environmental Response, Compensation, and Liability Act, and the Emergency Planning and Community Right-to-Know Act of 1986 matters (Docket No. EPCRA-04-2014-2041(b)) involving Medtronic Xomed, Inc. The CAFO was filed with the Regional Hearing Clerk, as required by 40 CFR Part 22 and became effective on the date of the filing.

Also enclosed, please find a copy of the "Notice of Securities and Exchange Commission Registrants' Duty to Disclose Environmental Legal Proceedings." This document puts you on notice of your potential duty to disclose to the Securities and Exchange Commission (SEC) any environmental enforcement actions taken by the U.S. Environmental Protection Agency. If you have any questions with regard to the SEC's environmental disclosure requirements, you may refer to the contact phone number at the bottom of the SEC Notice.

If you have any questions, please call Ms. Michiko Kono at (404) 562-9558.

Sincerely,

A handwritten signature in blue ink that reads "Mark I. Fite".

Mark I. Fite
Acting Chief
EPCRA Enforcement Section

Enclosures

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 4**

IN THE MATTER OF:)
)
Medtronic Xomed, Inc.)
)
)
Respondent.)
_____)

Docket Number: EPCRA-04-2014-2041(b)

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CONSENT AGREEMENT AND FINAL ORDER

I. Nature of the Action

1. This is a civil penalty proceeding pursuant to Section 109 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), as amended, 42 U.S.C. § 9609 and Section 325 of the Emergency Planning and Community Right-to-Know Act (EPCRA), 42 U.S.C. § 11045 and pursuant to the Consolidated Rules of Practice Governing Administrative Assessment of Civil Penalties, and the Revocation/Termination or Suspension of Permits (Consolidated Rules), codified at 40 C.F.R. Part 22. Complainant is the Director of the Air, Pesticides and Toxics Management Division, Region 4, United States Environmental Protection Agency (EPA). Respondent is Medtronic Xomed, Inc.

2. The authority to take action under Section 109 of CERCLA, 42 U.S.C. § 9609 and Section 325 of EPCRA, 42 U.S.C. § 11045, is vested in the Administrator of EPA. The Administrator of EPA has delegated this authority under CERCLA and under EPCRA to the Regional Administrators by EPA Delegations 14-31 and 22-3-A, both dated May 11, 1994. The Regional Administrator, Region 4, has redelegated to the Director, Air, Pesticides and Toxics Management Division, the authority under CERCLA by EPA Region 4 Delegation 14-31 dated March 8, 1999, and updated August 6, 2004, and the authority under EPCRA by EPA Region 4 Delegation 22-3-A, dated November 8, 1994. Pursuant to these delegations, the Director of the Air, Pesticides and Toxics Management Division has the authority to commence an enforcement action as the Complainant in this matter.

3. Complainant and Respondent have conferred for the purpose of settlement pursuant to 40 C.F.R. § 22.18(b) and desire to resolve this matter and settle the allegations described herein without a formal hearing. Therefore, without the taking of any evidence or testimony, the making of any argument, or the adjudication of any issue in this matter, and in accordance with 40 C.F.R. §§ 22.13(b) and 22.18(b), this Consent Agreement and Final Order (CAFO) will simultaneously commence and conclude this matter.

II. Preliminary Statements

4. Respondent, Medtronic Xomed, Inc., is a corporation doing business in the State of Florida.

5. Respondent is a "person" and an "owner and operator" of a "facility," as those terms are defined in: Section 329(7) of EPCRA, 42 U.S.C. § 11049(7) and Section 101(21) of CERCLA, 42 U.S.C. § 9601(21); Section 101(9) of CERCLA, 42 U.S.C. § 9601(9) and by Section 329(4) of EPCRA, 42 U.S.C. § 11049(4); and, Section 101 (20)(A) of CERCLA, 42 U.S.C. § 9601(20)(A).

6. Respondent's facility is located at 6743 Southpoint Drive North, Jacksonville, Florida.

III. EPA's Allegations of Violations

Violation of Section 103(a) of CERCLA

7. Section 102(a) of CERCLA, 42 U.S.C. § 9602(a), required the Administrator of EPA to publish a list of substances designated as hazardous substances which, when released into the environment, may present substantial danger to public health or welfare or the environment and to promulgate regulations establishing the quantity of any hazardous substance the release of which was required to be reported under Section 103(a) of CERCLA, 42 U.S.C. § 9603(a). EPA has published and amended such a list, including the corresponding reportable quantities (RQ) for those substances. This list which is codified at 40 C.F.R. Part 302, was initially published on April 4, 1985 (50 Fed. Reg. 13474) and is periodically amended.

8. Section 103(a) of CERCLA, 42 U.S.C. § 9603(a), and the regulations found at 40 C.F.R. § 302.6, require a person in charge of a facility or vessel to immediately notify the National Response Center (NRC), as soon as he or she has knowledge of a release of a hazardous substance from such facility or vessel in an amount equal to, or greater than the RQ.

9. Respondent was in charge of the facility during the relevant period described below.

10. On September 5, 2013, a release of ethylene oxide above the RQ occurred at the facility.

11. Ethylene oxide is a "hazardous substance" as that term is defined by Section 101(14) of CERCLA, 42 U.S.C. § 9601(14), with an RQ of 10 pounds, as specified in 40 C.F.R. § 302.4.

12. EPA alleges that Respondent violated the notification requirements of Section 103(a) of CERCLA, 42 U.S.C. § 9603(a), and the applicable CERCLA regulation, 40 C.F.R. § 302.6, by failing to immediately notify the NRC as soon as Respondent had knowledge of the release of ethylene oxide in an amount equal to or greater than its RQ at Respondent's facility and is therefore subject to the assessment of penalties under Section 109 of CERCLA, 42 U.S.C. § 9609.

13. Pursuant to Section 109 of CERCLA, 42 U.S.C. § 9609, and 40 C.F.R. Part 19, EPA may assess a penalty not to exceed \$37,500 for each violation of Section 103(a) of CERCLA, 42 U.S.C. § 9603(a), that occurred after January 12, 2009. Each day a violation of Section 103 continues constitutes a separate violation. Civil penalties under Section 109 of CERCLA, 42 U.S.C. § 9609, may be assessed by Administrative Order.

Violations of Section 304(a) EPCRA

14. Section 304(a) of EPCRA, 42 U.S.C. § 11004(a) and the regulations found at 40 C.F.R. Part 355, Subpart C, require the owner or operator of a facility at which hazardous chemicals are produced, used or stored, to immediately notify the State Emergency Response Commission (SERC) and Local Emergency Planning Committee (LEPC) when there has been a release of a CERCLA hazardous substance or an EPCRA extremely hazardous substance in an amount equal to or greater than the RQ. Section 304(a) does not apply to any release which results in exposure to persons solely within the site or sites on which a facility is located.

15. Respondent was the owner or operator of the facility during the relevant period, described below.

16. At all times relevant to this matter, the facility produced, used, or stored a "hazardous chemical" as defined under Section 311(e) of EPCRA, 42 U.S.C. § 11021(e) and under 29 C.F.R. § 1910.1200(c).

17. Ethylene oxide is an "extremely hazardous substance" as that term is defined by Section 329(3) of EPCRA, 42 U.S.C. § 11049(3), with an RQ of 10 pounds, as specified in 40 C.F.R. Part 355, Appendices A & B.

18. On September 5, 2013, a release of ethylene oxide above the RQ occurred at the facility. EPA alleges that the release resulted in the potential for exposure to persons beyond the site or sites on which the facility is located.

19. EPA alleges that Respondent violated the notification requirements of Section 304(a) of EPCRA, 42 U.S.C. § 11004(a), and the applicable EPCRA regulations of 40 C.F.R. Part 355, Subpart C, by failing to immediately notify the SERC and LEPC as soon as Respondent had knowledge of the release of ethylene oxide in an amount equal to or greater than the RQ at Respondent's facility, and is therefore subject to the assessment of penalties under Section 325 of EPCRA, 42 U.S.C. § 11045.

20. Pursuant to Section 325(b) of EPCRA, 42 U.S.C. § 11045(b), and 40 C.F.R. Part 19, EPA may assess a penalty of not more than \$37,500 for each violation of Section 304(a) of EPCRA, 42 U.S.C. § 11004(a) that occurred after January 12, 2009. Civil penalties under Section 325(b) of EPCRA, 42 U.S.C. § 11045(b), may be assessed by Administrative Order.

IV. Consent Agreement

21. For the purposes of this CAFO, Respondent admits the jurisdictional allegations set out above but neither admits nor denies the factual allegations and legal conclusions set out above.

22. Respondent waives any right to contest the allegations and its right to appeal the proposed final order accompanying the Consent Agreement.

23. Respondent consents to the assessment of and agrees to pay the civil penalty as set forth in this CAFO.

24. Respondent certifies that as of the date of its execution of this CAFO, it is in compliance with all relevant requirements of CERCLA and EPCRA.

25. Compliance with the CAFO shall resolve the allegations of violations contained herein. This CAFO shall not otherwise affect any liability of Respondent to the United States other than as expressed herein. Complainant does not waive any right to bring an enforcement action against Respondent for violation of any federal or state statute, regulation or permit, to initiate an action for imminent and substantial endangerment, or to pursue criminal enforcement.

26. Complainant and Respondent agree to settle this matter by their execution of this CAFO. The parties agree that the settlement of this matter is in the public interest and that this CAFO is consistent with the applicable requirements of CERCLA and EPCRA.

V. Final Order

27. Respondent shall pay a civil penalty of FIVE THOUSAND SEVEN HUNDRED FIFTY THREE DOLLARS (\$5,753) for the CERCLA violation which shall be paid within thirty (30) days of the effective date of this CAFO.

28. Respondent shall pay the CERCLA civil penalty by forwarding a cashier's or certified check, payable to "EPA Hazardous Substance Superfund" to one of the following addresses:

BY MAIL

U.S. Environmental Protection Agency
Superfund Payments
Cincinnati Finance Center
P.O. Box 979076
St. Louis, Missouri 63197-9000

BY OVERNIGHT

U.S. Environmental Protection Agency
Government Lockbox 979076
1005 Convention Plaza
Mail Station SL-MO-C2-GL
St. Louis, MO 63101
(314) 425-1818

The check shall reference on its face the name and the Docket Number of the CAFO.

29. Respondent shall pay a civil penalty of FIVE THOUSAND SEVEN HUNDRED FIFTY TWO DOLLARS (\$5,752) for the EPCRA violations which shall be paid within thirty (30) days of the effective date of this CAFO.

30. Respondent shall pay the EPCRA penalty by forwarding a cashier's or certified check payable to "Treasurer, United States of America," to one of the following addresses:

BY MAIL

U.S. Environmental Protection Agency
Cincinnati Finance Center
P.O. Box 979077
St. Louis, MO 63197-9000

BY OVERNIGHT

U.S. Environmental Protection Agency
Government Lockbox 979077
1005 Convention Plaza
Mail Station SL-MO-C2-GL
St. Louis, MO 63101
(314) 425-1818

The check shall reference on its face the name and the Docket Number of the CAFO.

31. At the time of payment, Respondent shall send a separate copy of each check, and a written statement that payment has been made in accordance with this CAFO, to the following persons at the following addresses:

Regional Hearing Clerk
U.S. EPA, Region 4
61 Forsyth Street, S.W.
Atlanta, Georgia 30303

Vinson Poole
U.S. EPA, Region 4
Air, Pesticides & Toxics Management Division
61 Forsyth Street, S.W.
Atlanta, Georgia 30303

Saundi Wilson
U.S. EPA, Region 4
Office of Environmental Accountability
61 Forsyth Street, S.W.
Atlanta, Georgia 30303

32. For the purposes of state and federal income taxes, Respondent shall not be entitled, and agrees not to attempt, to claim a deduction for any civil penalty payment made pursuant to this CAFO. Any attempt by Respondent to deduct any such payments shall constitute a violation of this CAFO.

33. Pursuant to 31 U.S.C. § 3717, EPA is entitled to assess interest and penalties on debts owed to the United States and a charge to cover the cost of processing and handling a

delinquent claim. Interest will therefore begin to accrue on the civil penalty from the effective date of this CAFO if the penalty is not paid by the date required. Interest will be assessed at the rate established by the Secretary of Treasury pursuant to 31 U.S.C. § 3717. A charge will be assessed to cover the costs of debt collection, including processing and handling costs and attorney fees. In addition, a penalty charge will be assessed on any portion of the debt that remains delinquent more than ninety (90) days after payment is due.

34. Complainant and Respondent shall bear their own costs and attorney fees in this matter.

35. This CAFO shall be binding upon the Respondent, its successors and assigns.

36. The following individual is authorized to receive service for EPA in this proceeding:

Mark J. Fite
U.S. EPA, Region 4
Air, Pesticides & Toxic Management Division
61 Forsyth Street, S.W.
Atlanta, GA 30303
(404) 562-9740

37. Each undersigned representative of the parties to this CAFO certifies that he or she is fully authorized by the party represented to enter into this CAFO and legally bind that party to it.

THIS SECTION INTENTIONALLY LEFT BLANK

VI. Effective Date

38. The effective date of this CAFO shall be the date on which the CAFO is filed with the Regional Hearing Clerk.

AGREED AND CONSENTED TO:

Medtronic Xomed, Inc.

By:  (Signed) Date: 9/11/2014

Name: Scot M. Elder (Typed or Printed)

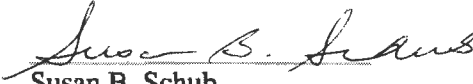
Title: Vice President, Chief Counsel (Typed or Printed)

U.S. Environmental Protection Agency

By:  Date: 10/2/14

Beverly H. Banister
Director
Air, Pesticides and Toxic Management Division

APPROVED AND SO ORDERED this 7 day of October 2014.


Susan B. Schub
Regional Judicial Officer

CERTIFICATE OF SERVICE

I hereby certify that I have this day served a true and correct copy of the foregoing
Consent Agreement and Final Order, In the Matter of Medtronic Xomed, Inc., Docket Number:
EPCRA-04-2014-2041(b), on the parties listed below in the manner indicated:

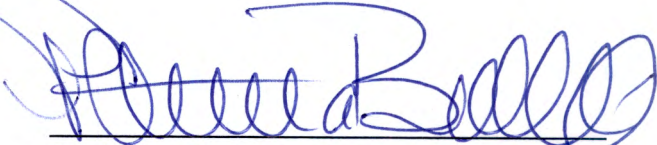
Mark J. Fite (Via EPA's internal mail)
U.S. EPA, Region 4
Air, Pesticides & Toxics Management Division
61 Forsyth Street
Atlanta, GA 30303

Robert Caplan (Via EPA's internal mail)
U.S. EPA, Region 4
Office of Environmental Accountability
61 Forsyth Street
Atlanta, GA 30303

Michiko Kono (Via EPA's internal mail)
U.S. EPA, Region 4
Office of Environmental Accountability
61 Forsyth Street
Atlanta, GA 30303

Michael G. Cooke, Esq. (Via Certified Mail - Return Receipt Requested)
Greenberg Traurig, LLP
625 E Twiggs Street, Suite 100
Tampa, Florida 33602

Date: 10-2-14



Patricia A. Bullock, Regional Hearing Clerk
United States Environmental
Protection Agency, Region 4
Atlanta Federal Center
61 Forsyth Street, S.W.
Atlanta, GA 30303
(404) 562-9511