



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2
290 BROADWAY
NEW YORK, NY 10007-1866

U.S. ENVIRONMENTAL
PROTECTION AGENCY-REGION 2
2008 JUL 21 PM 3:51
REGIONAL HEARING
CLERK

JUL 31 2008

Braulio Garcia-Jimenez, Esq.
Torres & Garcia, P.S.C.
P.O. Box 19539
San Juan, Puerto Rico 00910-1539

Re: Bristol Myers Squibb Manufacturing Company
Docket No. RCRA-02-2008-7106

Dear Mr. Garcia-Jimenez,

Enclosed is a copy of the Consent Agreement and Final Order ("CA/FO") in the above referenced proceeding signed by the Regional Administrator of the U.S. Environmental Protection Agency.

Please note that payment is due within forty-five (45) days of signature of the Final Order by the Regional Administrator. Please arrange for payment of this penalty according to the instructions given in that Order.

If you have any questions, please contact me at 212-637-3195.

Very truly yours,

Gary H. Nurkin
Assistant Regional Counsel
Waste & Toxic Substances Branch

cc: Julio Rodriguez, PREQB

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Region 2

U.S. ENVIRONMENTAL
PROTECTION AGENCY-REG-11
2008 JUL 31 PM 3: 51
REGIONAL HEARING
CLERK

In The Matter of:

**Bristol-Myers Squibb
Manufacturing Company,
Respondent**

**Proceeding Under Section 3008 of
the Resource Conservation and
Recovery Act as amended.**

**CONSENT AGREEMENT
AND
FINAL ORDER**

Docket Number RCRA-02-2008-7106

PRELIMINARY STATEMENT

This is a civil administrative proceeding instituted pursuant to Section 3008 of the Solid Waste Disposal Act as amended by various laws including the Resource Conservation and Recovery Act and the Hazardous and Solid Waste Amendments of 1984, 42 U.S.C. §§ 6901, et seq. ("RCRA" or the "Act").

Section 3008 of RCRA, 42 U.S.C. § 6928, authorizes the Administrator to enforce violations of the Act and the regulations promulgated or authorized pursuant to it. The Respondent Bristol-Myers Squibb Manufacturing Company ("BMS") owns and operates a manufacturing facility situated at Humacao, Puerto Rico 00792-0609. EPA inspected BMS on or about September 11, 2007 and concluded that BMS may have violated the requirements of RCRA and regulations concerning the management of volatile organic wastes.

EPA and BMS have subsequently engaged in settlement discussions with respect to two alleged violations that EPA discovered during the course of its inspection of BMS and have agreed to address the issues without the need for EPA to issue a formal Complaint. Pursuant to 40 C.F.R. § 22.13(b), where parties agree to settlement of one or more causes of action before the filing of a Complaint, a proceeding may be simultaneously commenced and concluded by the issuance of a Consent Agreement and Final Order ("CA/FO") pursuant to 40 C.F.R. § 22.18(b)(2) and (3). Both the EPA and BMS have agreed that entering into this CA/FO is an appropriate means of resolving the alleged noncompliance with RCRA requirements that EPA believes existed at BMS's Humacao facility without further litigation or other administrative action.

This CA/FO is being issued pursuant to, and under the authority of, 40 C.F.R. § 22.18(b). No adjudicated finding of fact or conclusions of law have been made. Respondent neither admits nor denies EPA's Findings of Fact or Conclusions of Law set forth below.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. The Respondent is BMS.
2. Respondent is a corporation and a wholly owned subsidiary of BMS.
3. BMS is a "person" as that term is defined in § 1004(15) of the Act, 42 U.S.C. § 6903(15).
4. Respondent owns and operates a manufacturing facility situated at Humacao, Puerto Rico 00792-0609.
5. Respondent manufactures and finishes pharmaceutical products at the facility.
6. The hazardous wastes generated at the Respondent's facility have included, without limitation, characteristic wastes ("D wastes"), wastes from nonspecific sources ("F wastes"), and discarded commercial chemical products including manufacturing chemical intermediates ("U wastes").
7. The organic hazardous waste (containing organic solvents) generated during the manufacture of the organic pharmaceuticals were stored in seven ("7") above-ground outdoor permitted hazardous waste storage tanks.
8. The organic hazardous waste stored in the seven above-ground outdoor hazardous waste storage tanks noted in paragraph "7," above, had a Volatile Organic Concentration ("VOC") of above 500 parts per million by weight ("p.p.m.w.").
9. The organic hazardous waste stored in the seven above-ground outdoor hazardous waste storage tanks noted in paragraph "7," above, has an organic concentration of more than 10% by weight.
10. The Respondent is, and has been, a "generator" at the Facility of "hazardous wastes" as those terms are defined in 40 C.F.R. § 260.10.
11. Since on or about August 1980, Respondent, or a corporate predecessor (Squibb), has generated 1,000 kilograms or more of organic hazardous waste each calendar month at the facility and has stored this waste for short periods of time in tanks at the facility.
12. Respondent has been a Large Quantity Generator (i.e., a generator who generates 1,000 kilograms or more of hazardous waste in a calendar month) at the facility.

13. Pursuant to Section 3010 of RCRA, 42 U.S.C. § 6930, Squibb Manufacturing Company (“Squibb”), a corporate predecessor of BMS, on or about August 18, 1980, notified EPA that it conducted activities involving “hazardous waste” at the Facility (the “notification”).
14. The EPA, on or about November 19, 1980, provided Squibb with EPA RCRA identification number PRD090021056.
15. On or about August 7, 1989, the EPA, based upon the Squibb’s Parts A and B permit applications (including all succeeding updates, revisions or modifications) and pursuant to Section 3005 of the Act, 42 U.S.C. § 6925 and 40 C.F.R. Part 270, issued a RCRA permit (PRD090021056) to Squibb for the operation of “seven hazardous waste storage tanks, and three hazardous waste liquid injection incinerators” at its facility (the “1990 permit”).
16. The 1990 permit became effective on March 1, 1990 and expired on March 1, 1995.
17. On or about July 7, 1994, including all succeeding revisions and data submissions (referred to collectively as the “Application”), Respondent submitted to EPA in a timely manner its RCRA Part B permit renewal application.
18. On or about September 29, 2000, the EPA, pursuant to Section 3005 of the Act, 42 U.S.C. § 6925 and 40 C.F.R. Part 270, issued a new RCRA permit to Respondent for the operation of a hazardous waste management facility at its Humacao facility (the “2000 permit”).
19. The 2000 permit took effect on or about November 13, 2000 and “shall remain in effect until November 13, 2010 unless revoked and reissued, modified or terminated in accordance with 40 C.F.R. §§ 270.41, 270.42 or 270.43, or continued in accordance with 40 C.F.R. § 270.51(a).”
20. On or about September 11, 2007, pursuant to Section 3007 of RCRA, 42 U.S.C. § 6927, an authorized representative of EPA conducted an inspection (hereinafter the “Inspection”) of the Humacao facility to determine Respondent’s compliance with the organic air emissions requirements of 40 C.F.R. § 264 Subparts BB and CC.
21. On or about October 23, 2007, EPA issued to Respondent a combined Notice of Violation (“NOV”) and Request for Information (“IRL”).
22. The NOV, which was issued pursuant to Section 3008 of the Act, 42 U.S.C. § 6928, informed the Respondent that EPA had identified a number of potential violations of both the air emission requirements for equipment leaks found at 40 C.F.R. § 264 Subpart BB and the air emission standards for tanks, surface impoundments and

containers found at 40 C.F.R. § 264 Subpart CC. The NOV also identified some minor violations associated with the labeling of a single container and a funnel improperly closed. Respondent was requested to provide a description and documentation of the actions BMS had taken to correct the violations identified by EPA in that NOV.

23. The IRL, which was issued pursuant to Section 3007 of RCRA, 42 U.S.C. § 6927, sought, in part, information and documentation relating to the air emission activities regulated under 40 C.F.R. §§ 264 Subparts BB and CC and required submittal of certain documentation relating to those air emission activities at the facility.
24. On or about February 28, 2008, Respondent submitted its response to the IRL.
25. Based on the Inspection and BMS's Response to the IRL, EPA believed that BMS failed to: (a) label one hazardous waste container found in the hazardous waste storage area, with the words "hazardous waste"; (b) mark with the accumulation start date, the same container identified as item (a) of this paragraph; (c) properly close a funnel subject to the air emission standards for equipment leaks; (d) monitor, on a monthly basis, using Reference Method 21, the twenty-one centrifugal pumps and twenty-nine to thirty-one diaphragm pumps used to pump organic hazardous waste to BMS's hazardous waste storage tanks in violation of 40 C.F.R. § 264.1052(a)(1) and Module VI.A.2. of its 2000 permit; and (e) perform monthly emissions monitoring of six hundred sixty-eight valves in light liquid organic hazardous waste service using Reference Method 21 in violation of 40 C.F.R. § 264.1057(a) and Module VI.A.2 of its 2000 permit.
26. BMS informed EPA in its Response that it will be monitoring its pumps and valves in accordance with the requirements of 40 C.F.R. § 264 Subpart BB. Furthermore, corrective actions were immediately taken to correct the labeling of the container and a double valve system was installed in the funnel identified during the September 11, 2007 inspection.

CONSENT AGREEMENT

Based upon the foregoing, and pursuant to Section 3008 of RCRA, 42 U.S.C. § 6928, and 40 C.F.R. § 22.18 of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation or Suspension of Permits, 40 C.F.R. Part 22, it is hereby agreed by and between Complainant and BMS, and voluntarily and knowingly accepted by BMS, that BMS, for purposes of this Consent Agreement and in the interest of settling this matter expeditiously (a) admits the jurisdictional allegations contained in the Preliminary Statement of the CAFO; (b) neither

admits nor denies the Findings of Fact And Conclusions Of Law stated above; (c) consents to the assessment of the civil penalty as set forth below; (d) consents to the issuance of the Final Order accompanying this Consent Agreement; and (e) waives its right to contest or appeal that Final Order.

It is further hereby agreed by and between Complainant and BMS, and voluntarily and knowingly accepted by BMS, that the parties shall comply with the following terms and conditions:

1. Commencing on the effective date of the Order and thereafter, Respondent shall comply fully with the requirements of 40 C.F.R. 264 Subpart BB with respect to the volatile organic hazardous waste that it generates and stores in the one remaining above-ground outdoor hazardous waste storage tank at its Humacao facility and to handle such wastes in accordance with the all the requirements of RCRA. (The other 6 hazardous waste tanks ceased operation on December 2007 and are currently undergoing closure in accordance with the 2000 permit).
2. Respondent hereby certifies, at the time of its signature to this document, that, to the best of its knowledge and belief, it is in compliance with all of the applicable hazardous waste regulatory requirements with respect to management of hazardous waste (including organic hazardous waste) at its Humacao facility.
3. This CA/FO is not intended, and shall not be construed, to waive, extinguish or otherwise affect BMS's obligation to comply with all applicable federal, state and local law and regulations governing the generation, handling, treatment, storage, transport and disposal of hazardous waste.
4. Nothing in this document is intended nor shall it be construed, to waive, prejudice or otherwise affect the right of EPA, or the United States, from pursuing any appropriate remedy, sanction or penalty prescribed by law against BMS for having made any material misrepresentations or for BMS's having providing materially false information in any document submitted to EPA.
5. BMS shall pay a civil penalty to EPA in the total amount of **FIFTY-TWO THOUSAND DOLLARS (\$52,000)**. Such payment shall be made by cashier's or certified check or by Electronic Fund Transfer (EFT). If the payment is made by check, then the check shall be made payable to the "**Treasurer, United States of America,**" and shall be mailed to:

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

The check shall be identified with a notation thereon listing the following: *IN THE*

MATTER OF BRISTOL MYERS SQUIBB MANUFACTURING COMPANY, and shall bear thereon the Docket Number *RCRA-02-2008-7106*. Payment of the penalty must be *received* at the above address on or before forty-five (45) calendar days after the Effective Date of this CA/FO (the "Due Date").

If BMS chooses to make the payment by EFT, then BMS shall provide the following information to its remitter bank:

- 1) Amount of Payment
- 2) SWIFT address: FRNYUS33, 33 Liberty Street, New York, NY 10045.
- 3) Account Code for Federal Reserve Bank of New York receiving payment: 68010727.
- 4) Federal Reserve Bank of New York ABA routing number: 021030004.
- 5) Field Tag 4200 of the Fedwire message should read "D 68010727 Environmental Protection Agency."
- 6) Name of Respondent: Bristol Myers Squibb Manufacturing Company.
- 7) Case Number: RCRA-02-2008-7106.

Such EFT must be received on or before forty-five (45) calendar days after the Effective Date of this CA/FO.

Whether the payment is made by check or by EFT, BMS shall promptly thereafter furnish reasonable proof that such payment has been made, to both:

Gary H. Nurkin, Esq.
Assistant Regional Counsel
Environmental Protection Agency, Region 2
290 Broadway, Room 1623
New York, New York 10007-1866

and

Karen Maples, Regional Hearing Clerk
Environmental Protection Agency, Region 2
290 Broadway, 16th floor
New York, New York 10007-1866

- a. Failure to pay the amount in full within the time period set forth above may result in referral of this matter to the United States Department of Justice or the United States Department of the Treasury for collection.
- b. Furthermore, if payment is not made on or before the date specified in this document, interest for said payment shall be assessed

at the annual rate established by the Secretary of the Treasury pursuant to 31 U.S.C. § 3717, on the overdue amount from the date said payment was to have been made through the date said payment has been received. In addition, a late payment handling charge of \$15.00 will be assessed for each thirty (30) calendar day period or any portion thereof, following the date the payment was to have been made, in which payment of the amount remains in arrears. In addition, a 6% per annum penalty will be applied to any principal amount that has not been received by the EPA within ninety (90) calendar days of the date for which the payment was required hereto to have been made.

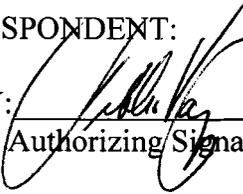
c. The civil penalty constitutes a penalty within the meaning of 26 U.S.C. § 162(f).

6. This Consent Agreement is being voluntarily entered into by the parties in full and final settlement of all civil liabilities that attach or might have attached under the Act to BMS as a result of any alleged failures described in paragraph "25" of the Finding of Facts And Conclusions Of Law that may have occurred and which were the subject matter of the Inspection and/or BMS's Response to the IRL.
7. The provisions of this Consent Agreement shall be binding upon both Complainant and BMS along with their authorized representatives and successors or assigns.
8. This Consent Agreement is being voluntarily and knowingly entered into by the parties to resolve (conditional upon full payment of the civil penalty herein and upon the accuracy of Respondent's certification in this proceeding) the civil and administrative claims resulting from the alleged violations which were identified based on the Inspection and/or BMS's Response to the IRL. Nothing herein shall be read to preclude EPA or the United States, however, from pursuing appropriate injunctive or other equitable relief or criminal sanctions for any violation of law. Respondent has read the Consent Agreement, understands its terms, finds it to be reasonable and consents to its issuance and its terms. Respondent consents to the issuance of the accompanying Final Order. Respondent agrees that all terms of the settlement are set forth herein.
9. BMS explicitly waives its right to request or to seek any Hearing on the terms and conditions set forth in the Consent Agreement and its accompanying Final Order and/or the Findings Of Fact/Conclusions Of Law, above.

10. BMS reserves its right to challenge Complainant's usage of the instant Consent Agreement and its accompanying Final Order and/or the Findings Of Fact/Conclusions Of Law, above, in a subsequent Complaint alleging violations of RCRA.
11. BMS waives any rights it may have pursuant to 40 C.F.R. § 22.8 to be present during discussions with or to be served with, and to reply to any memorandum or communication addressed to, the Regional Administrator or the Deputy Regional Administrator, where the purpose of such discussion, memorandum, or communication is to discuss a proposed settlement of this matter or to recommend that such official accept this Consent Agreement and issue the attached Final Order.
12. The undersigned signatory for BMS certifies that she is duly and fully authorized to enter into this Consent Agreement and all the terms and conditions set forth in this Consent Agreement.
13. BMS consents to the service of this Consent Agreement and Final Order by an EPA employee other than the Regional Hearing Clerk.
14. The effective date of this Consent Agreement and Final Order shall be the date that it is filed with the Regional Hearing Clerk, U.S. EPA Region 2, New York, New York.

15. Each party hereto agrees to bear its own costs and fees in this matter.

RESPONDENT: **Bristol Myers Squibb Manufacturing Company,**

BY: 

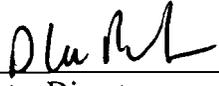
Authorizing Signature

NAME: Debbie Vazquez

TITLE: Vice President and General Manager

DATE: July 10, 2008

COMPLAINANT:



Dore LaPosta, Director
Division of Enforcement
and Compliance Assistance
U.S. Environmental Protection Agency Region 2
290 Broadway
New York, NY 10007

DATE: July 16, 2008

In the Matter of Bristol Myers Squibb Manufacturing Company,
Docket No. RCRA-02-2008-7106

FINAL ORDER

The Regional Administrator of EPA, Region 2 (or anyone duly delegated to act on his behalf), concurs in the foregoing Consent Agreement in the case of *In the Matter of Bristol Myers Squibb Manufacturing Company*, bearing Docket No. RCRA-02-2008-7106. Said Consent Agreement having been duly accepted and entered into by the parties, is hereby ratified, incorporated into and issued, as this Final Order, which shall become effective when filed with the Regional Hearing Clerk of EPA, Region 2. 40 C.F.R. § 22.31(b). This Final Order is being entered pursuant to the authority of 40 C.F.R. § 22.18(b) (3) and shall constitute an order issued under authority of Section 3008(a) of RCRA, 42 U.S.C. § 6928(a).

DATED: July 25, 2008
New York, New York



Alan J. Steinberg
Regional Administrator
U.S. Environmental Protection Agency Region 2
290 Broadway
New York, New York 10007-1866

In the Matter of Bristol Myers Squibb Manufacturing Company,
Docket No. RCRA-02-2008-7106

CERTIFICATE OF SERVICE

I certify that I have this day caused to be sent the foregoing fully executed CONSENT AGREEMENT and FINAL ORDER, bearing the above-referenced docket number, in the following manner to the respective addressees below:

Original and One Copy

By Hand:

Regional Hearing Clerk
U.S. Environmental Protection Agency Region 2
290 Broadway, 16th floor
New York, New York 10007-1866

Copy by Certified Mail,
Return Receipt Requested:

Braulio Garcia-Jimenez, Esq.
Torres & Garcia, P.S.C.
P.O. Box 19539
San Juan, Puerto Rico 00910-1539

Smildred N. Baez

Dated: JUL 31, 2008
New York, New York